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Reducing Inequities in Care of Hypertension: Lifestyle Improvement for Everyone (The RICH LIFE Project): Study Protocol

A study to compare the effectiveness of health systems versus multilevel interventions to reduce hypertension disparities

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Section 1: Background / Significance

A. The problem

1. **Cardiovascular disease (CVD) remains the leading cause of death and disability in the US -- despite the wide availability of effective therapy and prevention**.[1] Approximately 600,000 Americans die of heart disease annually (1 in every 4 deaths), and every year about 720,000 people in the US suffer from a heart attack.[1] Annually, the US spends about $108.9 billion treating coronary heart disease alone.[1] US racial and ethnic minorities are disproportionately burdened by CVD with African Americans (24.5%), American Indians/Alaska Natives (18%), Asians/Pacific Islanders (23.2%), and Hispanics (20.8%) representing a greater percentage of deaths from heart disease than their overall representation in the US population.[1-11] Persons with low income and those living in rural areas are also disproportionately affected by hypertension (HTN) and other CVD risk factors, and experience less access and poorer quality of care.[12-14] Numerous calls to action, including a recent PCORI Landmark Report[15] have highlighted the need to reduce the CVD burden by targeting the reduction of HTN and other major CVD risk factors (e.g., diabetes, high cholesterol, tobacco smoking) in underserved groups. Additionally, depressive symptoms among patients with diabetes and HTN are associated with higher rates of CVD, mortality, poorer adherence, and worse quality of life.[16-18]
2. **Disparities in HTN and other CVD risk factors are well-documented even among patients seen regularly in the healthcare system**. For instance, the prevalence of HTN in African Americans is among the highest in the world.[6] African Americans have higher rates of Stage 3 HTN, causing a greater burden of CVD-related outcomes, including an 80% higher stroke mortality rate, a 50% higher heart disease mortality rate, and a 320% greater incidence of end-stage renal disease than the general population.[2,19-22] Other groups, such as Hispanics and American Indians also suffer disproportionately from HTN in addition to other CVD-risk factors, such as diabetes.[2,22] Diabetes affects over 20 million people in the US, resulting in significant morbidity and reduced quality of life.[22-24] In addition to increased CVD-risk, other complications of diabetes include retinopathy, blindness, limb amputation, and macrovascular disease.[22, 24-27]
3. **Barriers to reducing disparities in HTN are complex and exist at multiple levels**, including factors related to the individual patient (e.g., behavioral, biological, attitudinal, sociodemographic);[28-30] family and social support systems (e.g., family dynamics, living arrangements, financial strain);[31,32] healthcare providers and organizations and practice settings in which health care occurs (e.g., healthcare quality, provider communication and trustworthiness);[33-36] the local community (e.g., neighborhood poverty, crime, residential segregation, availability of healthy foods);[37,38] and the policy environment (e.g., pay-for-performance models).[39] Prior literature points to a variety of approaches (e.g., practice-based quality improvement (QI)) designed to reduce HTN and other CVD risk factors with some tailored to minority patients (e.g., community-health workers (CHWs), culturally tailored physician training). However, few existing approaches were designed to explicitly address disparities in HTN care and control. Additionally, ethnic minority groups (other than African Americans) and rural populations are understudied. Finally, no group has attempted to combine multilevel strategies into a pragmatic and sustainable approach to reduce multiple CVD-related risk factors (HTN, diabetes, high cholesterol, smoking, and depressive symptoms) and improve patient-centered outcomes in underserved communities.

B. Literature review: Findings from studies with potential clinical significance

1. **Potential for Improvement in CVD Risk Reduction through Practice Based Interventions.** Practice based QI interventions can target several areas—health systems (case management, team changes, patient registry, facilitated relay of information to clinicians), healthcare providers (audit and feedback,

clinician education, clinician reminders, financial incentives), or patients (patient education, promotion of self-management, reminder systems).[40] Few QI interventions have measured reduction in disparities as an outcome; even fewer have targeted reduction in disparities as a primary goal or examined processes known to contribute to disparities in outcomes.

2. **QI Strategies for HTN.** Results from a Cochrane review of ***patient interventions*** to improve adherence to high blood pressure (BP) treatment suggest that simplifying dosing regimens is most effective; using motivational strategies such as home monitoring, small-group training, counseling by a nurse or other professional, and reminder calls for patients are somewhat effective; and patient education alone is not effective.[41] In our review of 11 more recent studies, 9 found some improvement in BP control compared with the control group.[42-51] Of these, only 1 showed improvement with patient education alone, while the other 8 included either nurse or pharmacist-directed programs or collaborative care (CC) of the patient with a pharmacist, providing additional evidence for the effectiveness of these approaches.[42-51] Studies of ***provider interventions*** that target only clinicians show improvements in guideline-concordant prescribing; none show improvements in patient adherence or BP control.[52-57] Recent systematic reviews suggest that ***audit and feedback interventions*** of clinical performance data are also associated with modest (but variable) improvements in HTN control and are most effective when they are delivered in written form, provide frequent (at least monthly) feedback, and suggest specific actions for improvement.[58-60] The availability of ***reliable and valid BP measurements*** can also enhance providers' willingness to titrate anti-HTN medications.[61] Results from our recent pragmatic trial suggest that rigorous BP measurement consistent with American Heart Association (AHA) guidelines can be successfully achieved, while evidence suggests that this rigorous approach may be required only when patients' initial clinic BP is ≥140/90 mm Hg.[62-64] Two systematic reviews show **team change interventions** that include assignment of some responsibilities to a health professional other than the patient's physician (such as a nurse or pharmacist) are associated with the largest reductions in BP.[65,66]
3. **QI Strategies for Diabetes and Other CVD Risk Factors.** Several prior meta-analyses have examined the impact of clinic-based interventions on risk reduction in patients with diabetes.[40,67,68] A meta-analysis of 58 studies of 66 distinct trials revealed that strategies associated with a reduction in hemoglobin A1c (HbA1c) included case management and team changes, with greater effects observed among those that included multidisciplinary, interactive teams.[68] A more recent meta-analysis found that multicomponent QI interventions resulted in lower HbA1c, LDL cholesterol and BP.[40] Another systematic review of 17 studies examining the effectiveness of patient, provider, and system interventions in socially disadvantaged populations found that most studies showed improvements in HbA1c but were less effective in improving body weight (2/9 studies), lipids (2/7 studies), and BP (2/4 studies).[69] Controlling BP significantly reduces CVD morbidity and overall mortality among patients with diabetes[70] further supporting the urgent need for programs to better address multiple risk factors and multi-level approaches, including broader interpersonal, community, and environmental influences.
4. **Potential for Reducing HTN and CVD Disparities through Multilevel Interventions.** Important gaps in the evidence base, described below, have hampered translation of multilevel interventions for disparities into practice and policy. We intend to address many of these gaps with our innovative study approaches.
5. **Community-Level Strategies.** Results from a recent multicomponent, cluster-randomized clinical trial targeting BP control in African Americans (the CAATCH Trial) found that the clinic-based intervention was no better than usual care in improving BP control in African Americans, suggesting that additional outreach services and stronger engagement of patients' social support and linkages to community resources may be needed.[71-73] Community based interventions involving the use of CHWs often incorporate the provision of culturally sensitive, relevant support for patient disease self-management.[74-76] This is accomplished through such activities as health education, one-on-one counseling, BP screening, and support for lifestyle modification.[74,75,77] In a systematic review of 14 studies examining

the effectiveness of CHWs in helping HTN patients achieve sustained BP control, Brownstein et al. observed a consistent trend toward positive outcomes relating to BP control, health care utilization, and improvements in mortality.[74] This is concordant with findings from Fleury and colleagues' 20-study appraisal of the effectiveness of lay health advisors in reducing CVD risk factors.[75] Locally, investigations conducted by members of our study team in communities throughout the city of Baltimore observed significant associations between the presence of CHWs and improvements in keeping appointments and continuity of care for HTN among those using emergency departments as their usual source of care;[78] reductions in BP and increases in entry of care among young African-American males;[79] and improved HTN self-management for those randomized to receive home visits from CHWs as compared with those receiving traditional care.[80] In combination with Nurse Practitioners, CHWs have been linked to statistically significant reductions in diastolic BP among African Americans with diabetes.[81] This is consistent with findings of reduced diastolic BP and systolic BP observed among a predominantly female, impoverished group of diabetic African Americans with a concurrent CVD diagnosis.[81] Community based approaches have also been shown to be effective in improving glycemic control and lipids among Hispanics[82-85] and American Indians[86] with diabetes. We have also demonstrated that CHWs serving as coaches to activate patients to participate more actively in their care are effective at improving shared decision-making and reducing BP (by 13.2-16.8 mm Hg) in ethnic minorities and poor persons with uncontrolled HTN.[87]

6. **System-Level Strategies.** Policy makers, medical professionals, and patients are increasingly calling for health systems to adapt to better meet the needs of diverse populations. Although equity has been integral to the definition of high-quality health care,[88] in practice addressing health care disparities and promoting health equity have lagged behind other concerns such as reducing medical error and improving patient satisfaction. While the Institute of Medicine and other organizations have highlighted the need for a learning healthcare system, including in the area of health equity, a true learning healthcare system remains elusive.[89] In previous work, we found that health care personnel perceived strong organizational orientation toward quality and patient centeredness in their practice network, but lower percentages perceived strong organizational cultural competency.[90] Larger percentages of survey respondents perceived barriers to addressing disparities than barriers to improving safety and quality, suggesting that leadership may face more challenges in supporting interventions to reduce disparities.[90]

C. Scientific justification for the study

1. **Study Approaches to Address Critical Research Gaps.** To support the need for our study, we present key conclusions drawn from 1) our rigorous review of the recent medical and social sciences literature on critical knowledge gaps in interventions developed to reduce BP control and overall CVD risk in underserved populations and 2) recommendations by major professional societies, such as the AHA and American Diabetes Association in **Table 1 on the following page**. We included elements of the PICOTS (**P**opulation, **I**ntervention, **C**omparator, **O**utcome, **T**imeframe, **S**etting) Framework to facilitate systematic identification and characterization of critical research gaps.[91] Additionally, we describe current intervention gaps in 1) addressing patient centeredness and engagement of support networks, and 2) sustainability and translation into practice.
2. **Our Innovative Study Approaches.** Within the right hand column of **Table 1,** we describe our innovative approaches designed to directly address gaps and reduce HTN disparities. In summary, our practice-based collaborative care team intervention, which is based upon the chronic care model (CCM),[92] is pragmatic in that we will utilize existing staff infrastructure. Incorporation of subspecialist advice into the patient care plan for minority and socioeconomically disadvantaged patients as part of a stepped care approach is also a highly innovative strategy to address access barriers. The CCM is an effective approach to successfully manage patients with HTN, CVD and multiple co-morbidities, such as diabetes and depression[42,93-96] but its use to reduce health disparities has been limited. The inclusion

of a community-based contextualized care intervention delivered by a CHW in the CCM is also novel. We will rigorously test the added benefit of a stepped care approach based on patient attainment of BP control. This approach includes either specialist consultation; a community-based component that engages patients' families and social networks; or both. Further, we will actively engage stakeholders to ensure that these approaches are achievable, sustainable, and scalable to other settings.

3. **Significance of the Proposed Study**. Our study will add tremendous value to current efforts to reduce HTN disparities among underserved populations. First, in addition to benefiting patients' self-management goals, activation levels, and BP control, identifying effective mechanisms through which patients can achieve better overall CVD risk control is extremely beneficial to providers and insurers facing critical decisions about how best to provide adjunctive behavioral approaches to enhance effectiveness of prescribed therapies among high-risk patients in real-world settings. Second, patient-centered interventions guided by patients, providers, and other stakeholders may be more powerful and more sustainable than interventions developed without such input. Third, combined practice site and community-based interventions training patients in CVD risk-management and decision-making skills should have a broader impact on the health of patients' communities by providing patients and their family members and friends with skills they can apply to their own health conditions and to the prevention of future CVD risk development. Finally, rigorously evaluated interventions that demonstrate the feasibility of leveraging existing resources in routine primary care should provide health care providers and policy makers with the confidence to endorse the widespread use of similar interventions in a variety of healthcare practice settings that serve at-risk populations.

Table 1: Critical Gaps in Current Literature to Reduce CVD Disparities and Innovative Ways to Address Them			
PICOTS Framework	**CRITICAL GAPS in Existing Clinic-Based Interventions**	**CRITICAL GAPS in Existing Community-Based Interventions**	**Our INNOVATIVE Study Approaches to Address Gaps**
Intervention	Few clinical interventions have used collaborative and coordinated care among primary care providers, specialists, nurses, pharmacists, social workers, and other key team members to improve multiple CVD risk factors.	Research is needed to better describe the required level of intervention intensity and detailed descriptions of successful CHW components (e.g., CHW education, training, expertise, supervision, attrition, satisfaction) for effectively improving outcomes.[15,74,97,98]	We will measure and document specific components of our collaborative care (CC) intervention (e.g., team dynamics, adherence to guidelines, relationships with patients) and CHW intervention (e.g., CHW personal traits, training) exposure to specialist consultation, that are critical for achieving improved CVD-risk reduction.
Comparator	Unknown whether multi-level interventions are more effective than those targeting only patient factors, and which health system QI interventions are most effective.[15]	Studies are needed to compare the effectiveness of different types of multi-level interventions (with detailed justification for the choice of comparators) across multiple patient populations.[15,98]	Our study will compare the effectiveness of enhanced standard of care with a clinic-based multi-level intervention with the added value of a CHW intervention or specialist consultation in reducing CVD risk factors in diverse, high-risk patient groups.
Outcome	Little evidence testing whether health system QI interventions are effective at reducing CVD disparities.[15] Many analyses of study outcomes are limited by small sample sizes.[93]	The evidence base is limited by variations in the specific confounders and effect modifiers that investigators have included or controlled for in their analyses of intervention effectiveness on patient outcomes.[98]	We will employ rigorous statistical methods to appropriately control for factors that may influence the observed effect of our CC interventions on reducing disparities in a large population with CVD-risk factors. We are recruiting a large sample with adequate power for subgroup analyses.
Timeframe	Most interventions are short-term (<12 months) and do not allow for the measurement of long-term clinical endpoints.[93,99]	Little is known about the required duration for interventions shown to be effective at addressing CVD disparities.[15]	We will implement our interventions over a 2-year time frame with detailed documentation about intervention duration and long-term outcome measurements (up to 36 months).
Setting	Many existing studies are conducted at single clinical sites.[93] More studies are needed to create effective linkages between the community and clinic-based systems to also address social barriers and community factors influencing patient outcomes.[101]	There is little evidence on the comparative effectiveness of CHW programs implemented within patients' homes compared to within clinical settings.[100]	We will compare a clinic-based intervention to one that adds a community-based component and/or specialist consultation among 1,890 underserved patients receiving care at 30 community-based primary care practices, many of which are Federally Qualified Health Centers (FQHCs) in Maryland with underserved minority populations.
***Patient Centeredness & Engagement of Social Networks**	Most existing clinical programs have not actively built collaborations between patients, social networks, communities, minority-serving health systems, and large-scale medical research institutions.[99,101]	Little evidence about patient knowledge, comfort, and satisfaction with CHWs and what role patients ideally want and expect CHWs to play in empowering them to engage in their disease management.[74,98]	We will develop patient and family and community-centered interventions to enhance patient engagement in HTN control and broad CVD-risk reduction using CBPR principles. We will use validated tools to measure patient goal attainment, preferences, and experiences with the interventions.
***Sustainability & Translation into Practice**	Rigorously designed studies are needed to demonstrate sustainability of effective clinical interventions and models for program reimbursement.[79]	Policy aspects of CHW programs (e.g., reimbursement for services, integration into healthcare practice, credentialing, sustainability) and lessons learned need to be examined and translated into guidelines and protocols.[74]	We are actively engaging multiple stakeholders throughout the study, and we will utilize existing clinical staff infrastructure to improve likelihood of sustainability and translation into practice.

Section 2: Objectives

A. UH2 Aims

UH2 Planning Phase Specific Aim 1: In the UH2 planning year, we worked collaboratively with our community of stakeholders and health system partners in all aspects of the study, from study design, to identification of patient-centered outcomes, to developing protocols, measures and toolkits that will meet the needs of the study and the interests of our group of constituents.

1. **Health System Partnerships.** We worked closely with our health system partners in the development of this protocol, and have received their letters of support to be part of this project. We have finalized these arrangements, through a series of meetings to formulate official agreements between Johns Hopkins School of Medicine and each health system. We have confirmed the specific practices within the health systems that will be participating. We spent time with practice staff – from office medical directors to medical assistants – to understand the cultures of each practice and assess the needs of each health system and each individual practice. As part of these partnerships, we have identified system-level physician and administrative champions for each partner, and continue to identify practice-level clinical champions and certified medical assistant (CMA) super-users. We executed the necessary paperwork to formalize the partnerships before the implementation of the care management intervention.
2. **Patient and Other Stakeholder Engagement.** We established a community advisory board (CAB) in previous work, and we continued to build on this CAB, expanding and strengthening our ties to the community and with our key stakeholders in the business, government and local organization communities. Our CAB has representation of patients at local practices, and we will continue to invite patients from participating health systems to join us. We have worked closely with local organizations, large (e.g., the American Heart Association, the American Diabetes Association, the YMCA) and small (e.g., Sisters Together and Reaching, the Men and Families Center, the East Baltimore Collaborative), and have sought their continued involvement. In addition to our quarterly CAB meetings, our efforts included a dedicated staff member whose responsibilities focus on staying in touch with our health system, practice-level, and community stakeholders and keeping them informed of our progress, as well as participating in regular outreach efforts in the community (e.g., attending local health fairs, speaking at community events, and training lay health workers at local institutions). We consulted with our stakeholders during the protocol and instrument development stages, and we continue to do so, asking them to review materials, pilot-test surveys and be test subjects in training sessions for interventionists. Using a community-based participatory approach, we will continue to review and update the bylaws established by our current CAB that outline the roles and decision-making authority of patients and other stakeholders in the design, monitoring, and dissemination of the current study.
3. **Feasibility Study.** We conducted a feasibility study to identify and address likely failure modes prior to full implementation in the first cohort. We identified a practice site from those assigned to the first cohort that was willing to allow us to conduct feasibility testing at its location. Actual involvement of the site staff was confined to reception services when patients came to the practice to meet with the study-team-provided care manager and providing EMR data about the patient to the care manager. We identified a list of patients eligible for the study from the EMR using the study selection criteria identified below and from this list selected a random sample of white patients, and selected all of the minority patients to create a pool of 200 patients. This sample allowed for a combined ineligible and refusal rate of 70%. We attempted to draw patients of White, Black and Hispanic background in 1/3-1/3-1/3 proportions to match the planned study design; however the practice site had fewer eligible patients in the Black and Hispanic categories than would allow us to reach this goal. We tracked percent identified as eligible in each category, and reviewed enrollment rates carefully (see Table 2 below).

Patients received letters co-signed by the study lead and the practice medical director inviting them to participate in the feasibility test.

Research assistants contacted potentially eligible patients that did not return an opt-out postcard by phone to ascertain their willingness to participate, further screen for eligibility, and to obtain oral consent. We tracked the percent agreeing to participate in each racial/ethnic category. The consent form provided specific details of the feasibility study. Patients who participated in the feasibility study are allowed to participate in the full study; however, they still need to be eligible based on the EMR pull, and need to be screened, consented and re-take the baseline patient survey.

We collected screening and baseline surveys from identified patients with a goal to reach 60 (to allow a margin of as much as 50% attrition before completion of the First Intervention Visit). We monitored refusals to participate and the rate of failure to complete the survey (again by race/ethnicity). During the conduct of the telephone surveys, we identified problems, errors, and participation and completion barriers and will be discussing some of these with the CAB in March to identify potential solutions, such as patients who only speak Spanish. Examples of problems that we identified and have already corrected are:

a. Inadvertent recruitment of spouse of the eligible patient: the recruiter thought that it was a woman's name and asked for "Mrs." John Doe. We have revised the screener to have the recruiter ask for the patient by name, without a title, and to also have the sex of the patient "piped" into the screener.
b. Identified another ICD code for end stage renal disease that was not included on our specifications for the EMR data pull of potentially eligible patients. We added the code N18.5 (chronic kidney disease, stage V) to our exclusion criteria and a question on the screener about whether the patient is on dialysis in order to exclude those with CKD, who have recently progressed to dialysis.

Research assistants scheduled patients who responded to the telephone survey for a First Intervention Visit (FIV), with a goal of 30 (to allow as much as 33% attrition for no-shows). We tracked the percentage in each racial and ethnic category agreeing to and completing the FIV. We monitored the length of time to complete enrollment of the feasibility sample, dropout rates and no-show rates, allowing for a margin of up to 30% attrition. The majority of the FIVs were conducted at the practice location in an office setting by a nurse member of the research team who acted in the Care Manager (CM) role for this test. Additional visits were conducted via telephone.

Finally, the care manager conducted FIVs until all willing patients were seen. We anticipated that at least 20 would participate fully. During this phase of the feasibility study, we recorded:

a. The average time spent with each patient planning their care
b. The applicability of the available protocols (e.g., are protocols adequate, are other protocols needed)
c. The number of patients anticipated to need specialist consultation and/or assignment of a CHW.
d. The final racial and ethnic distribution among the full-participation group. We will also assess the number of Medicaid and commercial insurance patients included.

We made notes of lessons for scheduling, FIV agenda, the care protocols, and the patient survey as we parse the results of the feasibility study. Table 2 shows the recruitment outcomes of the feasibility study.

Table 2: RICH LIFE Project Feasibility Study Recruitment Report				
	All Patients	African American	Hispanic	White
Invitations mailed	**200 (100)**	**40 (20)**	**8 (4)**	**152 (76)**
Returned by post office	0 (0)	0 (0)	0 (0)	0 (0)
Returned opt-out post card	15 (8)	1 (2)	0 (0)	14 (9)
Patients to be contacted	**185 (92)**	**39 (98)**	**8 (100)**	**138 (91)**
Not attempted to contact	27 (15)	0 (0)	0 (0)	27 (20)
Attempted to contact	**158 (85)**	**39 (100)**	**8 (100)**	**111 (80)**
Unable to contact	63 (40)	13 (33)	2 (25)	48 (43)
Incorrect person contacted*	1 (1)	0 (0)	1 (12)	0 (0)
Contacted	**94 (60)**	**26 (67)**	**5 (62)**	**63 (57)**
Not interested	41 (44)	13 (50)	3 (60)	25 (40)
Undecided/call back	13 (14)	2 (8)	1 (20)	10 (16)
Screened	**40 (43)**	**11 (42)**	**1 (20)**	**28 (44)**
Ineligible	7 (18)	2 (18)	0 (0)	5 (18)
Eligible	**33 (82)**	**9 (82)**	**1 (100)**	**23 (82)**
Not interested	3 (9)	0 (0)	1 (100)	2 (9)
Undecided/call back	5 (15)	2 (22)	0	3 (13)
Consented	**25 (76)**	**7 (78)**	**0**	**18 (78)**
Undecided/call back	3 (12)	2 (29)	0	1 (6)
Baseline survey completed	**22 (88)**	**5 (71)**	**0**	**17 (94)**
Care manager visit	**19 (86)**	**4 (80)**	**0**	**15 (88)**

* Note: there was one person who was not on our recruitment list who was incorrectly recruited, screened, consented, and completed the baseline survey. She was the wife of the Hispanic patient that we did not attempt to contact. Her data are not included in the table.

i. **UH2 Hypothesis**: We will be able to successfully engage our stakeholders to design and perform a feasibility study based on our grant proposal.

ii. **The UH2 hypothesis was sustained.**

B. UH3 Aims

1. **UH3 Specific Aim 1:** We will conduct a pragmatic clinical trial to test practical, scalable approaches to close the HTN disparities gap. We will compare the effectiveness of a standard of care plus (SCP) intervention (that includes audit/feedback and education) to practice-based collaborative care with a stepped approach (CC/stepped care) that includes community-based contextualized care delivered by a CHW, specialist consultation, or both, to reduce disparities in HTN and improve patient-centered outcomes (self-management behaviors, goal attainment, activation).
2. **UH3 Specific Aim 2:** We will demonstrate patient and stakeholder engagement by applying principles of community-based participatory research (CBPR) to build upon our existing local community board and engage a regional and national stakeholder advisory panel.
3. **UH3 Specific Aim 3:** This study will inform the important question of whether a multi-level intervention that adds a contextualized (i.e., patient and family-centered, community-based) approach to practice-based CC/stepped care will be more effective than SCP alone at improving clinical outcomes and self-management behaviors among patients with hypertension and other common comorbidities and CVD risk factors.

i. **UH3 Hypothesis**: The multi-level intervention with a contextualized (i.e., patient and family-centered, community-based) approach to practice-based CC/Stepped Care will be more effective than SCP in improving clinical outcomes and self-management behaviors among hypertensive patients with other designated conditions.

Section 3: Design

A. Research design/methodology

1. The design of this study is a prospective cluster-randomized trial of superiority of CC/Stepped Care over SCP. Evidence exists for the effectiveness of both intervention approaches; however, they have not been sustained or translated to practice in real-world settings caring for underserved populations. Further, the proposed comparison has not been done, using a pragmatic approach, to address HTN management to reduce disparities in patient outcomes (see Section 1: Background/Significance).

B. Study population: Inclusion/exclusion criteria

1. **Inclusion Criteria:**
    a. Practice sites: Thirty primary care clinics in the mid-Atlantic have been enrolled and randomized. Practices must either be Federally Qualified Health Centers (FQHCs) or serve diverse racial and ethnic populations.
    b. Patients: An average of sixty-three adult patients from each of the 30 participating practices, for a total of 1,890 patients, will be enrolled. Inclusion/exclusion criteria are listed in Table 3.
    c. We include a focus on co-morbidities for several reasons:
        i. Patient and provider stakeholders who participated in our prior HTN intervention studies indicated that they needed guidance in addressing non-HTN co-morbidities
        ii. HTN, diabetes, hyperlipidemia, and coronary heart disease (CHD) are co-existing illnesses with compatible management guidelines, making them amenable to a collaborative care approach;[95,102]
        iii. Depression is highly prevalent in patients with CHD[103] and diabetes[104] and associated with poor self-management, complications, and death
        iv. Smoking is common in individuals with depression,[105,106] contributing to CHD and diabetes risk.
        v. Finally, in a recent Institute of Medicine report, "Living Well with Chronic Disease," CHD, diabetes, and depression were highlighted as 3 of 7 co-morbidities associated with poor patient outcomes, increased disability, and high healthcare costs.[107] These conditions were identified as being clinically important; affecting patient function and disability; impacting communities, families, and caregivers; and presenting important public health challenges.
2. **Exclusion Criteria**: We would like to include as many people who are eligible and able to participate in the study as possible, and therefore are only excluding patients with the characteristics listed in Table 3.

Table 3: Study Participant Inclusion and Exclusion Criteria	
Inclusions (all criteria must be met)	**Exclusions**

• ≥21 years of age as of date of data extraction
• EMR identified as non-Hispanic white, non-Hispanic African-American or Hispanic
• Have a diagnosis of HTN (defined by ICD-9 or ICD-10 code AND most recent systolic blood pressure (BP) measures (≥140 mm Hg systolic)
• Have at least one of the following CVD risk factors:
  • Diabetes mellitus (ICD 10: E10, E11 or ICD 9: 250)
  • Hyperlipidemia (ICD 10: E78 or ICD 9: 272*)
  • Diagnosis of coronary heart disease (ICD 10: I25* or ICD 9: 402*, 410-414, or 429.2)
  • Current tobacco smokers (ICD-10: 305.1, F17*, Z72.0 or ICD-9: 305.1, or EMR note)
  • Diagnosis of depression (ICD 10: F32*,F33*, F32.9 or ICD 9: 296.2, 296.3, 311)
• Receives primary medical care at participating practice
	• <21 years of age
	• Diagnosis of end stage renal disease (ESRD) (ICD 10: N18.5, N18.6 or ICD 9: 585.5, 585.6)
	• Condition which interferes with outcome measurement (e.g., dialysis)
	• Serious medical condition which either limits life expectancy or requires active management (e.g., certain cancers)
	• Patients with cognitive impairment or other condition preventing their participation in the intervention
	• Those with an active alcohol or substance use disorder (i.e., not sober/abstinent for ≥ 30 days)
	• Pregnant or planning pregnancy in the next 24 months
	• Currently nursing a child
	• Current participation in another research study focused on reducing BP
	• Current participation in a care management program related to health conditions (e.g. weight reduction, smoking cessation)
	• Those planning to leave the practice or move out of the geographic area within 24 months
	• Those who no longer consider the practice site the location where they receive primary care
	• Unwillingness to provide informed oral consent

Certain conditions in ICD-10 have a coding convention that require the underlying conditions be sequenced first followed by manifestation. Wherever such a combination exists, coders are required to use additional code. For our purposes, any of the conditions that follow the initial code are acceptable. To save space, we are listing these codes with an "" after the condition code.	

C. Definition of disease of interest (measurement criteria)

1. **Hypertension (HTN)**: BP is a measurement of the force exerted against the walls of the arteries as the heart pumps blood to the body. HTN is the term used to describe high BP. BP readings are given as two numbers. The top number is the systolic BP. The bottom number is the diastolic BP. For example, 120 over 80 (written as 120/80 mm Hg). One or both of these numbers can be too high. Normal blood pressure is when blood pressure is lower than 120/80 mm Hg most of the time. The 2017 Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults categorizes BP as normal (systolic BP [SBP] <120 mm Hg AND diastolic BP [DBP] <80 mm Hg); elevated (SBP 120-129 mm Hg AND DBP <80 mm Hg); stage 1 hypertension (SBP 130-139 mm Hg OR DBP 80-89 mm Hg); and stage 2 hypertension (SBP ≥140 mm Hg OR DBP ≥90 mm Hg). Thus, according to the new categorization, this study targets patients with Stage 2 Hypertension.
2. **Uncontrolled diabetes:** Diabetes is a chronic disease in which the body cannot regulate the amount of sugar in the blood. When a person has diabetes, the fat, liver, and muscle cells do not respond correctly

to insulin. This condition is called insulin resistance. As a result, blood sugar does not get into these cells to be stored for energy. It is considered uncontrolled with random glucose measurement of 200 mg/dL higher or a hemoglobin A1c of 7% or higher.

3. **Coronary heart disease (CHD):** A narrowing of the small blood vessels that supply blood and oxygen to the heart. CHD is also called coronary artery disease. It is caused by the buildup of plaque in the arteries to the heart. This may also be called hardening of the arteries.
4. **Hyperlipidemia:** The medical term for high blood cholesterol. Cholesterol is a fat (also called a lipid) that your body needs to work properly. Too much bad cholesterol can increase the chance of getting heart disease, stroke, and other problems. General targets are:
    a. LDL: 70 to 130 mg/dL (lower numbers are better)
    b. HDL: more than 50 mg/dL (high numbers are better)
    c. Total cholesterol: less than 200 mg/dL (lower numbers are better)
    d. Triglycerides: 10 to 150 mg/dL (lower numbers are better)
5. **Depression:** Depression may be described as feeling sad, blue, unhappy, miserable, or down in the dumps. While most people may feel this way at one time or another for short periods, clinical depression is a mood disorder in which feelings of sadness, loss, anger, or frustration interfere with everyday life for two weeks or more.
6. **Current tobacco smoking:** A person who habitually directly inhales tobacco smoke. A current tobacco smoker will be defined as a person who reports smoking at least 100 cigarettes in their lifetime and who currently smokes either every day or some days.

D. Primary outcomes defined

1. **Clinical Primary Outcome**: Percent of patients with BP <140/90 mm Hg. Although we are aware of the new 2017 HTN guideline and we largely agree with the more aggressive goal of <130/80 mm Hg for control in most patients, we do not plan to change the study goal for blood pressure control at this time. Our rationale for keeping the study outcome is as follows: 1) We expect uptake of the new guidelines will be slow in the field and 2) We wish to maintain consistency in our data. We anticipate conducting a sub-analysis of study data at the close of the study period to examine what percentage of patients achieve lower targets (i.e. <130/80 mm Hg and <120/80 mm Hg) using the RICHLIFE interventions.
2. **Patient Reported Primary Outcomes**: Change from baseline in self-reported level of patient activation, measured using the Patient Activation Measure®-13, at 12 months.

E. Secondary outcomes defined

1. **Clinical Secondary Outcomes**:
    a. Change from baseline in mean systolic BP at 12 months
    b. Change from baseline in diastolic BP at 12 months
    c. Change from baseline in 10-year projected probability of a CVD event (global Framingham Risk Score) at 12 months
    d. Mean change from baseline in total cholesterol, low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein (HDL)
    e. Change from baseline in the percent with controlled total cholesterol, LDL, and HDL at 12 months for all patients and for the subgroup with hyperlipidemia
    f. Mean change from baseline in hemoglobin A1c and change from baseline in the percent with hemoglobin A1c< 7.0 at 12 months in patients with a diagnosis of diabetes

2. **Patient Reported Secondary Outcomes (all at 12 and 24 months)**:
    a. Attainment of self-determined goals related to self-management behaviors (e.g., medication adherence, healthy diet, physical activity, and smoking cessation).
    b. Medication adherence –4-item score
    c. Health related quality of life – PROMIS Global scale
    d. Depressive symptoms – PHQ-8 score
    e. Patient Assessment of Care for Chronic Conditions – PACIC-Plus
    f. Patient Ratings of Trust
    g. Hypertension knowledge and attitudes
    h. Patient ratings of intervention (for those in CC/Stepped Care practices)

F. Pragmatic elements

1. **Less stringent selection of participants**: We are recruiting from a pool of all patients at the practice location with HTN and who are in need of additional services – those with uncontrolled HTN with at least one other comorbidity/risk factor from the following list: diabetes, hyperlipidemia, depression, smoking, or coronary heart disease. We are using electronic medical records (EMRs) data to identify HTN patients not attaining BP control targets and clinical targets for comorbidities (e.g. HbA1c≥8%, Patient Health Questionnaire-2 depressive symptoms score ≥3). The only patients we have excluded are those with serious medical, psychological, or geographic impairments preventing participation and follow-up.
2. **Flexible interventions applied in normal primary care practices**: Instructions on how to apply the CC/Stepped Care intervention are flexible. The collaborative care team, including CHWs, have protocols, but patients' goals, priorities, and needs guide the content, location, and frequency of contacts. Interventionists have a toolkit from which they can tailor the program for each patient.
3. **Use of existing practice staff to apply and monitor the interventions:** Our CC/Stepped Care intervention is delivered by staff already working at participating practices whenever possible. We only budgeted to cover the costs of new CHWs for the practices that either lack such resources or have limited resources. Additional training and resources is provided to all staff, for them to use at their discretion. We have provided guidelines and recommendations on the functions needed at each practice for the CC team, the frequency of care coordination meetings, and the domains to be covered in assessments. The team has leeway in how the meetings will be run; how specific tasks will be allocated and shared across available staff; and how the assessments will be used to formulate each patient's care plan.
4. **Use of 'best alternative' comparison strategy**: The comparator intervention is SCP, an enhanced version of systematic audit and feedback and provider and staff education used in many practices to guide their quality improvement efforts.
5. **Administrative 'routine' follow-up of participants:** We are relying in large part on data from routine practice visits, documented in the EMR, or claims data. This study will evaluate outcomes based, in part, on BP measurements that are collected by PCPs and MAs, and entered into practices' EMR. Although this approach deviates from the approach used in traditional clinical trials, where a small pool of highly trained research staff measure BP, it offers several advantages from a pragmatic perspective. This issue is discussed further in Section 7A, Primary Outcome Measure – Blood Pressure. Our surveys collect patient-reported measures not typically found in the EMR and provider and manager responses not available from other data sources. We will obtain clinical measures from the EMR and patient-reported adverse events every 6 months, and patient-reported measures at 12 and 24 months by survey. For patients with several chronic diseases, many of which are not adequately controlled, this is a reasonable time frame to assess their responses to the program and experiences with it.

6. **Measurement of multiple outcomes directly relevant to patients, providers, funders, and communities**: Our primary clinical outcomes are systolic BP and BP control measured at approximately 12 months, which are objectively measured under usual conditions of clinical practice. These measures are important to patients who worry about the risk of stroke or heart attack. We will also include patient reported measures.
7. **Unobtrusive measurement of participant compliance:** We are relying only on typical practice procedures for encouraging patient compliance to the strategies discussed with the care team. Furthermore, the care plan is driven by patient needs, goals, and priorities. We are tracking attendance and number of contacts but there will be no detailed measurement of patients' use of materials and tools provided.
8. **Passive surveillance of practitioner's adherence to study protocol:** We are making no intrusive efforts to monitor adherence to the study protocol by practice clinicians or staff after initial observations to assess the effectiveness of BP measurement training. Beyond offering opportunities for training, we are not being proscriptive about how the intervention should be delivered. We are offering toolkits and allowing practice teams to drive the content, intensity, and format of the intervention.
9. **Inclusive analysis of primary outcomes**: Our analyses will include all study patients regardless of compliance with the recommended intervention protocol (i.e., intent-to-treat). We are interested in whether the interventions work under usual conditions.
10. **Collaborations**: We partnered with a primary care association, MACHC, and built on their relationships with FQHCs in Maryland to secure health system partners.
11. **Allowing for site flexibility**: We are balancing a need for fidelity in implementation with the practice sites' need to tailor the interventions for their individual locations. For instance, we are providing a set amount of funding for staffing the interventions to each practice along with some suggestions on how to allocate the funds, however we are leaving the exact disposition of the funds up to each system.
12. **Generalizability**: By measuring the fidelity of the intervention implementation while allowing for tailoring to individual practices, we hope to be able to show that our interventions can be successfully implemented in a wide variety of settings.

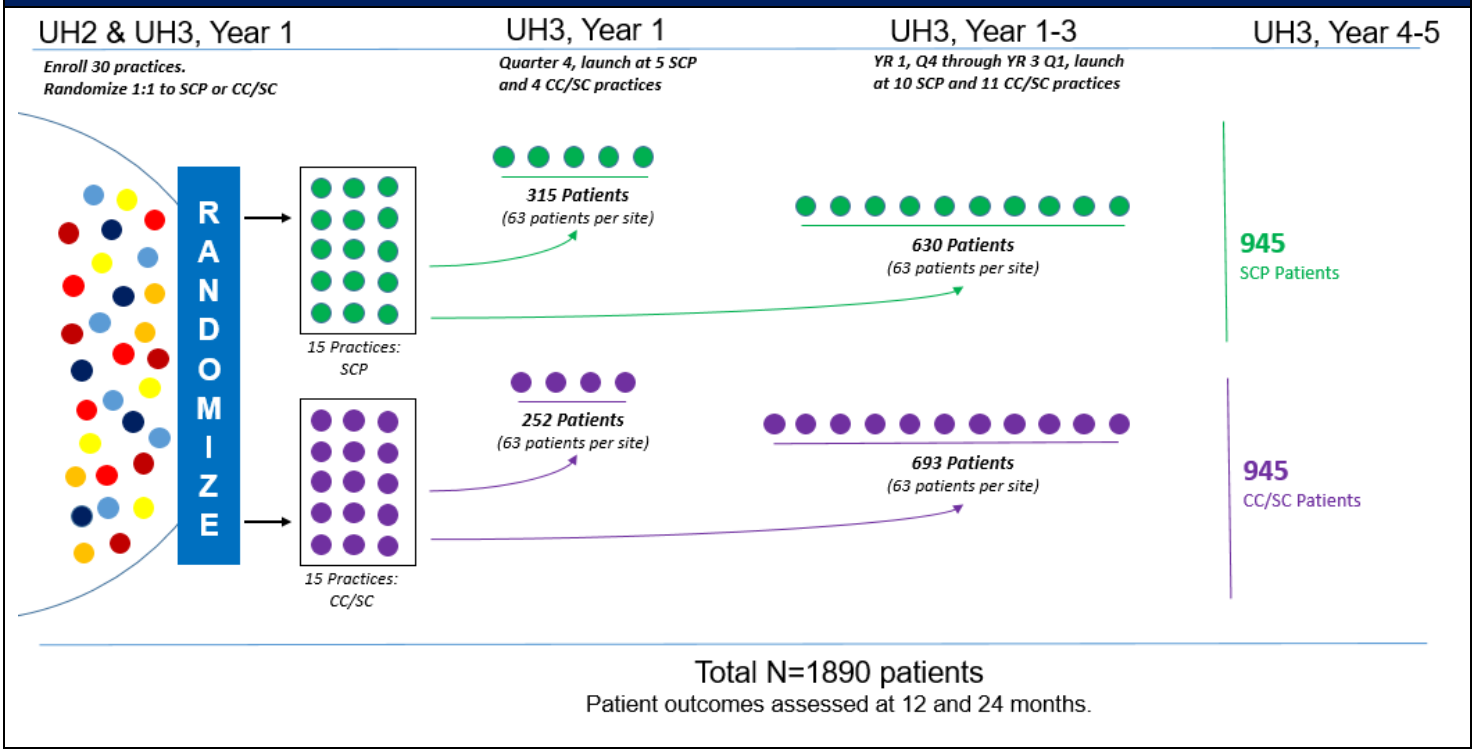
G. Randomization and intervention rollout

1. **Randomization Scheme**. Practice randomization took place early in the UH3 phase after all original 30 practices were identified. Our analysis will be conducted at both practice and patient levels. We combined practice networks as necessary to create two cohorts. All of the original participating practices from a health system are in the same cohort. Randomization was stratified by practice network and blocked to balance the intervention allocation within networks (to the degree possible if an odd number of practices in a network) and cohort. Health systems learned the outcome of the randomization in March 2017. They did not share the outcomes of randomization with the individual practices until after blood pressure measurement training had been completed.

   The randomization of replacement practices is described on pages 21 and 22.

2. **Phased intervention rollout.** Different health systems began the intervention on a staggered basis (see Figure 1: Phased intervention roll-out). Beginning in the UH3 phase, we distributed automated devices to train staff on evidenced-based BP measurement, audited fidelity to the BP measurement protocol, and enrolled patients, which for the first 9 practices took 6 months. Thereafter, the 21 additional practices began the intervention, starting at least 3 months after the first 9 practices. Intervention roll-out will continue until all 30 practices have implemented either SCP or CC/Stepped Care. As practices complete the intervention, we will continue to monitor outcomes data to assess sustainability.

Figure 1: Phased Intervention Roll-out



H. Expected duration of subject participation

The intervention period for the entire study will last three years, but each set of practices will have at least one year of active collaborative care intervention. Discipline-specific clinician and staff training on the interventions will occur in all practices prior to their assigned roll-out date during practice orientation. Each patient participant will be exposed to two years of active intervention.

Section 4: Recruitment of practices

There are two levels to our site recruitment strategy. We began by identifying multi-practice systems with which to partner. Generally, the systems agreed to include all of their participating adult medicine sites in the study; however, in one large system, there were more site locations than needed to include to reach the desired power level. Furthermore, we wanted to use the large, non-FQHC private nonprofit system to provide a counterpoint to the included FQHCs without overwhelming them in number.

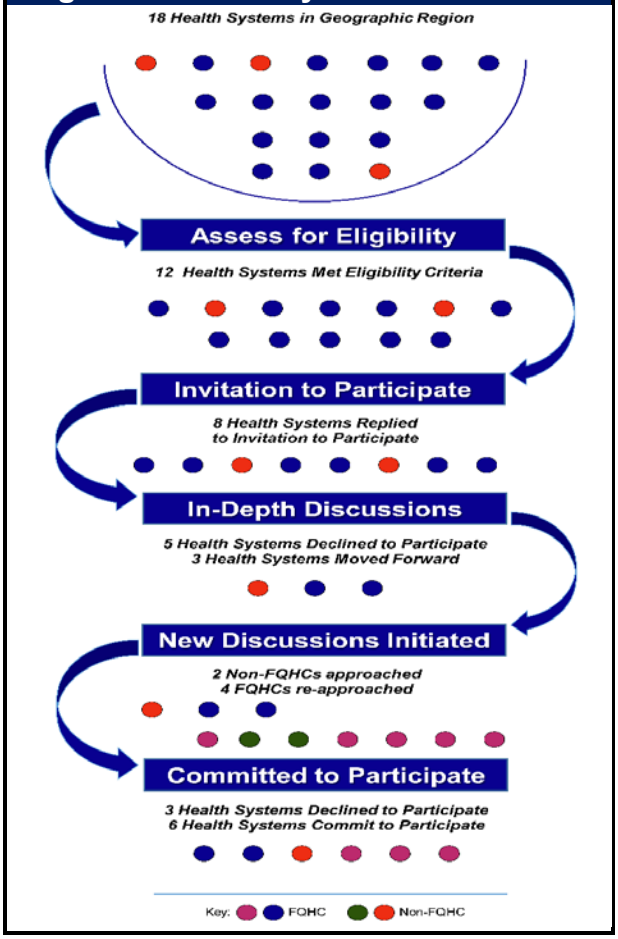
A. Number of practice sites: Thirty primary care practices across Maryland and Pennsylvania have been enrolled and randomized.

B. Practice inclusion/exclusion criteria:

1. Practices must be FQHCs or other primary care practices that serve diverse racial and ethnic populations
2. Practice demographics: From the FQHCs, we preferentially included larger practices. From the non-FQHC health system (JHCP), we preferentially selected practices with larger populations of ethnic minorities and patients from underserved communities, including sites with a greater likelihood of drawing from rural areas.
3. Patient population demographics: We have preferentially selected practices with larger adult and ethnic minority populations and larger populations with Medicaid insurance coverage.

C. System recruitment methods: During the writing of the grant for this project, and through the initial months of our planning year, we evaluated 18 health systems in Maryland and Pennsylvania for trial eligibility and inclusion. Fifteen health systems are FQHCs – shown in blue in Figure 2 (all of the Maryland FQHCs at time of evaluation) – and three health systems are non-FQHCs (shown in orange). Two are located in the greater Baltimore-Washington metropolitan region, and the final one was located in rural central Pennsylvania.

Figure 2: Health System Recruitment



Of the 15 FQHCs, five FQHCs did not meet our eligibility criteria (e.g., more than one practice in the health system providing care to the general adult population; not a pediatric or specialty practice such as obstetrics/ gynecology, substance abuse, or HIV/AIDS). Working with the primary care association for all of the Maryland FQHCs (MACHC), we invited the eligible FQHC health systems to participate via an emailed letter of invitation. Along with the invitation email, we sent each of the eligible FQHC health systems a two-page project and grant overview.

Of the three non-FQHC health systems based in Baltimore and Pennsylvania, two met the eligibility criteria of more than one practice. We conducted the same process of sending an email letter of invitation and grant overview as in the FQHC health systems.

Eight of the 12 health systems responded to the invitation email (six of the 10 eligible FQHCs and both of the eligible non-FQHCs).

We conducted in person meetings with leadership at each health system responding to the initial email invitation. During these in-person meetings, we reviewed the proposed project, addressed questions about the project from the health system leaders, and discussed available resources for health system and practice participation by study arm. After the introductory meetings with the eight eligible health systems, four health systems declined to participate, citing participation barriers that included change in health system leadership, HTN treatment as a low priority of the health system, competing demands, or inadequate resources to support their involvement in the study.

Of the 12 health systems evaluated responding to the initial email, three (two FQHCs, one non-FQHC) health systems continued to partner with the study team, through the end of the planning year and signed letters of agreement to participate. These three systems represent 19 of our practices for the study. In order to reach the total of 30 practices needed to power the study, we met with two additional non-FQHC systems, one in Delaware and the other in Pennsylvania (shown in green). Although we had extensive conversations with both systems, both declined to participate based on concerns about needed resources and time commitments for the CC/Stepped Care locations, as well as a planned migration of EMR platforms for one of the systems. The Pennsylvania system, however, had brought one of their partners, an FQHC based in Reading, to our initial meeting as another potential partner. After the non-FQHC system bowed out, this FQHC indicated their interest in participating, and in 2016 signed a letter of agreement. This brought the number of participating health systems to four and the total number of practices up to 21.

Working with MACHC, we reached out again to two FQHCs with a large number of clinics, one on Maryland's Eastern Shore and the other in southern Maryland (shown in purple). Although they were on our original list, they had not responded to our initial email. At the same time, we leveraged existing relationships from our research team and community advisory board to reach out to two additional FQHCs in Baltimore; neither of which responded to the initial invitation (also shown in purple). This time, we met with leadership from each system. As we moved forward in our conversations, we received enthusiastic response from one of the systems on the Eastern Shore of Maryland which agreed to participate in the summer of 2016, bringing the number of participating health systems to five, and their five sites raised our total number of practices to 27. Despite initial interest, the other Eastern Shore health system indicated they were in a transition period with their leadership, and eventually decided not to participate. The two Baltimore FQHCs both expressed interest, and we held extensive discussions with both systems. The larger Baltimore FQHC declined to participate after internal discussions. Family Health Centers of Baltimore signed a letter committing three locations to participate in the summer of 2016, and this brought us to our target of 30 practices (from six health systems).

D. Practice Site Selection within the large non-FQHC system: The one non-FQHC system that agreed to participate has on the order of 30 practice locations. It should be noted that although it is not an FQHC, it serves many patients from vulnerable populations in Maryland. To select appropriate study sites, we provided the system with an initial list of 17 practices for their consideration that met the following specific selection criteria:

1. Adult medicine practices
2. Patient population greater than 4000 patients
3. At least thirteen percent ethnic minority OR ability to draw rural patients.

The last criterion sought practices with at least the same proportion of racial or ethnic minorities seen in the American population. However, exceptions to this rule were made for some practices that border rural areas and are likely to serve rural patients. After consultations with the non-FQHC system and the insurance entity that it uses for care managers, we made adjustments to our original eligibility criteria for practice sites in order to honor requests that we use existing care managers as our study interventionists. We also removed the panel size criterion, recognizing that practices with fewer than 4,000 patients overall could serve the needs of the study adequately if they served large numbers of ethnic minority patients. Therefore, our revised eligibility criteria are as follows:

1. Practices with adult patients
2. Presence of a pre-existing care manager
3. Racial and ethnic minority populations at or above 13% OR access to rural patients

Nineteen practices met these criteria. At the request of the health system, we excluded seven of the 19 eligible practices for the following reasons: high staff turnover, practice productivity concerns, new practice leadership, change in practice location, and concurrent research projects. From the remaining 12 practices, we excluded 2 additional sites that shared a care manager with another practice on the list. This was done to avoid cross-contamination of the care management intervention between study arms. When a pair of practices on the list shared a care manager with each other, we preferentially included the practice that was larger and/or had a larger ethnic minority or Medicaid population. Including the added practice in June 2017, the final 11 practices included six with embedded care managers and five with regional care managers that were not shared with another practice on the list.

One of the health systems that we recruited informed us in July 2017 that one of its practices was closing on December 31, 2017. Another health system) offered for us to enroll an additional practice in their system. The advanced stage of trial preparation necessitated quick action to address the problem in order to avoid disruption of the overall timeline.

We put considerable thought into the best way to allocate the new practice since all of the practices had already been randomized and informed of their condition, and trial preparations had already progressed to the point where re-randomizing all sites was not feasible. We decided that we should follow our original randomization procedure, i.e., combining two health systems with odd numbers of practices and constraining the last randomization so that there is equal allocation. We performed the constrained randomization because the number of clusters (practices; n=30) is relatively small and we wanted to optimize our power. If we had not constrained the randomization, which was stratified by health system, there could have been a fairly large imbalance in the allocation and that imbalance could become worse if we lose any other practices over the course of the study.

The health system adding practices originally had an even number of practices so there was equal allocation at that health system. Fortunately, at the health system where we lost a practice, there remained an even number of practices and they were equally allocated to intervention arms. We could constrain randomization to have equal allocation. The new practice being assigned to the same intervention arm as the practice that we lost (in this case, the CC/Stepped Care arm).

In summary, given that randomization had already occurred for all of the other practices and implementation had begun, it was not feasible to completely re-randomize. If we had added the new practice to the randomization of the health system to which it belongs, then we would have had two health systems with an odd number of practices and neither in a constrained randomization.

In addition to the closure of a practice in 2017, the same health system experienced a change in leadership in the fall of 2017. In January 2018, the new leadership informed us that they no longer wished to participate in the RICH LIFE Project. We had completed BP training at this health system; however, patient recruitment had not begun at any of the FHCB practices.

Given the stage of the trial, it was too late to try to recruit a new health system. However, we did not want to drop down to 28 practices and possibly be underpowered to achieve our aims. One of our other health systems offered us the opportunity to select two out of three additional practices in their system that meet eligibility criteria for the trial. Two of these practices were in Baltimore City, which was where the practices we lost were also located. With approval from the DSMB, we enrolled the new practices and randomized them using a blocked randomization (1 in each arm).

E. Practice compensation: Each health system is compensated based on the number of practices participating and the arms to which the practices will be randomized. Below is an example of the compensation scheme for a health system with eight participating practices, four of which are randomized to the CC/Stepped Care arm. Based on our past experiences and to allow us to plan for equity in the amounts we provide to each of the systems that we are partnering with, we are proposing the funds be spent in the following manner. However, it is up to each system's discretion as to how the funds are actually spent, and they may choose to redistribute the provided funds in a manner that aligns with their organization's needs, structure, and policies.

Table 4: Sample Health System Compensation Plan

Salary support			
Development Year: October 2015 – August 2016			
System level champion	$3000	1 site-wide	$3000
2 Years of Active Intervention: TBD			
System level champion	$3000	1 site-wide	$3000/year
System level administrative champion	$1600	1 site-wide	$2000/year
Practice level physician champion	$1000	8 sites	$8000/year
CMA Super User stipend	$200	8 sites	$1600/year
Salary support for Care Manager*	$16,000	4 sites	$80,000/year
Salary & benefits to fully support practice CHW*	$35,682	4 sites	$142,728 /year
1 Year of Observation without Intervention: TBD			
System level champion	$3000	1 site-wide	$3000/year
CMA Super User stipend	$200	8 sites	$1600/year
Analysis Year: September 2019 – August 2020			
System level champion	$3000	1 site-wide	$3000
CMA Super User stipend	$200	8 sites	$1600/year
Additional Material Support			
Omron HEM-907XL, with power adapter and XL cuff	$700	1 per PCP	$22,400
Home BP monitors*	$90	63 per practice	$22,680
Food Models*	$180	4 sites	$720

For CC/Stepped Care Sites Only
Scenario assumes 8 sites with 4 primary care providers (PCPs) per practice

F. System and Practice Champions: We provided to our practice partners descriptions of the expectations of the System Level Champion, the Practice Physician Champion, the System Administrative Champion, and the CMA Super Users. Each system has identified or is in the process of identifying the members of their staff that will fulfill these roles. Providers/CMAs/Non-Physician Providers are invited to participate in the research study through a variety of channels depending on the participating health system's preferences and guidelines. These channels include electronic communication such as email, word of mouth in the practice, and/or presentations during practice meetings. For surveys, the invitation to participate is via email. When possible, we recruited providers/CMAs/Non-Physician Providers prior to the "Kick-off Town Hall" (prior to intervention start) and in the quarter prior to implementation at participating practices. Surveys for providers and practice staff at participating sites include the language, "by completing and returning this survey you are giving your consent to participate in this research."

1. The System Level Champion provides system level oversight of the system's participation in the study. He or she attends regular research meetings (e.g., monthly team meeting, CAB meeting, and smaller work group meetings as needed) in person or by conference call to provide input regarding the impact of the study on providers, staff, and patients cared for by the organization. He or she also assists in implementation (e.g., presentations to providers and staff and to the CC teams in the intensive intervention practices). He or she serves as an advocate for the project within the health system, encouraging adoption of the project, and helping to expedite the integration of the interventions into the practices.
2. Practice Clinical Champions may be based at one practice, or may be responsible for more than one of the practices within an organization. The number of practices within each organization that are randomized to each intervention arm could range from as low as one site to as high as seven sites. In the SCP practices, the champion assists in implementation of the interventions by encouraging provider and staff participation in the BP training, web-based modules, and review of audit and feedback data. In the intensive CC/Stepped Care practices, the champion assists in implementation of the interventions by assuring that the CC team has any clinical oversight needed beyond each patient's primary care clinician. Practice champions in all practices attend research team meetings if requested by the system level champion. If requested by the system level champion, they are the key clinical contact for the research team's Project Manager about the status of the intervention in their practice.
3. The System Administrative Champion facilitates the integration of the studies and the study staff into the practice settings across the system. In CC/Stepped Care intervention practices, the administrative champion arranges for all members of the collaborative care team to have access to clinical IT systems as appropriate. They assure that each practice has meeting space for care team meetings and work with administrative staff at each practice to assure that all care team members' space needs are met. In all practices, the administrative champion serves as the key administrative contact for the research team's Project Manager regarding the intervention in their system, and works closely with the practice champion.
4. Each practice has a certified medical assistant (CMA) or other clinical staff member designated as a Super User, who is trained in BP measurement techniques and then trains co-workers in the use of the protocol and be the lead troubleshooter for the OMRON machines. The Super User also helps to train new hires.

Section 5: Recruitment of participants

A. Number of participants per site: An average of sixty-three adult patients from each of the 30 participating practices, for a total of 1,890 patients, will be enrolled.

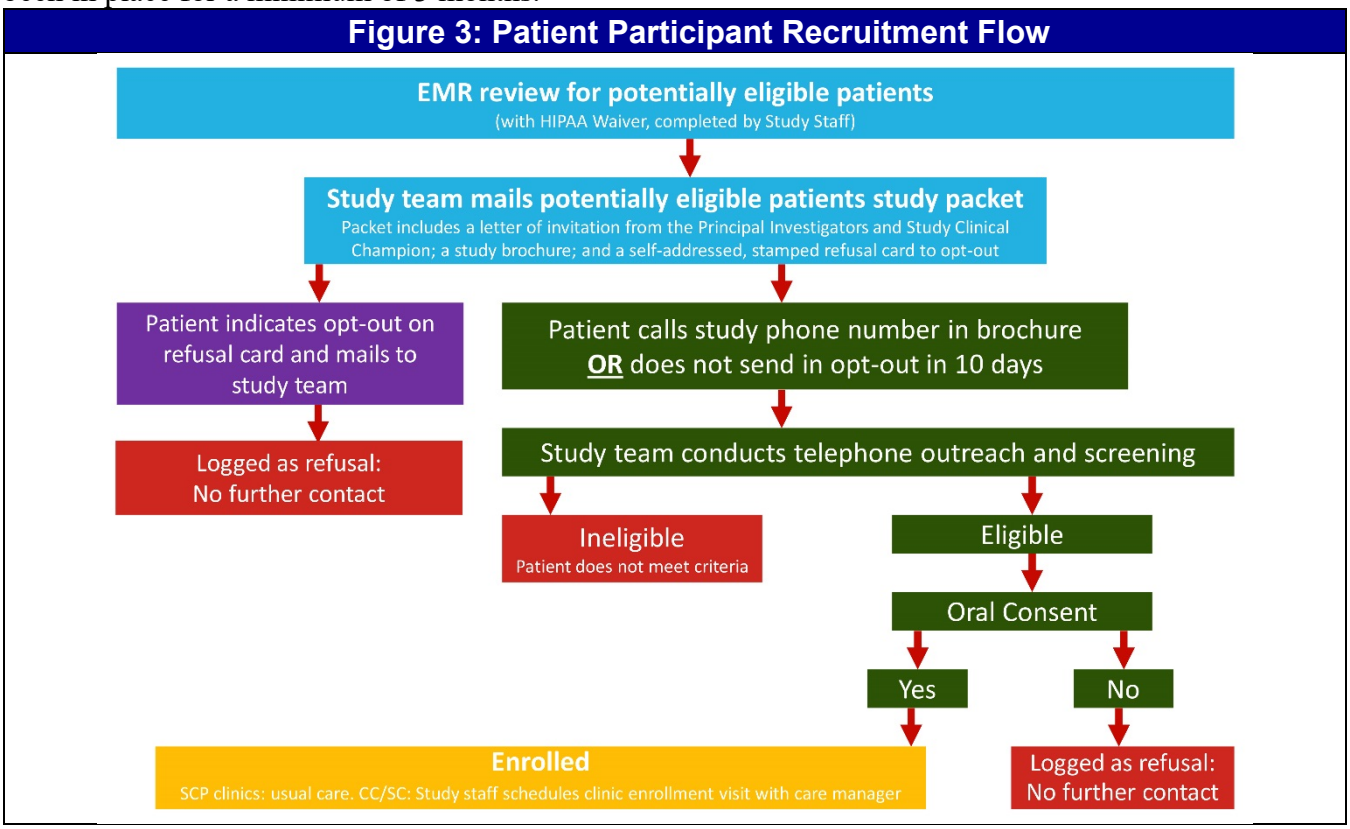
B. Participant inclusion / exclusion: See Table 3 in Section 3 above for inclusion and exclusion criteria.

C. Withdrawal criteria: Patients may choose to withdraw from the study at any time. The study team tries to collect as much data as possible from patients who withdraw – e.g., if patients move to another practice, we still try to collect survey data, and if they remain within the same health system, we are able to obtain EMR data. However, the study team may withdraw a patient from the study if the patient's PCP believes the patient should be withdrawn or the patient:

1. Becomes pregnant
2. Suffers a cardiovascular event
3. Develops a medical condition that limits life expectancy or requires active management (e.g., certain cancers)
4. Develops a condition that severely limits ability to participate (e.g., dialysis)
5. Moves primary care to another practice location
6. Develops cognitive impairment to the point it limits their continued participation
7. Develops a clinically diagnosed active alcohol or substance abuse disorder

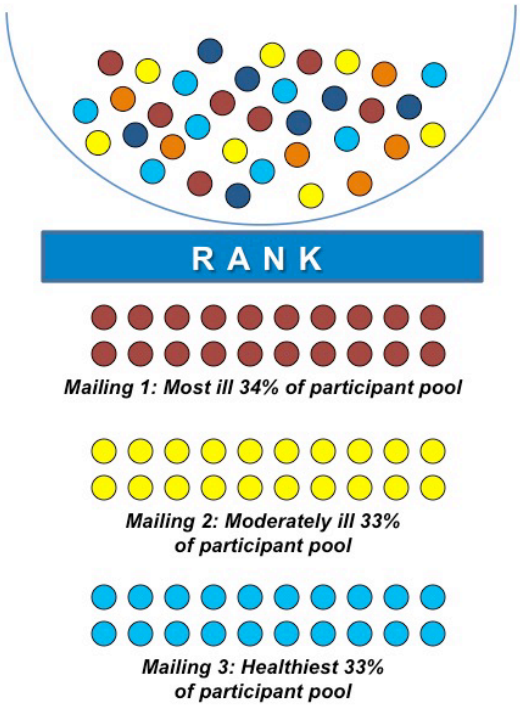
D. Participant recruitment method: We began study recruitment procedures at the first 9 practices following JHU IRB approval in August 2017. We screened the health systems' EMR data for 12 months prior (e.g., on April 1, 2017, data will be requested for April 1, 2016, through March 31, 2017) to identify patients seen at the participating practices during the 12-month period, who are potentially eligible for participation in our study. This screening took place after the OMRON BP intervention had been in place for a minimum of 3 months.

Figure 3: Patient Participant Recruitment Flow



1. **Step 1 – Identification of Participant Pool.** We identify patients with uncontrolled hypertension using EMR data (including participants' dates of visits, race, ethnicity, and BP) collected in participating health systems' EMR databases (e.g. Epic, Centricity) maintained at the health systems. We identify all active patients, ≥ 21 years of age for whom the most recent BPs meet the eligibility criteria listed above. We have a HIPAA waiver to identify patients using this method, as it would be impracticable for us to identify patients with uncontrolled HTN and an additional CVD risk factor during the allotted study time through any other means. Once we identify all potentially eligible patients in the database, if we have sufficient numbers of patients in each race/ethnicity stratum, then we will use ranking criteria (such as those in the JHHC risk-prediction model) to identify patients at highest risk and most in need of additional services. Providers at the health systems can also refer potential eligible patients and provide provider referral via fax. Provider referral will be reviewed by a research program manager to determine the eligibility of the patient and to identify if the referred patient is found in the EMR database. We will follow step 3 to reach out to the patient.

Figure 4: Participant Recruitment Mailings



2. **Step 2 - Mailed letter of invitation:** The JHU Study Recruitment Center staff mail to potentially eligible patients a packet that includes a letter of invitation describing the opportunity for them to participate in a study for which they may be eligible, a study brochure, a copy of the oral consent, and a pre-posted "opt-out" postcard. If the potential participant pool is large enough, these packets are mailed in batches, beginning with the highest risk patients. The number of packets in a batch varies depending on the number of potentially eligible patients, response rates from previous mailings, etc. Though we are targeting the highest risk patients when possible, we are also sampling patients based on race, ethnicity, and geographic location in order to have fairly balanced groups for analysis.

We are recruiting more than 63 patients at some practices. This is necessary due to the fact that some practices are smaller and therefore have fewer eligible patients from which to select. It is our goal to maintain an average of 63 patients per practice in each health system. Our strategy for recruitment at any practice is to begin recruitment with the racial or ethnic group that has the least representation at that practice, whatever that maybe (i.e., at some practices it may be the white population), in order to maximize possible recruitment in that specific group at that practice.

The real-world distribution of race and ethnicity of patients varies across practices as a function of the residents of neighborhoods from which the practices draw. Although we continue to attempt to recruit up to 21 non-Hispanic white, non-Hispanic African-American, and Hispanic eligible patients at each practice, we acknowledge this variation and are aware that in some practices we will not be able to meet the recruitment goals for each race or ethnicity. In order to approach a somewhat balanced distribution in the overall analytic sample, we will oversample non-Hispanic African Americans in practices with high percentages of African-American patients and Hispanic patients in practices with high percentages of Hispanic patients. In turn, there are practices with percentages of whites so low that we are unlikely

to reach 21 participants. We have already de facto oversampled non-Hispanic whites in several practices because of low numbers of eligible participants in the other two targeted racial and ethnic groups.

We do not know the exact racial and ethnic distribution of patients eligible for our study until we receive recruitment data for each practice. Thus, to date, we have not able to predetermine a race/ethnicity oversampling plan. As additional practices join the study, however, we will over-recruit among Hispanics to increase balance among the three groups at the overall sample level. This will require that we recruit additional Hispanic hypertensive patients at the remaining 20 practices. It should be noted that these additional patients will be recruited in lieu of white patients in order to keep the average number of patients at CC/Stepped care practices at close to 63 (for care management purposes). It is our goal to obtain a sample of sufficient size to analyze Hispanics separately; however, the group size may ultimately be limited to 10% of the overall sample.

With respect to balance across intervention arms, we may face greater challenges reaching goals for Hispanic patients due to allocation of practices through randomization.

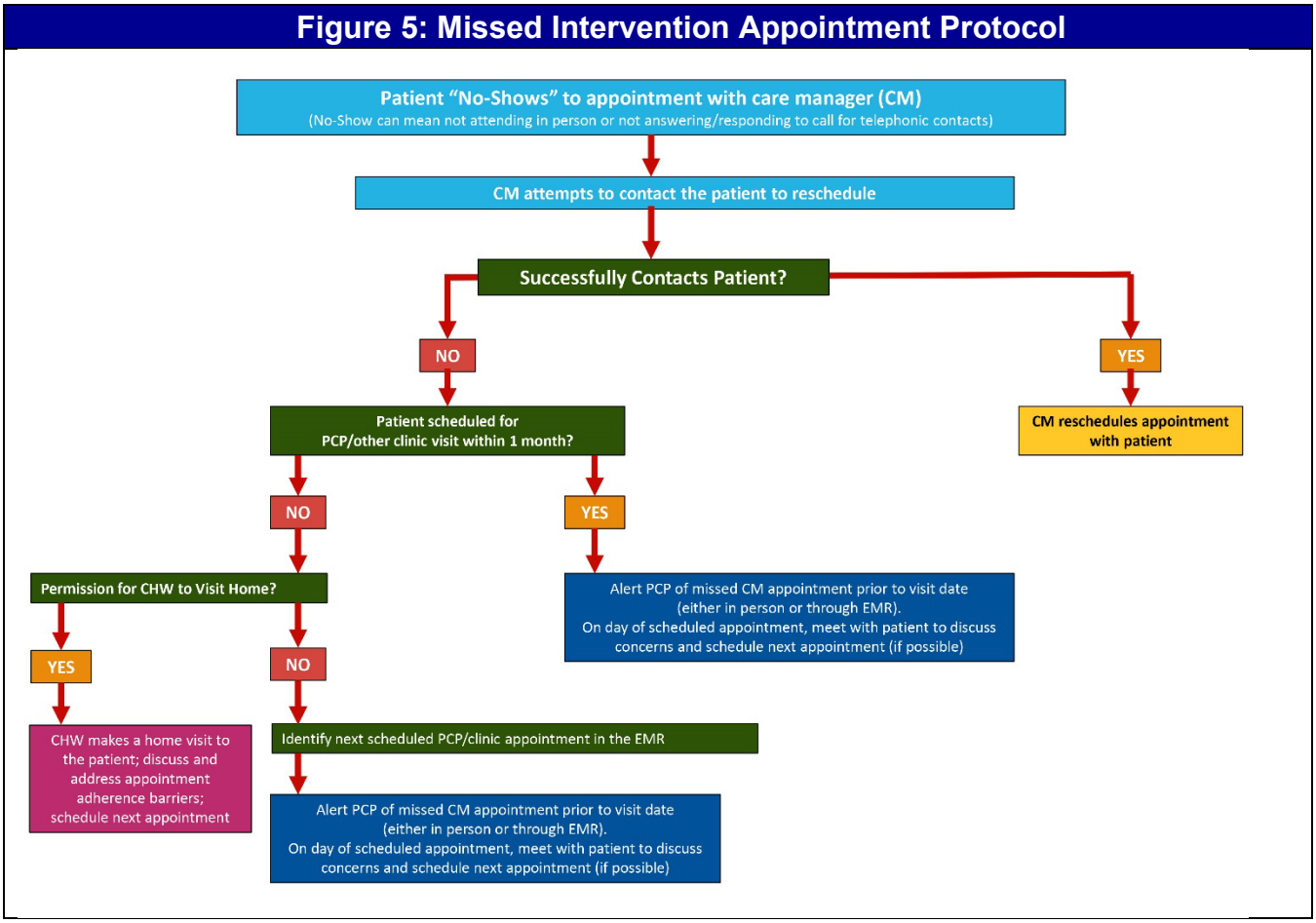
E. Participant Screening and Consent:

1. **Step 3 - Telephone Screening and Oral Consent**: After a waiting period of 10 days, patients who have not contacted the study recruitment center to opt out of the study are followed up by telephone. During the phone call, potentially eligible persons are asked if they are interested in participating in the study. We screen persons (both those contacted by us and those who reach out to us in response to the mailing) for eligibility using a set of prepared questions. Eligible patients who remain interested in the study are read the oral consent form. If the patient agrees to participate, the telephone baseline interview is completed. In cases where patient is unable to complete telephone baseline interview due to limited phone minutes, paper version of the baseline interview will be mailed to the patient with returned envelope. When the baseline data collection has been completed, patients are informed of the assignment group of their practice. If the recruitment goal has not been reached within a reasonable amount of time, we mail another batch of letters and repeat this process until the recruitment goal of an average of 63 participants per practice is met, or recruitment closes at the practice.
2. **A participant is considered enrolled in the study once they have completed the baseline survey**. In order for a participant to successfully complete the baseline survey they must complete the PAM, PHQ, PROMIS Global scale, adverse events questions, and demographics questions. The eligibility BP measurement will be the participant's baseline BP measurement in both arms. Consented participants in both arms will continue to attend their typical schedule of primary care appointments. We do not require a specific frequency of primary care visits during the study period.
3. **Step 4 – First Intervention Visit for Patients in CC/Stepped Care Practices Only:** The First Intervention Visit is conducted by the Care Manager (CM) at the participant's primary care practice. The participant is invited to meet both the CM and CHW. BP, height and weight measurements will be taken by typical personnel and in a manner that follows the practice site's normal procedures. The participant receives and is trained on the use of the home blood pressure monitor.
4. **Timeline for recruitment and consent**: Recruitment and enrollment of patients begins at least two months after the introduction of the OMRON machines in each practice, which is one month before we introduce the rest of the interventions in both arms. We are estimating that it will take seven months to fully enroll an average of 63 participants at each practice.
5. **Loss to follow up**: We are using a very pragmatic approach to follow-up in the study. If a patient requests to withdraw, no further survey data will be collected for that participant but EMR data will continue to be collected. A patient will be considered lost to follow up if he or she does not have a BP measurement recorded in the EMR within 24 months of enrollment.

To attempt to minimize loss to follow up:

i. The study will send out a 6- and 18-month survey reminder letter to all study participants two weeks prior to the month in which their follow-up survey call is due.
ii. The study will send out a 12- and 24-month survey reminder letter to all study participants approximately six weeks prior to the month in which their follow-up survey call is due.
iii. The study call center will call participants a minimum of six times in the 6 months after the follow up date for the 12 month survey and 6 months after the follow up date for the 24 month survey. The study may also send up to two reminder letters for 12- and 24-month follow-up survey calls. The call center will also reach out to contacts provided by participants to attempt to reach the participant.
iv. In cases where a patient cannot complete follow-up interviews due to limited phone minutes, we will mail a paper version of follow-up interviews with a return envelope.
v. In addition, at intensive intervention sites, the CC/Stepped care team will attempt to engage the participants. The team will follow the missed intervention appointment protocol shown in Figure 5.

Figure 5: Missed Intervention Appointment Protocol



F. Participant compensation: Each patient participant will be compensated as follows:

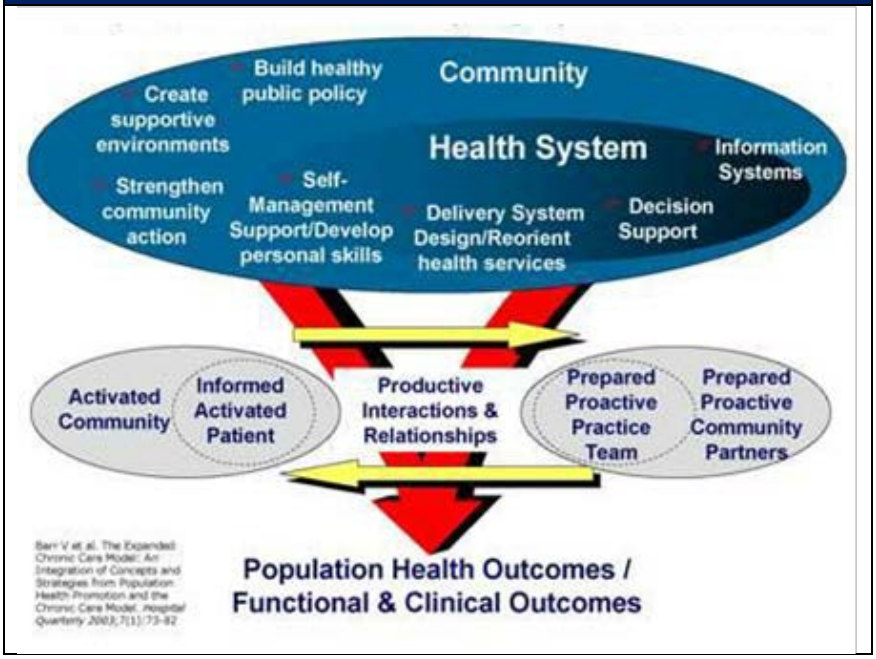
1. Patients in the **CC/Stepped Care arm** receive:
    i. A **home BP monitor**, valued at $90. These monitors serve several purposes. First, they serve to engage the patient in self-management and as the incentive to complete the First Intervention Visit for the study. Second, they provide additional BP data for analysis for the research team. Finally, it provides the CC team a picture of the patient's BP between visits and allow them to compare home readings with office readings to determine whether clinical readings are falsely elevated due to doctor's office anxieties (otherwise known as "white coat hypertension").
    ii. A **7-day pillbox**, valued at $5. Patients receive the pillboxes at their First Intervention Visit to assist with medication adherence.
    iii. A **tote bag**, valued at $5. Patients receive the tote bags at their First Intervention Visit (FIV) to carry their home BP monitors to and from primary care visits, as well as to store education materials.

2. **All patients**, in both arms, receive an **honorarium of $25** for completing each of the baseline, 12-month, and 24-month surveys to assess patient-reported outcomes. They also receive an **honorarium of $10** for the adverse events surveys conducted at 6 and 18 months. This will total $95 for participants who complete all surveys.
3. Patients who participate in an additional 60-90 minute interview about their life experiences related to trauma will receive an **honorarium of $60.**

Section 6: Interventions

A. Implementation/Conceptual Framework: Our previous research on CVD health disparities has been guided by an ecological model, which we adapted to address domains relevant to the identification, health behaviors, shared decision-making, guideline-concordant care, and disparate outcomes of HTN among racial and ethnic groups.[108] For our overall approach, we will continue to use this broad and inclusive framework. We are intervening at the practice level by introducing a new model of care delivery and additional staff; at the provider and staff level by offering training to increase technical, interpersonal, and cultural competencies; and at the individual patient and interpersonal levels via training, encouraging home monitoring and including patients' family members and caregivers if desired. Community and policy levels are addressed by engagement of community residents and organizational leaders, payers and policy-makers on our CAB in all aspects of the research. This project transforms primary care delivery to address the needs of patients with HTN and other chronic conditions; thus, we have selected the Expanded Chronic Care Model (ECCM)[109] to guide our intervention implementation (Figure 6).

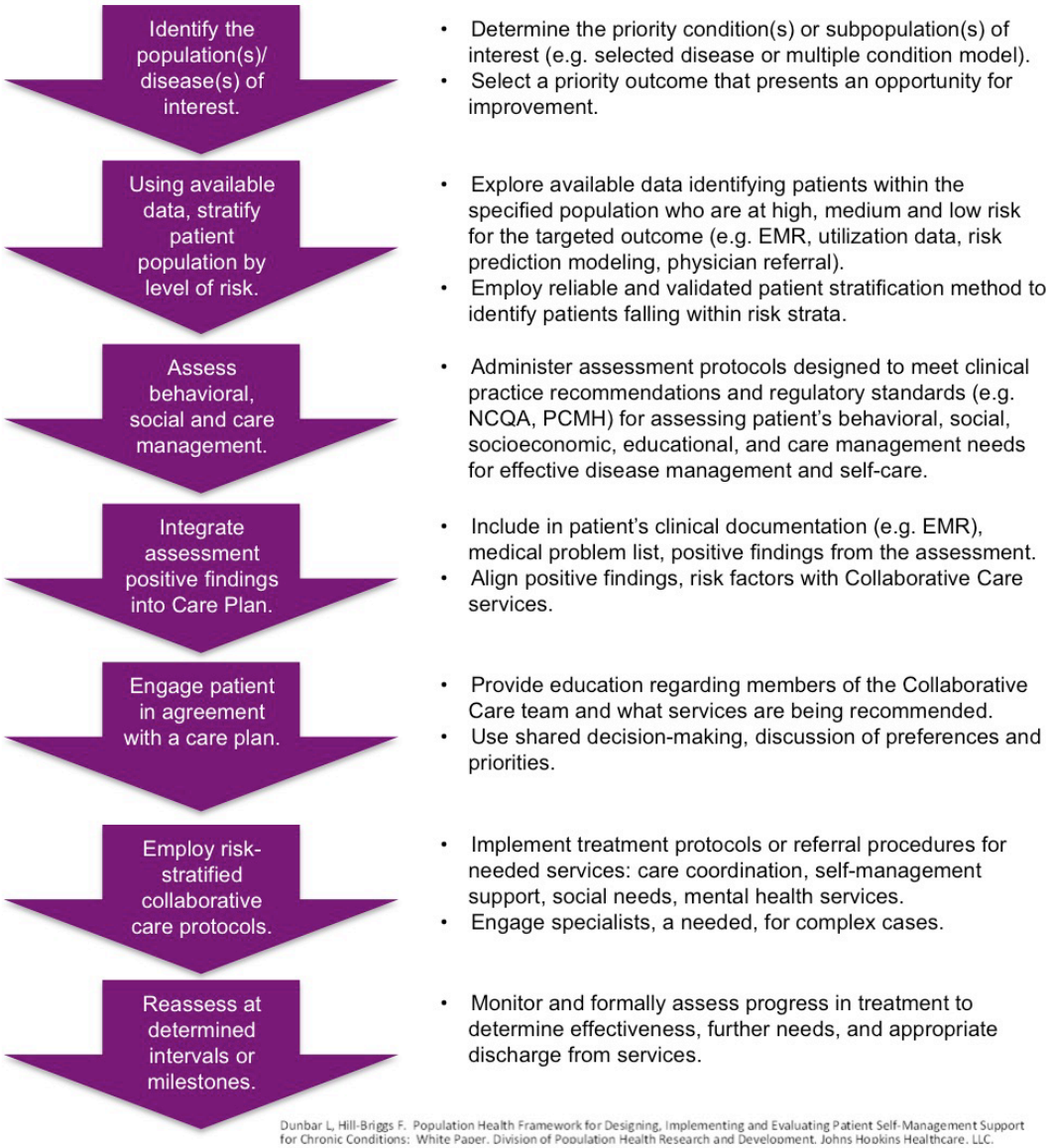
Figure 6: Expanded Chronic Care Model



The ECCM is a framework for redesigning health care and addressing deficiencies in care of chronic conditions. It builds on the CCM[92] by integrating concepts and strategies from population health promotion. The model can be applied to several chronic conditions, including HTN, diabetes, CHD, and depression. It can also be used in different target populations and care settings. The elements of the model are: community, health system, self-management support, delivery system design, decision support, and clinical information systems. Evidence-based change concepts in each element, when combined, lead to activated patients, responsive healthcare teams, productive interactions, improved care and health outcomes, and reduced costs.[110] We also are using a Collaborative Care Framework modeled after TEAMcare[111] in our CC/Stepped Care arm.

We used the Johns Hopkins Health Care (JHHC) Population Health Framework (see Figure 7) to inform our practice-based CC model for high and medium risk patients with HTN. We selected the interventions and comparator to meet increasing health care standards focused on quality improvement, care management and attention to high-need populations, integration of behavioral health in primary care, and team-based care.[112-114]

Figure 7: Johns Hopkins Health Care (JHHC) Population Health Framework



1. **Population identification and risk stratification – see Section 5**
2. **Assessment of behavioral, social, and care management needs.** Once patients at CC/Stepped Care sites have been enrolled in the study, a Care Manager at each site performs a clinical/health status and behavioral/psychosocial assessment with the patient using a comprehensive health assessment tool developed to address NCQA Patient-Centered Medical Home Population Health Management requirements[115]. The clinical assessment, completed with the patient, includes the following domains: health status, medication history, activities of daily living, life-planning activities, cultural and linguistic needs, caregiver resources, barriers to care, available benefits, substance abuse treatment/social resources, and pain. The behavioral/ psychosocial assessment, also completed with the patient, includes the following domains: smoking/tobacco use, alcohol/substance abuse, nutrition, physical activity, stress, depression, literacy, and cognitive function. Patients also complete personal health goals and priorities assessments.[116]
3. **Integration of assessment findings into care plan.** A CC team consisting of a PCP, a Care Manager (who is an RN or LPN), and other available professionals, is created at each

CC/Stepped Care practice site using existing staff (if possible) or new staff (if needed) who are trained to address the components of the patient's care plan.

4. **Engage patient in agreement with a care plan.** After patients have enrolled in the study (see Recruitment and enrollment above), Care Managers from CC/Stepped Care practices complete a comprehensive health assessment built to address NCQA population health management domains, including each patient's personal health goals and priorities. The goals tool asks if they have goals related to their health and probes specifically about goals related to CVD risk factors and treatment, diabetes, and depression. The Care Manager asks patients to choose at least one goal with a target (e.g., lose weight, increase physical activity, improve diet, monitor BP and/or blood sugars more often, take medications regularly, quit smoking). Care Managers work with each patient to develop a specific action plan and determine resources necessary to achieve the identified goals.
5. **Employment of risk-stratified CC protocols.** The experimental intervention is implemented at half of the practices (n=15). This multilevel intervention includes the practice-based CC team with the option of stepping patients up (if their SBP remains ≥140 and/or DBP ≥90 after 3 months or 1 month in extenuating circumstances) to either obtain subspecialist consultation or to see a CHW. The CHW is an integrated member of the team and supports patients in reaching their self-management goals; helps patients address social and environmental barriers to engaging in care through outreach and navigation services; and engages, activates, and empowers patients and their support system to participate in the care process. After three additional months (or one month in extenuating circumstances), if a patient's BP continues to be uncontrolled or becomes uncontrolled, the CC team has the option of stepping the patient up again (adding either subspecialist consultation or CHW, as guided by the protocol). Thus patients in CC/Stepped care can receive CC only; CC+CHW; CC+Specialist; or CC+CHW+Specialist care.

   The CM may deploy a CHW prior to one month if the patient is willing to work with a CHW AND at least one of the following conditions is met: no-show or difficult to engage patient; cardiac event in the last 12 months, with no follow-up appointment; inability to perform activities of daily living with no resources; no access to transportation; utility shut offs; food insecurity; domestic violence; poor/unstable housing; special request from the patient and/or the PCP.
6. **Reassessment at determined intervals or milestones.** Patients in CC/Stepped Care are reassessed per protocols based on their levels of BP and CVD risk factor control, weekly, biweekly, or monthly, until goals are attained.

B. Intervention approach: In UH2, our intervention was a stakeholder engagement process to plan and test recruitment for the trial. In UH3, we are conducting a two arm, prospective cluster-randomized trial and study of multi-level factors affecting implementation, quality improvement & disparities.

1. **Arm 1: Standard of Care - Plus (SCP) Comparator Intervention: BP Training, HTN Education, and Audit/Feedback.** Consistent with our conceptual model, practices in the comparator group are receiving an audit, feedback and education intervention that targets the health system overall (designated practice champion leadership support for improvement); the delivery system (evidence-based training to improve BP measurement, improve HTN care and overcome practice inertia for providers and staff); and the clinical information system (feeding back HTN control performance at practice and provider levels). This multi-level strategy is designed to reinforce and standardize evidence-based HTN care practices across intervention and comparator practices. SCP is being implemented at half of the practices. SCP includes audit and feedback using a HTN dashboard and a linked educational intervention. The latter aims to: 1) standardize BP measurement technique and 2) enhance provider and staff awareness of evidence-based approaches to overcome practice inertia, improve follow-up, and engage patients in self-

care. Our goal is to integrate audit and feedback of HTN control performance, proper BP measurement techniques, and HTN care best practices as "usual care" at each practice. Each practice is required to have capacity to generate reports on HTN control rates by practice and provider using EMR data and to identify a practice champion (usually a physician) to lead the audit, feedback, and education intervention implementation. Education for all staff on proper BP measurement technique is also featured in this study arm. Practice champions receive support for facilitating: 1) distribution of feedback reports; 2) delivery of training on BP measurement technique and evidence-based strategies to improve HTN care and control, and 3) standardized BP measurement with automated BP measurement devices for screening and confirmatory measurement. Many of the materials provided to practice champions are adapted from previously developed materials and given to practice teams in both interventions (see Table 5 below). The interventions given to this arm are:

i. BP Measurement Training
ii. HTN Care and Control Best Practices Training
iii. HTN Dashboard
iv. System Level Leadership Intervention

Table 5: Tools available to Practice Level Champions, Providers, and Staff in Both Interventions

Category	Tool/material name	Description
Tools to facilitate team meetings	Dashboard Champion Guidebook	Describes best practices for facilitating discussions on feedback reports, with emphasis on applying a non-punitive approach, collecting input from diverse sources, and generating an action plan
Tools to collect supplemental data	Dashboard Champion Guidebook	Describes how to use the practice's EMR to filter, stratify or disaggregate feedback data to facilitate sense-making by providers
	IHO:BP Act Rapidly tool[117]	A brief chart audit tool that uses data from 12 office visits to identify care patterns related to practice inertia and suboptimal follow-up
	IHO:BP Partner with Patients tools[117]	Set of brief patient survey cards designed to solicit patient input prior to or after an office visit. Includes a tool to solicit perceptions of interactions with the care team during an office visit, and a tool to obtain patient perceptions barriers to adherence.
Tools to generate improvement ideas and engage patients	Fast Facts sheets	Brief 1-2 page evidence-based summaries of interventions to overcome practice inertia, improve follow-up, and engage patients in self-care
	Million Hearts Campaign compendium of resources[118]	Online collection of tools, videos and resources collected by the Million Hearts Campaign and available for public use
	Heart360[119]	Online collection of patient self-management tools, educational resources and patient-provider communication tools developed by the American Heart Association/American Stroke Association. Many tools may be used with mobile devices
	Patient education tools compendium	Indexed collection of online patient educational handouts published by federal and state health agencies
	Five Plus, ACT, and DECiDE, study educational modules[108,120,121]	Educational tools to promote healthy eating and food purchasing, physical activity, taking medications, and self-monitoring to control blood sugar, BP, and lipids
Training materials	Evidence-based strategies to improve HTN care and control	Online, asynchronous didactic training will be provided through enduring webinars on: 1) Improving High Blood Pressure Treatment and Control Introduction, 2) Hypertension Guideline Updates: 2017 ACC/AHA, 3) Promoting Timely Treatment and Follow up, 3) Engaging Patients in Self-Managing their Hypertension.
	MDQuit.org	Online collection of self-help tools and Maryland resources for smoking cessation
	ReDCHiP communication skills modules[62]	Online, interactive patient-provider communication skills training
	ReDCHiP BP measurement training[62]	Online training videos targeting BP measurement technique

2. **Arm 2: Multilevel, Collaborative Care/Stepped Care Intervention (CC/Stepped Care).** Consistent with our conceptual model, our intensive intervention includes changes in the health system (leadership support for improvement, promotion of comprehensive improvement strategies); delivery system (defined roles and distributed tasks among team members, clinical care management for complex patients, planned interactions to support evidence-based care, regular follow-up, culturally and linguistically tailored care); decision support (use of proven provider education methods, evidence-based guidelines embedded into daily practice, information sharing with patients to encourage participation);

clinical information systems (subpopulation identification for proactive care; monitoring performance of practice teams, sharing of information to coordinate care); self-management support (emphasis of the patient's central role in managing their health, use of effective self-management support services); and organization of internal and community resources to provide ongoing support to patients. Everything included in SCP is provided to practices randomized to the CC/Stepped Care arm. The interventions given to this arm are:

i. BP Measurement Training (see description on page 35)
ii. HTN Care and Control Best Practices Training (see description on page 39)
iii. HTN Dashboard-Audit/Feedback (see description on page 40)
iv. Collaborative Care Intervention (see description on page 42)
v. Step up to: Community Health Worker (see description on page 45)
vi. Step up to: Subspecialist consultation core (see description on page 50)
vii. System Level Leadership Intervention (see description on page 52)

Section 6C: Interventions Description: UH2 Engagement

1. **Approach/Background**: Our Center has relied on the Baltimore community since its inception, incorporating community input to shape the center, interventions tested in our research projects, and plans for dissemination of our work. The process of working together has allowed us to begin bridging the cultural gap between researchers and the Baltimore community and for traditionally marginalized communities to gain power through the acquisition of new knowledge. To guide the Center's goals and objectives, a CAB was formed, which includes important stakeholders — political leaders, health care providers and administrators, patients, insurers, the Baltimore City Health Department and state of Maryland Department of Health and Mental Hygiene, faith community representatives, and community organizations. The board meets as a group 4 times a year; but CAB members are involved in other Center activities throughout the year. Community input has been vital to the success of the Center, with faculty and staff asking the community for feedback on research methods and support of our training activities. In turn, Center faculty attend community forums where we educate the public about health and healthcare research and connect individuals with local health-related resources. We also provide technical support to community groups seeking funding and resources for their services. During UH2, we engaged a wide variety of stakeholders that fell broadly into four categories: Health System-level leadership, Site-level leadership, CC Team Members, and CAB members, including patients and caregivers. We engaged with them on all aspects of the study, but in particular at three main levels, described below.

2. **Engagement plans by stakeholder group and level of engagement**
    a. **Level 1: Introduction to Project:** We oriented each stakeholder group to the study, giving them information that will provide context for their involvement in the study.
        i. Health System-level leadership:
            1. At initial orientation meetings, we began an exchange of information between project team and health system leadership. Together we identified appropriate contacts to weigh in on the implementation of this project (e.g., IT, clinical education, nursing)
            2. At subsequent integration meetings, we discussed how the project fits into the organization's priorities including appropriate contacts provided during orientation, and explore site-specific challenges, such as processes and culture, that need to be incorporated in the intervention protocols and training
            3. We conducted individual in-depth interviews with system leaders
            4. We also facilitated in-person introductions at the kick-off meeting
        ii. Practice-level leadership:
            1. When the health system identified practice-level champions, we provided these individuals with a detailed written overview of the entire project along with a cover letter that explains the nature of the practice's involvement in the study.
        iii. Practice-level clinicians and staff:
            1. Prior to the launch of the blood pressure measurement intervention, we provided a written introduction to all the providers, nurses, and clinical staff at the participating practice. This introduction will include:
                a. A welcome letter
                b. An overview of the study
                c. A project timeline for the participating practice
                d. A table outlining project activities and how the activities impact the providers and staff/what is required of the providers and staff
                e. Next steps
        iv. CC Team Members:
            1. We provided a detailed written overview of the entire project along that explains the role of CC team members

v. CAB
    1. We summarized the purpose of the project and protocol on a high level during each CAB meeting

b. **Level 2: Protocol Review:** Several of our stakeholders joined us in developing the protocols for the study. We continue to make a concerted effort to have the various groups review the protocols at each stage of development to ensure that the perspectives of each type of stakeholder are incorporated. We believe this ensures a study that is scientifically sound and responsive to the pragmatic needs of the practices, patients, and the broader community.
    i. Health System-level leadership:
        1. We conducted a series of meetings to review and solicit feedback on the planned intervention components.
            a. Before the meetings, we:
                i. Sent relevant sections of the protocol with basic questions to the leaders
            b. Attendees at these meetings included:
                i. Health System champions
                ii. Administrative champions
                iii. Practice champions
                iv. Other health system staff: IT, clinical educators, existing CHWs and/or CMs
        2. Requested their support to engage clinicians and patients at their practices in protocol reviews
        3. Reviewed and provided thoughts on planned health equity leadership curriculum and network schedule/structure
    ii. CAB
        1. We engaged CAB members to read sections of the protocol related to patient recruitment, surveys, and intervention contacts, and provide feedback
        2. We requested CAB members to participate in workgroups developing protocols
        3. Some CAB members were invited to review health equity leadership curriculum and network schedule/structure

c. **Level 3: CAB meetings:** We continue to hold quarterly meetings of our CAB to facilitate communication with our community stakeholders, keeping them informed of our progress as well as making outreach efforts to the community. CAB meetings are a forum wherein we can ask for stakeholders to discuss big picture issues, review materials, and pilot-test surveys.
    i. Health System-level leadership: We will continue to:
        1. Invite System-Level Champions to attend CAB Meetings
        2. Request assistance in recruiting patients from each system to serve as patient representatives
    ii. Practice-level champion: We will continue to:
        1. Ask practices to identify patients to include on CAB
        2. Ask practices for representatives to participate in study work groups
    iii. CC Team Members: We will continue to:
        1. Ask for input on questions and topics to discuss with the CAB (e.g. patient and community attitudes regarding CHWs making home visits)
    iv. CAB: We will continue to:
        1. Provide high-level status updates with additional details in documentation

2. Engage with regard to finding additional patient representatives. We continually ascertain feedback on how best the CAB may contribute to study protocol, implementation, and dissemination of results.

Section 6C: Interventions Description: BP Measurement Training

1. **Both Study Arms:**
   a. **OMRON HEM-907XL BP Devices**: We distributed one OMRON HEM-907XL BP device kit (which include the main unit and key accessories) for each PCP-MA pair at 29 of our 30 practice sites. The OMRON HEM-907 is the gold standard for automated BP devices and has been validated against the British Hypertension Society Standard.[122] It has an excellent record of reliability and validity and has been used in numerous research studies including those done by our team here at Johns Hopkins. Our team is familiar with these machines and has found them highly durable. Each kit will contain one device, four sizes of cuffs (S, M, L, XL), a rolling stand, and an AC power adapter. The devices have been introduced and *practice staff were trained on their use at least 3 months* before the collaborative care and stepped care interventions rolled out in the practices.

   One practice had recently installed automated blood pressure machines, the *Welch Allyn Connex Spot Monitor with Sure BP NIBP, model 71XX-B* in all of the examination rooms and elected to not use the OMRON HEM-907XL. The device that they use was validated in a published report in 2011 which uses the American National Standards Institute, the Association for the Advancement of Medical Instrumentation, and the British Hypertension Society protocol for validation. These devices have also been programmed to automatically obtain 3 back-to-back measurements after a timed rest period, consistent with the Screen/Confirm process we have implemented at other sites. The patient's blood pressure would be measured on the same device at baseline and follow-up and our blood pressure outcomes are based on change in blood pressure or blood pressure control. On final analysis, we would conduct a sensitivity analysis removing this practice to determine if it affects our results.

   b. **Practice champion leadership support for improvement:** Each practice has identified, or is in the process of identifying a practice champion (usually a physician), to lead the audit, feedback, and education intervention implementation. See section 4E of protocol for details on identification, engagement and responsibilities of practice champion at each site. Practice champions and super-users receive support for facilitating: 1) delivery of training on BP measurement technique and standardized BP measurement with an automated BP measurement device: 2) web-based training in evidence-based strategies to improve HTN care and control and 3) distribution of feedback reports (see section 6C: Hypertension Dashboard);
      i. **Practice Champion Guidebook**: Practice champions are provided with access to the online Practice Champion Guidebooks. The guidebooks describe best practices for promoting required training, facilitating discussions on feedback reports, with emphasis on applying a non-punitive approach, and collecting input from diverse sources. These also serve as the Manual of Operations with detailed BP measurement protocols.
      ii. **Education:** The education intervention includes 1) BP measurement training and 2) HTN care and control best practices training. The educational content is delivered to practice-based providers and staff through asynchronous online modules with interactive assessment. (Modules are available to providers and staff online at www.richlifeprogram.org. If a member of the HDR-PP team or the DSMB would like to preview the website, please contact the study team for a login.) Content is

understandable to all members of the care team and describes how practice-based teams could address each of these topics. Though online modules are asynchronous to allow flexible viewing for providers and staff, sites are encouraged to consider practice team "group" education sessions using the training modules and return demonstration application exercises. Ongoing site support and reinforcement of BP measurement and HTN care and control best practices is provided through several mechanisms including an online discussion board with monitoring by study staff to address frequently asked questions and troubleshoot BP measurement challenges, and a periodically updated blog on the RICH LIFE website. Each of these training and support mechanisms is made available to sites prior to entering active intervention status, and will be available to sites through the duration of the study. We continue to work with health system partners to identify which support mechanisms the health systems and practice sites prefer.

iii. **Role of Health System Champion:** The study team introduced health system champions to the educational training materials/resources prior to training implementation and full access to training materials, resources, and recommended training timeline 4 weeks in advance of the introduction of the devices into their practice. This was done so that site teams could complete training and "ramp up" in preparation for the active intervention phase. Health system champions were responsible for connecting the research team with the clinical education and/or clinical operations team to review the protocol and tailor implementation plans for the health system. Along with the study team, health system champions coordinated communication between the health system's clinical education team and the practice champions.

iv. **Role of Practice Champion:** Champions, together with clinical education/operations, have helped to lead implementation of the education intervention at the site level. The study team provided password-protected access to online materials only after pre-intervention data were received. Along with clinical education/operations, practice champions informed providers and staff of the training modules and resources and encouraged them to visit the online training site and complete the training during the two weeks just after the introduction of the devices to the practice. All practice team members at each site were asked to complete all relevant modules within 4 weeks of receiving online training site access. The study team monitored completion of module viewing and provided the practice champion with a list of completers and non-completers on a weekly basis. Provider and staff turn-over is expected over the course of the study and new providers and staff are encouraged to complete the training modules within 4 weeks of joining the site team. Study staff monitors completion of online training modules by site.

c. **BP Measurement Training:** Practice staff received standardized BP measurement protocols, training materials, and resources to standardize BP measurements at all participating practices using a "tiered" approach.

i. Role of Health System's Clinical Education Department and Super User

1. Clinical education departments, with input from practice champions and administrators, are identifying super-users at each practice. Super-users will be responsible for BP measurement operations at their site, including Omron HEM-907XL troubleshooting and assisting in staff training as requested by the health system.
2. Romsai Boonyasai, MD, MPH; Jeanne Charleston, RN; Cheryl Dennison Himmelfarb, RN, PhD, who have expertise in clinical education and implementation of BP measurement processes, conducted "train-the-trainer"

sessions with each health system's clinical education department (or equivalent) on the standardized BP measurement protocol and how to certify practice staff for BP measurement competency. The health system may have chosen to include super-users in the train-the-trainer session or independently train the super-users prior to the clinical staff training and certification. Super-users must demonstrate facility in training methods prior to teaching practice staff and will be recertified annually.

(1) Super-users may assist clinical educators in teaching practice staff a standardized process whereby patients with screening BP ≥140/90 mm Hg should receive a confirmatory BP measurement, also using the Omron HEM-907XL device. Once activated, the Omron HEM-907XL will delay cuff inflation for 5 minutes and then perform a series of three BP measurements spaced 30 seconds apart. The mean of these three readings will be recorded in the EMR, in the 2nd BP reading field, (the screening measurement will be recorded in the 1st BP reading field).

3. Clinical educators and super-users "certify" all CMAs as competent to measure BP by directly observing at least 1 BP measurement per CMA and confirming that they have been performed in accordance with a standardized certification checklist.
    (1) All CMAs receive detailed, interactive online education focused on techniques to measure BP
    (2) All PCPs and supervising staff receive detailed education focused on information needed to supervise/support CMAs
    (3) The competency process involves remedial training/testing of CMAs who fail the initial competency process
    (4) The research team is monitoring terminal digit preference through EMR data and are sharing this information with clinical educators, super-users, and practice administrators. The research team is working with health system leadership, practice leadership, and clinical education to develop system- and practice-wide approaches to address high levels of terminal digit preference including, but not limited to: one-on-one and group meetings with providers and staff, health system purchasing of additional BP devices, and problem-solving workflow issues.
    (5) Clinical educators apply a standardized protocol for formally re-assessing CMAs' BP measurement technique annually.
4. Clinical educators, super-users, and practice administrators also received:
    (1) Information about annual maintenance and calibration of the OMRON devices.
    (2) Educational labels for each OMRON device, written and video training materials, and role-play scenarios to use in training sessions.

ii. Fidelity Audit of BP technique by study staff

1. The objectives of the blood pressure measurement Fidelity Audit Process are to:
    (1) Assess fidelity to the RICH LIFE blood pressure measurement process ("the BPM protocol") in order to (a) confirm the validity of clinical blood pressure measurements obtained during the RICH LIFE study and (b) provide clinics with

feedback on their adherence to the BPM protocol so that they may continually improve their blood pressure measurement procedures.

(2) Identify process-related, health care worker-related, and/or patient-related factors that may contribute to non-adherence to the BPM protocol. These factors may supplement feedback on adherence with additional, actionable information that may direct clinics to areas where they can most effectively improve.

2. One of our clinical experts or a research assistant certified in proper BP measurement techniques is visiting each practice site twice in the year following the introduction of the OMRON devices, and once per year thereafter, until a total of three fidelity audits occur, to observe the CMAs and ensure that they are following the BP measurement protocol and using the devices (Table 6). We had intended to complete four fidelity audits at each practice; however, the COVID-19 pandemic caused significant disruption in the planned timing of the fidelity audits. Additionally, safety concerns for research staff, patients, and practice staff have led us to eliminate the fourth fidelity audit.

Table 6. BP Measurement Fidelity Audits Purpose and Timing

Audit Occurrence	Purpose of the Visit	Timing of Visit
Fidelity Audit Visit 1	• Provide formative feedback • Offer opportunities to improve	N/A
Fidelity Audit Visit 2	• Provide formative feedback • Offer opportunities to improve	6 months after visit 1
Fidelity Audit Visit 3	• Provide formative feedback • Offer opportunities to improve	6-8 months after visit 2

3. The observer attempts to observe all of the CMAs working the day they visit the practice, not just one CMA multiple times. If there are more than 10 CMAs working, the observer stops after 10 sessions.
4. The observer, with the permission of the patient being observed, records whether the CMA follows the evidence-based measurement process. These observations are reported back to each practice champion so that, if needed, re-training on protocol procedures can be initiated.

d. BP Measurement Protocols

The BP Measurement Protocols are a comprehensive resource to promote proper BP measurement technique that are available to all site providers and staff and serves as a training resource for super-users. Key BP measurement procedures detailed in the Champion Guidebook and online at www.richlifeprogram.org include:

i. Obtain an automated screening BP measurement
ii. Obtain a manual screening BP measurement (to be used when a patient does not fit the available automated device cuffs, or if there is another patient-related reason why the automated device cannot be used)
iii. Obtain an automated confirmatory BP measurement
iv. Daily maintenance of the BP measurement equipment
v. Annual inventory and inspection of BP measurement equipment. In addition, the manual provides information about the OMRON HEM-907XL automated device, a certification test for BP measurement, and a performance checklist for BP

measurement training.

e. Online Training Module(s) Targeting BP Measurement Technique

A series of 4 modules, approximately 28 minutes in total length will address key aspects of BP Measurement Procedure:

i. Patient preparation
ii. Use of automated BP measurement device (OMRON) to obtain a screening BP measurement Position
iii. Use of automated BP measurement device to obtain confirmatory BP measurements
iv. Use of sphygmomanometers for screening and confirmatory BP measurements of patients who cannot have an accurate reading taken using automated device.

To promote provider buy-in, we provide evidence supporting the validity of the project's BP measurement process and describe the importance of accurate BP measurements.

1. **Online training modules**: **Online training modules**: We will deliver online, didactic training on evidence-based strategies to improve HTN care and control. The training will be available online at www.richlifeprogram.org. The training will be offered through four asynchronous, 5-7-minute online modules, which providers and staff can view at their convenience, with interactive knowledge assessment. Modules will address critical aspects of improving HTN care and control:
    a. **Introduction to Improving High Blood Pressure Treatment and Control:** Objective is to inform physicians of the significance of hypertension and then to offer strategies to achieve a better hypertension control rate.
    b. **2017 AHA/ACC Hypertension Guidelines Update:** Objective is to introduce the 2017 AHA/ACC guidelines and discuss clinical care implications.
    c. **Promoting Timely Treatment and Follow up**: Objectives include review hypertension treatment guidelines, barriers to guideline adherence, and strategies to ensure guideline adherence.
    d. **Engaging Patients in Self-Managing their Hypertension**: Objectives include identifying strategies to establish and modify an individualized care plan through shared decision making, and to review patient and provider barriers to implementing the care plan.
2. **Ongoing Site Support and Reinforcement of BP Measurement and HTN Care and Control Training:** Ongoing site support and reinforcement of BP measurement and HTN care and control best practices is provided through several mechanisms including an online discussion board, coaching calls, and a periodically updated blog at www.richlifeprogram.org. Each of these mechanisms is made available to sites upon entering active intervention status and will be available to sites through the duration of the study.
    a. **Online Discussion Board**
    We have created an online discussion board with monitoring by study staff to facilitate timely response and assistance to sites for frequently asked questions and troubleshooting of BP measurement or equipment challenges. Frequently asked questions and common solutions are curated to allow topical searches by site teams.

    b. **Coaching Calls**
    Twice quarterly conference calls promote site engagement and provide support for ongoing study interventions including BP measurement and HTN care and control best practices. Health system champions, practice champions and Super-users are encouraged to participate in the coaching calls. Jill Marsteller, PhD, MPP leads the conference calls and invites Lisa Cooper, MD, MPH, Romsai Boonyasai, MD, MPH, Jeanne Charleston, RN, or Cheryl Dennison Himmelfarb, RN, PhD to provide ongoing consultation on implementation and workflow concerns as needed.

    Beginning in April 2019, we transitioned from twice quarterly coaching calls to once quarterly coaching calls. This change in frequency occurred after the implementation of all the interventions at all health systems.

    c. **Blog**
    A periodically updated blog shares information with practices on a variety of topics. Practice champions are encouraged to print and share information with their teams. Current and future content may include (1) Written or video responses to practice questions about the protocol and OMRON, (2) reinforcement of proper BP measurement technique, (2) examples of successful site HTN care improvement strategies, (3) HTN treatment guideline updates, and (4) summary of recently published HTN research that may influence treatment decisions.

Section 6C: Interventions Description: HTN Dashboard-Audit/Feedback

1. **Rationale:** Transparent and timely access to and review of clinical performance data are among the key elements of successful improvement activities. For this reason, our study provides access to practice- and physician-level data through the study dashboard. Data is uploaded to the clinical dashboard and new reports generated quarterly. Reports display data from the previous 3 months.

2. **Description of the Dashboard and instructions regarding its use**:
    a. **Dashboard (for both SCP and CC/Stepped Care):**
        i. The Practice Dashboard provides a display of percentage of patients achieving BP control, defined as <140/90 mm Hg for the overall practice.
        ii. The Provider Dashboard provides a display of percentage of patients achieving BP control, defined as <140/90 mm Hg for each provider's patient panel.
        iii. Both the Practice and Provider Dashboards break down hypertension performance by race (White, non-Hispanic; Black, non-Hispanic; and All Hispanic).
        iv. Specific instructions, or dashboard logic, for generating reports will be provided to each health system's clinical IT team.

3. **SCP Arm specifics**
    a. **Providers**
        i. Reports providing an overview of overall practice performance data are available quarterly through the project dashboard. Health systems notify providers following each dashboard update. Providers are encouraged to review the hypertension dashboard quarterly to obtain a snapshot of their progress in meeting the practice's goals.
        ii. The study team encourages health systems to make the practice dashboard accessible to all care team members both online and via hard copy. The provider dashboard is only be available to individual providers and practice administrators and medical directors, but should also be accessible online and via hardcopy. Each provider will be strongly encouraged to review the overall practice data to assess health center performance in meeting the health center's hypertension control goals.
    b. **Practice Champions**
        i. Each practice champion will be encouraged to promote review of the dashboard among providers and clinical staff.

4. **CC/Stepped Care Arm Specifics**
    a. **Providers**
        i. Reports providing an overview of overall practice performance data are available each month through the project dashboard. All care team members may access reports online and/or hardcopy. Providers are strongly encouraged to review their individual patient panels. In addition, providers are able to review overall health center performance in meeting the health center's hypertension control goals. Our team places emphasis on examining the data stratified by race, ethnicity, and payer status (if available). When disparities in BP control are noted, providers are asked to reflect upon the potential reasons for the disparities and consider ways to mitigate the disparities. This may include identification of best practices among their peers with smaller disparities in their panels.
        ii. Providers are strongly encouraged to actively participate in project-focused quarterly team meetings. During these meetings, practice champions, care managers, providers and others will discuss performance data and progress on attaining the goals of the practice's action plan. Suggestions for improving HTN control rates in areas noted as requiring improvement will be elicited and discussed during these meetings.

iii. Coaching calls provided for CC/Stepped Care sites as part of the SLL intervention also train participants on use of the dashboard to support practice improvement.

b. Practice Champions

i. With input from providers and project care managers, and using guidance provided by the project team, practice champions develop an action plan to address their practice's HTN management goals. Examples of action plans and action planning activities may be found on the Million Hearts Website.[123]
ii. The practice champion, along with the care manager and other health systems' leadership, participates in quarterly coaching calls to discuss dashboard dissemination and action planning strategies.
iii. Champions are encouraged to review the HTN dashboard updates on a quarterly basis to monitor progress on the practice's action plan. With others, the practice champion generates strategies for addressing commonly found data patterns indicating performance that is not meeting practice goals.
iv. Champions are encouraged to lead quarterly team meetings. During each meeting the Practice Champion should:
    1. Provide an update regarding the progress on meeting the goals of the practice's action plan.
    2. Facilitate care team discussions of feedback reports
    3. Using materials provided by the project team, provide feedback and suggest specific actions for improvement for care providers who are not meeting the goals of the practice's action plan.
v. Champions are encouraged to collect and present supplemental contextual data such as data stratified by race and insurance status (if available). This review will identify discrepancies in BP control outcome. With the care manager and other providers, identify approaches to address identified discrepancies.
vi. The project team provides materials for training providers and practice staff on a variety of HTN-control related topics as well as project performance, including use of the dashboard. With the nursing lead, the practice champion shares training materials with practice staff members.

c. Care Manager

i. The practice champion, along with the care manager and other health systems' leadership, participates in quarterly coaching calls to discuss dashboard dissemination and action planning strategies.
ii. At the request of the Practice Champion, the CM may:
    1. Facilitate care team discussions of feedback reports
    2. If desired and requested, assist with the collection and presentation of supplemental contextual data on patients with uncontrolled blood pressure
    3. Discuss feedback and ancillary data
    4. If desired and requested, assist in generating an action plan for next quarter
    5. Assign specific tasks for individual team members
iii. On a periodic basis, review stratified data to identify disparities in BP control outcome. With physician champion and providers, identify approaches to address identified disparities.
iv. On a quarterly basis, review quarterly HTN dashboard updates to monitor progress on practice's action plan. With the practice champion, the CM may generate strategies for addressing commonly found data patterns indicating performance that is not meeting practice goals.
v. The project team will provide materials (see Table 5 above) for training providers and practice staff on a variety of HTN control related topics as well as project performance,

including use of the dashboard. With the practice champion, the CM will share training materials with practice staff members.

Section 6C: Interventions Description: Collaborative Care Intervention

A. Objectives. The CC team: 1) develops the medical management plan in partnership with patients; 2) uses care coordination to maximize interaction of the patients' PCPs with other care providers addressing medication management, patient self-management, and psychosocial support on a regular, consistent basis; and 3) determines patient access to CHW support and subspecialty consultations.

B. Approach and Implementation.

1. **Organizational structure of the CC team**: The site practice champion, who is either a physician or an advanced practice clinician, may serve as the CC team leader for the practice. A nurse (RN or LPN) or LCSW serves as the CM. A basic CC team includes the PCP and CM; however, depending on availability of other health professionals at the practice, the CC teams may include additional team members such as pharmacists, nutritionists, health educators, and behavioral or mental health specialists. Responsibilities of the care team, stepped elements (subspecialist consultation or community-based contextualization), types of clinicians or service providers who are able to deliver care at various sites, and descriptions of the issues addressed are summarized in **Tables 7 and 8** below.

Table 7: Components of Practice-Based Collaborative Care Model

Collaborative Care Team Member	Collaborative Care Team Responsibilities	Description of Issues Addressed
Primary Care Physician or Advance practice clinician*	Development of Diagnosis and Treatment Plan	Diagnose and evaluate HTN for secondary causes, additional risk factors, target organ damage
	Medication Management	Modify medications; titrate and adjust dosages; address adherence issues
Care manager	Care Management and Coordination	Conduct initial behavioral/psychosocial assessment that covers NCQA domains. Educate, activate, and counsel; provide ongoing case management
	Medication Management	Recommend medication titration; address adherence issues and/or refer to PharmD/Pharmacist
	Patient Education and Self-Management Support	Counsel about diet and weight loss strategies; promote medication adherence and/or refer to dietitian, health educator, or health coach
	Psychosocial/Behavioral/ Mental Health Services	Provide counseling to address smoking, depression and other psychosocial stressors; assist patients in addressing health insurance, housing, employment, education, and other social or financial issues through referrals and advocacy and/or refer to Licensed clinical social worker, Psychologist, Psychiatrist, or Mental Health RN

* Nurse practitioners, physician assistants

Table 8: Components of Stepped Care Elements

Stepped Elements	Type of Clinician/Service Provider	Description of Issues Addressed
Subspecialist Consultation Services	Subspecialty trained physicians	Engage specialists in the areas of HTN, diabetes, psychiatry, preventive cardiology, and smoking cessation to assist primary care team in managing complex cases and educating providers
Community-based Contextualization	Community health workers	Support patients in reaching self-management goals; help patients address social and environmental barriers through outreach and navigation services; engage, activate, and empower patients to participate in the care process

2. **CC team process:** System and administrative champions of the study at the system level and practice champions at the practice level facilitate communication between the research and

practice teams regarding issues such as patient enrollment in the intervention; procedure for interacting with the subspecialist service core; trainings and town hall meetings. The practice champion introduces the Care Manager and CHW and their roles to the practice's PCPs, and establishes standardized communication channels about patient care between the CM and CHW – including recommending referrals to specialists and medication changes. The patient's PCP develops the **medical management** plan along with the CM. The practice champion and CM (and any other health professionals involved in the patient's care) communicate regularly (i.e., through rounds, informal encounters, or health system EMR platforms) to **coordinate care plans for patients assigned to the intervention**.

i. *Use of Protocols:* Care managers use protocols for **medication management**. We have also adapted protocols used in our previous work to deliver individualized **training in self-management behaviors** to patients and to assist in **management of psychosocial issues** and **care coordination needs**. We will make all study protocols available to clinicians and other clinical staff at the practices. (DSMB members, please contact the study team if you would like the complete CHW and CM MOPs).

ii. *Mission and Goals:* Through the CAB, system level leaders will participate in an exercise to develop a broad mission statement related to this project to which all of the partnering health systems can subscribe. From this statement, the team will devise specific goals that have clear, realizable endpoints and objectives that provide a specific means of achieving these goals. These goals will take into account the resources and needs of each practice and team.

iii. *Tasks and Roles:* The practice champion and CM review the CM's roles and responsibilities with the PCPs and clinical staff at each practice. They define the functions of the care team, including the roles of other staff that may be available to support the CM. They communicate that the decisions of who does what can be guided by availability, level of training and scope of practice guidelines, or member preferences when more than one team member is qualified to perform the task.

iv. *Leadership and Decision-making:* The patient's PCP and CM address the following questions in developing a mechanism for making decisions regarding each patient: 1) What needs to be decided? 2) Who should be involved in the process? 3) What decision-making process should be used? 4) Who will be responsible for carrying out the decision? 5) Who needs to be informed about the decision?

v. *Communication:* An effective, coordinated team must have an efficient mechanism for exchange of information. At the simplest level, this requires the time, space, and regular opportunity for members to meet. An ideal system for communication would include:

- **A well-designed record system**. All encounters with patients will be documented in the EMR using standardized templates. We have developed templates that users can scan into the patient's chart in the EMR.
- **A regular forum for members to discuss patient management issues**. The CM solicits input from PCPs and bring patients and issues to be discussed to the encounter.
- **A mechanism for communicating with the external systems within which the team operates**. Team notes will be the primary mechanism of communication with PCPs and specialists; however, the CM may initiate phone calls or emails to other providers and systems as needed.

C. Practice Champion Roles and Responsibilities: The practice champion assures that the CM has any clinical oversight needed in the absence of the patient's primary care clinician. Important qualities of the practice champion are that they have credibility with the other providers, perform well in the targeted measure (BP control), work well with other team members, has institutional knowledge of the site/how to get things done and is optimistic regarding the potential for change--understands the problem

and wants to change/challenge status quo. The champion should be committed to reducing disparities in care. Because we are following well-established guidelines for care, we do not anticipate many conflicts between these protocols and existing protocols and performance measures at the sites. However, prior to launching the study, we engage the practice champions in reviewing the protocols and work to resolve any conflicts.

D. Care Manager (CM) Roles and Responsibilities: The overarching role of the care manager (CM) is to spearhead organizing the delivery of care and appropriate interventions to the patient. The CM is the chief point-of-contact for the care team and for patients enrolled in the trial. He/she determines, using evidence-based protocols, when to enlist the support of other members of the care team and deploy them to deliver the protocols forming the crux of needed interventions. This is accomplished, in part, by administering an assessment developed to cover the NCQA key behavioral and psychosocial domains, which elucidates patients' clinical and social needs. The CM uses the results of the assessment to develop care plans with patients and allocate other care team resources in accordance with patients' priorities and needs. The CM monitors all aspects of each patient's progress toward achieving improved cardiovascular health outcomes and disease self-management, with a primary focus on medical management of HTN, CHD, diabetes, hyperlipidemia, depression, and tobacco cessation. To address the patient's psychosocial, behavioral, and mental health needs related to these conditions, the CM (or another behavioral health specialist, if available at the practice) provides counseling for health behavior change as well as psychosocial stressors and trauma (such as financial, job/non-job conflicts, relationship stressors, and community stressors). The CM employs psychosocial, behavioral, and mental health services protocols whenever the patient screens positive for depression (PHQ-8$\geq$ 5); is a current smoker and is either contemplative or ready to quit smoking in the next 30 days; and if the patient stress rating is >5 on the baseline patient needs assessment. If stressors remain high after 3 months of the basic CC intervention, the team will step the patient up to working with a CHW, and if these stressors contribute to depression or anxiety, the CM will step the patient up to consultation from the psychiatrist in the subspecialist core. If the patient's HTN or other conditions remain uncontrolled at 6 months, the CC team has a second opportunity to step up the patient's care to specialist consultation, CHW or both. For both CHW and specialist consultation, exceptions may be made to the timing of the initial step-up by special request from the patient and/or PCP, or for extenuating circumstances found to preclude successful achievement and management of BP control. Such circumstances include immobility, housing, transportation, utilities, and poor social/caregiver support. For specialist consultation, circumstances include poor disease control despite patient reports of adherence to several optimized regimens, and conflicting treatment recommendations for different conditions. Factors guiding the decision to step a patient up to a CHW, a specialist, or both are further elaborated in this document.

The CM performs a weekly caseload review of each patient. Priority areas for review and communication with the care team will include:

1. Newly enrolled patients
2. Determining a patient-centered plan of action to support those with persistently poor disease control
3. Patients who have not been contacted within 1 month and need to be reengaged in care
4. Patients who have emerged as a source of concern among the care team
5. Health outcome measures
6. Developing action plans to enhance treatment adherence
7. Determining who among the care team will deliver specific protocols to patients

Although the CM's chief focus lies in the clinical realm of patient care, he/she also supports the amelioration of patients' social determinants of health by serving as the practice site supervisor for the CHW. The CM engages Social Workers as available and/or needed. The CM is an experienced RN or LPN. The CM may also be an LCSW. The CM's main goals are to serve as a **patient change agent,** an

educator, and a **care facilitator** to assist the patient in achieving cardiovascular risk factor reduction goals. He/she uses self-management support and condition-specific medication management protocols to deliver and oversee interventions targeting HTN, CHD, hyperlipidemia, diabetes, depression, and tobacco cessation and will do so in a patient-centered manner. He/she should not duplicate current services but enhance those services and increase the patients' capacity to manage/control their chronic disease. These roles, and their tasks, are summarized in Table 9. Some health systems have CM supervisors in place. In those cases, the health system's CM supervisor supervises the CMs. In health systems where there is no CM supervisor, the practice champion for the study supervises the CM.

Table 9: Care Manager's Primary Responsibilities

CORE RESPONSIBILITY	DESCRIPTION OF ACTIVITIES
Patient Change Agent	- Identify barriers to CVD risk factor management - Develop a plan with the patient and members of the care team to reduce patient and system barriers impeding optimal control of CVD risk factors - Use motivational interviewing (as well as behavioral activation) skills with the patient to facilitate progress
Educator	- Identify patient misconceptions and knowledge deficits impeding successful management of CVD risk factors - Develop tailored patient education program that considers patient's literacy level, personal preferences, cultural orientation, and resources - Develop patient's ability to effectively interact with health care resources including physician, practice, lab and pharmacy services
Care Facilitator	- Collaborate with the primary care provider in providing CVD risk reduction management - Continuously review panel for problem patients and have these patients discussed at monthly meetings; also share overall panel data with the care team to review progress/problems - Provide ongoing CVD risk factor monitoring (lipid levels, blood glucose levels and HbA1c, BP checks) - Initiate and maintain a system to aggressively track patient CVD risk factor status (lipid levels, blood glucose and HbA1c and BP) - Monitor for the development of new CVD risk factors - Assess patient adherence to treatment regimen - Engage additional resources, including family and community support, to assist patient in achieving CVD risk factor reduction goals

Ideally, the patient will see the CM on the same day he or she comes in to see the PCP. If the CM wishes to engage another team member in the patient's care plan and the patient is willing, the CM either arranges for the patient to see the team member the same day while they are already there and engaged, or introduces the patient to the team member via a "warm hand-off" and then assists the patient in scheduling a follow up visit.

E. Caseload Supervision. Depending on the size of the assigned practice, the CM may have an average caseload of 63 patients in various stages of treatment. This can be a busy job, and it is important that good clinical **supervision and back up** is available at all times in case of an emergency. In addition to the practice site PCPs, the practice champion and specialists from the specialist core provide clinical consultation and oversight. For behavioral health issues, the psychiatrist and smoking cessation specialist provide supervision. In particular, the study psychiatrist should **communicate at least biweekly** with the CMs to review the caseload of study patients with clinically diagnosed depression or anxiety and assist with difficult cases or problems. Additionally, the CC team has **daily access to telephone consultation** from a psychiatrist in case they encounter a mental health emergency with a patient.

To ensure maximum effectiveness, the CM must have the following core skills/competencies:

Table 10: Care Manager's Core Competencies	
CORE COMPETENCY	SKILLS
Communication Skills	- Verbal, non-verbal and written - Active listening and problem solving skills - Ability to put therapeutic goals and risk factors into language that is understandable to each patient. - Ability to chart accurately and comprehensively - Ability to communicate in a timely and accurate manner with other members of the care team
Interpersonal Skills	- Relationship building - Team building with members of care team - Openness to patients' experiences and perspectives
Knowledge Base	- Broad knowledge of CVD risk factors, drugs, titration, interpretation of lab tests - Broad knowledge of smoking cessation, depression, nutrition, and physical activity - Some knowledge of the community - Knowledge of barriers patients experience in following treatment protocol
Service Coordination Skills	- Ability to identify and access resources - Ability to function as member of a team and leader of a team - Ability to follow up - Ability to follow study protocols
Organizational Skills	- Ability to set realistic patient and program goals and plans - Ability to juggle priorities and manage time - Ability to chart clearly and promptly
Technical Skills	- Physical exam and ROS for systems relevant to CVD and Type II Diabetes - BP measurement according to JNC-8 guidelines - Use of digital equipment - Use of computers

F. Protocol for Difficult to Engage Patients. CMs should implement the following steps when attempting to engage with patients who have missed first intervention visits or become disengaged: 1) make at least 8 phone attempts for missed FIV appointments and 4 phone attempts for follow-up appointments to engage a patient by phone (phone attempts should be done on different days of the week and at different times of the day); 2) send a "trying to reach you" letter; 3) communicate with the PCP that the CM has had difficulty reaching the patient; 4) monitor the EMR for upcoming patient visits at the practice or other practices both within and outside of the health system, making sure appropriate follow-up occurs by trying to meet the patient at one of these appointments; 5) monitor the EMR and/or CRISP for notifications of patient visits to the emergency department or hospital admissions; 6) conduct an outreach phone call if a patient has been hospitalized or has gone to the emergency department; 7) refer the patient to the CHW if the previously stated actions do not result in successfully engaging with the patient.

G. Plan for Discharging Patients from Care Management. The care manager may discharge patients that achieve and maintain all clinical goals for a period of 6 months AND indicate a preparedness to exit the program. Upon 6 months of clinical goal maintenance, the care manager gauges the patient's preference for on-going participation by asking if the patient prefers to have the care manager continue to call and check in regularly or if the patient would prefer to reach out to the care manager if they feel they need more support in goal maintenance. The care manager emphasizes that regardless of the patient's choice, the care manager and study team will remain available to the patient and the study team will continue to call the patient every 6 months to complete study questions. This pragmatic approach for discharging patients factors in the typical resource constraints of care

management programs while emphasizing patient preferences in the patient's care plan. Patient withdrawal criteria is described in *Section 5. Recruitment of Participants, Item C. Withdrawal criteria*.

Section 6C: Interventions Description: Community Health Worker

A. Background: Community Health Workers (CHWs) are crucial members of the clinic care teams. Their main **purpose** is to support patient participants' BP control by (1) educating participants on how to manage their own BP through self-monitoring and practicing healthy self-management behaviors (e.g., diet and exercise); (2) reinforcing participants' positive BP self-management behaviors through repeated follow up encounters (i.e., by telephone or in person); and (3) helping participants liaise with existing clinical and administrative services. CHWs also support participants by making them aware of community resources (e.g., local grocery stores, safe exercise venues) they can use to support their BP management. CHWs **engage with participants** through home visits, telephone contacts, and in-person visits at their practices on the day of their primary care appointments. The form of CHW engagement is flexible, participant-centered, and varies based on participants' stated preferences.

1. **Hiring and training.** Initially, we envisioned that the CHWs would be hired and trained by our research team; however, in response to feedback from our stakeholders, and for the purposes of sustainability, we have partnered with community-based organizations (CBOs) and payers to assist with hiring CHWs, as well as initial and ongoing training. Our approach depended on the desires expressed by each practice's leadership, and we worked collaboratively with all relevant entities to ensure that the hiring and deployment of CHWs was consistent with what the practices need. For practices that already had CHWs or wish to introduce them into their practices, we provided the requisite training to support their implementation of appropriate interventions for our study population. For practices that elected to have CHWs hired and placed by an outside CBO, we worked with both the practice leadership and the CBOs for hiring and training.
2. Regardless of the approach, the **minimum qualifications** for CHWs include: at least high school education, prior work experience, experience working with the target population, geographical familiarity with the community, leadership qualities, appropriate background checks and letters of recommendation, specified levels of expertise in health and the community, technology skills, and ability to communicate effectively and in a culturally sensitive manner. We developed job descriptions and recruitment strategies with input from our advisory board and project champions from each practice.
3. We developed **training guides and CHW protocols** through guidance from national competencies, investigators' and partners' prior experiences, and CHW Source Books. Initial training occurs over a two-week period before the intervention begins and is delivered by the research and stakeholder team, including experienced CHWs. These sessions cover CVD and Type II diabetes risk factors, medication adherence, stress, patient-centered interviewing and cultural competency (with a particular focus on motivational interviewing), community resources, human subjects research training, and record-keeping skills for tracking and monitoring. On-going training reinforces these topics and will address additional topics that emerge during the project's implementation, including opportunities to discuss case management issues.
4. **Supervision.** CHWs implement interventions upon receipt of notification, from the CM, that the patient has been elevated to the stepped-up intervention. They receive direct oversight and supervision from a CHW Supervisor and the practice CMs, which entails regular meetings consisting of caseload review; assessment of productivity, effectiveness, and efficiency, adherence to protocols; and the clinical team feedback. Supervisors should create a welcoming and responsive, yet structured environment for CHWs; assign appropriate roles and duties to

them; communicate CHWs' scope of practice to the other healthcare staff; promote frequent communication and address workflow, time-management, and any challenging issues CHWs face.

B. CHWs' Roles and Responsibilities

The table below summarizes CHWs' core responsibilities and their associated activities.

Table 11. Community Health Worker's Core Competencies

CORE RESPONSIBILITY	DESCRIPTION OF ACTIVITIES
Reinforce patient education about disease self-management behaviors and attainment of personal goals	- Reinforce education on hypertension, Type II diabetes, coronary heart disease, hyperlipidemia, smoking cessation, depression, nutrition, exercise, and medication adherence through motivational interviewing - Conduct a home visit to deliver equipment and provide training on the use of a home BP monitor - Conduct phone follow ups or return home visits with patients to reinforce skills and address barriers to self-monitoring
Assist patients in accessing care and address barriers to care and treatment	- Conduct outreach calls and home visits to encourage patients who are hard to reach to access health care and to provide education; make referrals; and offer psychosocial support to patients who do not access healthcare services
Serve as facilitator and navigator to clinical and social services and other	- Work with care manager in initial patient assessment - Conduct routine follow-up assessments by telephone or in-person (dependent upon patient's preference) to identify barriers to BP control and address questions and concerns - Identify community-based resources - Communicate patients' status with CC team and report barriers to BP measurement and other self-monitoring behaviors, as well as high reading alerts (blood glucose, BP) - Document findings in EMR to keep members of CC team abreast of patients' status - Document outreach activities in CHW database - Liaise with patients and clinical status

Support patient adherence to disease self-management behaviors and communication with providers	- Engage, activate, and empower patients and their family members by:
	  ○ Working with patients to identify and address barriers to adherence to antihypertensive regimens
	  ○ Providing ongoing support and encouragement
	  ○ Facilitating identification of challenges
	  ○ Coaching patients to disclose concerns to healthcare team
	  ○ Building skills in asking questions
	  ○ Discussing treatment options
	  ○ Helping them learn to make joint decisions regarding treatment options
	  ○ Overcoming common communication barriers
	- Address competing family priorities and needs
	- Assess and reinforce patient's and family members' pro-adherence beliefs and behaviors
	- Assess and reinforce patient's and family members' communication skills around disease-related needs and goals

C. Patient Assessment and Longitudinal Engagement

1. Patient Assessment

a. Initial patient assessment

i. CHWs participate in the initial assessment alongside the Care Manager, in order to establish rapport with patient and help patient to become familiar with members of the clinic care team

a) Care Manager determines whether or not patient requires immediate assistance from CHW

b) At 3 months, the CM deploys the CHW as a step-up intervention if **at least one** of the following conditions are met:

i. Patient's BP or other conditions remain uncontrolled

ii. Patient continues to experience barriers to care and food insecurity
iii. Patient is willing to work with a CHW

c) For both CHW and specialist consultation, exceptions may be made to the timing of the initial referral by special request from the patient and/or PCP, or for extenuating circumstances found to prevent successful achievement and management of BP control. In these situations, referral may occur immediately or at 1 month instead of at 3 months.
d) The CM may make an immediate referral to a CHW if The CM may deploy a CHW prior to one month if the patient is willing to work with a CHW AND at least one of the following conditions is met:
    i. Cardiac event in the last 12 months, with no follow-up appointment
    ii. Inability to perform activities of daily living with no resources
    iii. No access to transportation
    iv. Utility shut offs
    v. Food insecurity
    vi. Domestic violence
    vii. Poor/unstable housing
    viii. Special request from the patient and/or the PCP

b. Ongoing patient assessment
    i. CHWs conduct **monthly assessments** of patients' needs in order to monitor psychosocial status as well as progress on addressing social determinants affecting self-management of chronic conditions

2. Longitudinal Engagement

a. Initiation of longitudinal patient engagement
    i. **Purpose of initial engagement:** to review problems identified at baseline, review patient's progress with care plan developed with Care Manager, review patient's barriers to care, and to begin to implement appropriate interventions as guided by the Care Manager (coaching, empowerment, reinforcement of education, etc.)
    ii. Procedures:
        a) CHWs initiate engagement with patients upon notification from the Care Manager that the patient requires CHW services.
        b) CHW conducts the baseline home visit if the patient is willing to have a visit in his/her home. Otherwise the CHW arranges a mutually convenient location to meet the patient.
            i. Purpose of baseline home visit: to support patient's self-management of hypertension and to build rapport and trust with the patient and his/her family.
            ii. CHW to give patient individual home BP monitor and personal logbook
            iii. CHW reviews hypertension self-management education materials
            iv. CHW reviews patient's medications
            v. CHW reviews his/her role in helping patient achieve BP control
            vi. CHW assesses whether patient has any immediate needs to liaise with patient's care team
            vii. CHW reinforces other behaviors to support BP management

b. Ongoing patient engagement
    i. **Purpose of ongoing engagement:** to monitor patient's progress with care plans; elicit and address patient's concerns regarding treatment; coach patients on communication

with providers; reinforce health education provided by Care Manager; model facilitative communication; and facilitate patient and family empowerment
    ii. CHWs contact patients via biweekly telephone calls and in-person visits (whether at home or at a location based on patient's preference) and to carry out monthly appraisal/assessment of patient's status with barriers and facilitators to care
    iii. CHWs document all intervention activities in care management database, which will interface with the health system's electronic health record
    iv. Face-to-face interactions with patients
        a) CHWs schedule face-to-face interactions with patients (home visits, visits at neutral locations, face-to-face contact after visits with members of care team)
        b) The frequency of face-to-face interactions is determined in conjunction with study team, care team, and patient
    v. Per confirmation from patients regarding level of desired interaction with/involvement from family members/caregivers, CHWs engage with members of patients' caregiving networks to support their adherence to antihypertensive regimens
        a) CHWs share upcoming appointments with providers on an as-needed/as-desired basis
c. Patient-initiated telephone calls or in-person visits to CHW
    i. CHWs use open-ended questions to ascertain patient's needs
    ii. CHW strategizes with patients on ways to obtain any needed assistance
d. Strategies to contact hard-to-reach patients
    i. To be employed when CHWs encounter difficulty reaching patients
        a) Make at least 4 phone attempts within 1 months of referral (1 attempt per week).
        b) Send a "trying to reach you" letter.
        c) Attempt a home visit if there is no response to the letter within 2 weeks.
        d) If the home visit cannot be done, review REDCap to see if the patient has provided an alternative contact with their information, and attempt to reach alternative contacts over the phone until at least one alternative contact provides updated information for the patient or until all alternative contacts are called).
        e) Attempt an additional 4 phone contacts with the patient.
        f) Work with the CM to identify upcoming patient visits and coordinate meeting the patient at the visit, including at other practice locations.

D. Barrier Identification and Mitigation

1. **Purpose:** to identify and address the array of proximal social/cultural/structural factors affecting patients' self-management of hypertension
2. **Barrier Identification Procedures**
    a. CHW follows a prepared script to assess patients' self-identified barriers and facilitators to key behaviors targeted in the study (done on a scheduled, quarterly basis)
    b. CHW also receives instructions from the CM regarding patients' identified stressors
3. **Barrier Mitigation**
    a. CHWs use community resource guides and to identify resources and will provide a list of those resources to the patient.
    b. CHWs follow up with patients to find out whether or not they contacted the organizations found through the resource guides
        i. **If patient followed up:** CHW works with patient to develop next steps
        ii. **If patient did not follow up:** CHW follows up with key staff at the relevant organizations

c. CHWs provide social and emotional support to patients whose financial, relationship, and/or community stressors pose as barriers to care

E. Patient Reinforcement, Coaching, and Empowerment

1. **Purpose:** to reinforce Care Manager interventions and to support patient's achievement of BP control through performing motivational interviewing, modeling appropriate communication styles, eliciting patient's concerns in a compassionate manner, and demonstrating patient-centered communication
2. **Procedures**:
    a. Care Manager alerts CHW to specific issues requiring more intensive reinforcement
    b. CHW reviews the "Every Heartbeat is Life" NHBLI CHW Toolkit[124] and other resources, and, with assistance from Care Manager, select materials to review with patient
    c. CHW engages with patient (either via telephone or in-person) and uses basic motivational interviewing and coaching skills to encourage desired attitudinal changes
        i. Assess patient's progress with self-BP monitoring as well as any problems or successes patients may be having with other aspects of self-management (i.e., diet, exercise, adherence to medication, adherence to scheduled appointments, etc.)
        ii. Positively reinforce successful behaviors (e.g., consistent BP self-monitoring)
        iii. Remind patient about prior conversations and touch bases on issues discussed
        iv. Probe for new issues and encourage patient to discuss them with doctor during next visit
        v. Use structured coaching guide to:
            a) Ask clarifying questions about patients' perceptions of hypertension management
            b) Help patient identify and articulate any concerns regarding his/her medical condition, medication regimen, and issues communicating with primary care provider and/or members of care team
            c) Identify, model, practice, and reinforce simple communication skills (question-asking, decision making, and negotiation)

F. Care Team Participation

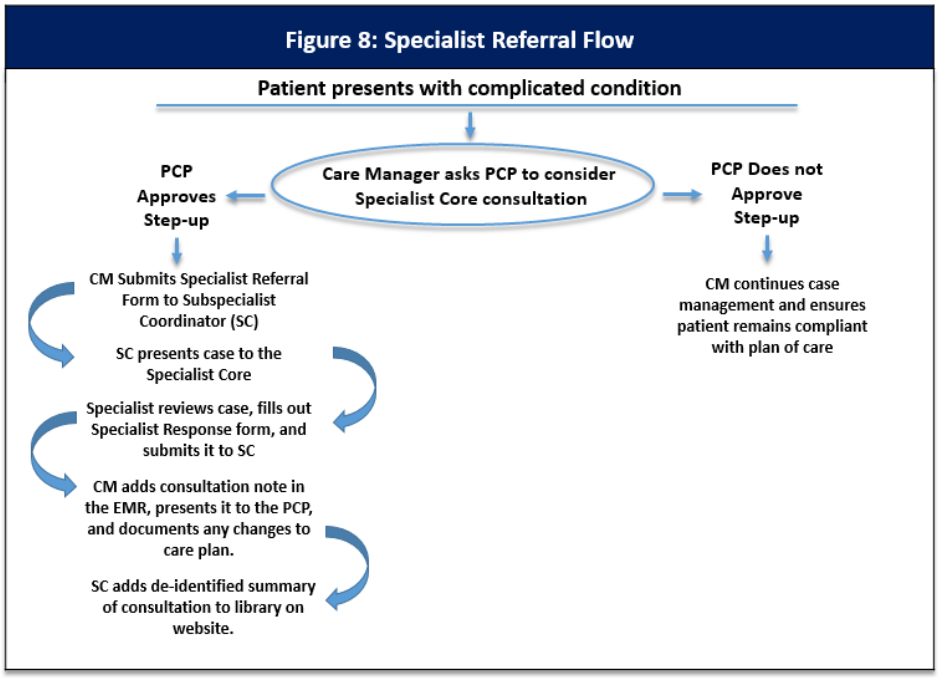
1. CHW to document all activities undertaken on patients' behalf in case management database and electronic health records
2. CHWs liaise with members of care team through rounds, in-person meetings, and ongoing follow-up with Care Manager, PCP, and specialists

A. Approach: The subspecialist intervention engages subspecialty consultation services (see Table 8 in the Collaborative Care description) in the care of more complex patients at the 15 intensive arm practice sites. The subspecialist core includes experts in:

1. Clinical HTN
2. Preventive cardiology
3. Endocrinology
4. Psychiatry
5. Smoking cessation
6. Nephrology

B. Consultation

1. For patients where the PCP or CC team leaders believe that case-specific consultation is required, we may arrange a communication with the specific subspecialist by phone or electronic communication.



2. The CM recommends patients for specialist consultation to the PCP or the PCP may request a step up to specialist consultation. CMs and PCPs decide jointly:
    a. Desired specialty to consult
    b. Urgency of response requested (2-3 days, 1 week, 2 weeks)
3. Using a standardized referral form for each specialty, the CM reaches out to the specialist coordinator on the research team, providing the above information. Elements in the referral form include:
    a. PCP name
    b. Patient study ID number
    c. A password-protected file containing the following information (to be passed on a secure server, not via email):
        i. Patient details: Age, gender, race and ethnicity
        ii. Reason for consultation
        iii. Duration of condition
        iv. Associated signs and symptoms
        v. Exacerbating factors
        vi. Medications and allergies
        vii. Investigations biopsy results/laboratory data, medications tried and removed from regimen
        viii. Diagnosis (provisional)
        ix. Previous therapies tried

4. The specialist coordinator contacts the appropriate specialist, with relevant information and a link to the case file on the secure server. The specialist prepares recommendations based on the provided information. The specialist uses a standardized response form to write up the recommendations and place on them on the secure server.
5. The specialist response form should be considered suggestions by the CM and PCP and not clinical decisions. The response form includes suggestions on:
    a. Follow-up plan
    b. Recommended tests for the referring clinician to organize and communicate with the patient
    c. A statement on whether or not the specialist believes the patient should be seen in person by a specialist
6. The specialist coordinator then lets the CM know that the recommendations are available. The Care Manager retrieves the recommendations, enters them into the patient's EMR chart, and alerts the requesting physician that the recommendations are available.

Section 6C: Interventions Description: System Level Leadership Intervention

A. Approach. Organizations typically afford inadequate organizational priority to the domain of health equity, leaving healthcare leaders unprepared to situate their organizations to address disparities in the delivery of care. For example, in our previous work with some of the same sites participating in this study, we found that larger percentages of health care personnel perceived barriers to addressing disparities than to improving safety and quality, and personnel perceived strong organizational focuses on quality and patient centeredness. This revelation exposes the need for greater concentration on health disparities.[90] The Institute of Medicine and other organizations have highlighted the need for a learning healthcare system, including in the area of health equity, but a true learning healthcare system remains elusive.[89] Learning organizations are those in which people continually learn and seek to grow in order to achieve the results they envision as best.[125] Members of learning organizations also recognize that they work in a system that both facilitates and constrains their choices and actions. To address CVD disparities in a comprehensive manner, system-level changes to create and support a learning system in these practices are needed.[126] System leaders play a critical role, as they are able to set appropriate tones, provide resources, guidance and rewards to employees, and create the necessary infrastructure to support a learning environment so as to improve equity in care. Few existing approaches have been designed to promote learning health care systems to reduce disparities, however, and fewer still offer system-level strategies. This System-Level Leadership intervention therefore aims to create a learning network through an inter-organizational approach to reduce CVD disparities.

B. Description. This System-Level Leadership intervention aims to create a learning network through an inter-organizational approach to promote health equity and reduce CVD disparities. We assume in most organization, leaders monitor financial performance and some quality indicators but do not have specific priorities around reducing CVD disparities, nor extensive exposure to improvement techniques for equity and quality. Elements of the system-level leadership intervention, then, include: 1) an introductory session during the kick-off event (baseline); 2) a quarterly 1 hour "content call" with a presentation on leading for equity and discussion among system-level leaders, community organization leaders, and interested practice champions in the CC/Stepped care arm conducted via conference call/webinar; and 3) twice quarterly "coaching calls" for the system and practice level leaders, CMs, and CHWs in the CC/stepped care arm to discuss the interventions, while they are actively engaged in the intervention phase. As previously described, we reduced the frequency of coaching calls to once per quarter in April 2019.

1. **Brief questionnaire for Leaders.** Early in the UH3 phase, we used a brief web-based questionnaire to get input from system-level and community organization leaders on the design and themes to be covered in the system-level leadership's health equity learning network.
2. **Interviews with System Leaders.** Also early in the UH3 phase, we conducted in-person or telephone interviews with system leaders about the mission of their organization and past efforts to reduce disparities and/or to improve quality of BP measurement and management. Additionally, we will conduct in-person or telephone interviews with system leaders at the end of the active intervention period.
3. **Leadership training.** We conducted an introductory presentation on Health Equity for all attendees for participating practices and from community-based organizations as a session at the baseline Kick-Off event. This covered one topic of educational content. In addition, the group participated in a "Pre-mortem" exercise, which allowed participants to imagine potential sources of failure of their efforts and to brainstorm preventive solutions.
4. Ensuing quarterly content calls show an appreciation for leaders' existing skills and knowledge and use brief didactic presentation mixed with interactive opportunities to discuss and apply

information to real-world circumstances. Inclusion of local community organization leaders is purposeful, to increase collaboration with and understanding of leaders who are in touch with the community and patients. **Table 12** details examples of session topics and interactive activities, as well as the learning objectives associated with each learning session. The content call topics are modified from a workshop used previously to promote leadership in continuous learning.

5. **Pre-post assessments of knowledge, attitudes, and behaviors among participants in the health equity learning network**. Surveys take no more than 15 minutes to complete, and are collected online at the beginning of the first cohort's intervention period as well as at the end of the intervention period.

Table 12: Examples of Leadership Workshop Curriculum

Session	Topics	Activities	Learning Objectives
1	Key Understanding of Health Disparities & Health Equity	☐ Emotional engagement using video clips ☐ Excerpts from case studies related to health disparities, and sharing of relevant anecdotal evidence to situate the overarching aim of the SLL intervention ☐ Some discussion around Quality Improvement (QI) and disparities reduction, including the unintended consequences of QI	☐ Explain why health equity is important both in itself and in support of other organizational priorities to create buy-in internally and for external messaging ☐ Describe the impact of health disparities on excess deaths, morbidity rates, costs, and lack of social justice in our society ☐ Explain how the healthcare system contributes to health disparities (and conversely, how it could help our society achieve health equity)
2	Health Disparities and the Community	☐ Q&A discussion (panel-style)	☐ Describe the social determinants of health, sentiments within the community, and strategies for true community engagement ☐ Discuss caveats in Health Disparity Work (e.g., how health care quality work can widen the disparity gap)
3	Equity, Safety, and Quality Monitoring	☐ Review sample dashboard data ☐ Discuss how to review the data and engage providers in how to use the information in their practice	☐ Interact with sample dashboards ☐ Learn to monitor and track performance, discuss possible actions to take in response to data
4	Practical Strategies to Address Health Disparities & Health Equity	☐ Use the 4E's implementation framework to plan how to Engage, Educate, Execute and Evaluate for four audiences: frontline workers; team leaders; senior leaders; and patients and families. ☐ Discuss practices within seven health equity system strategies: demonstrating a commitment to health equity; using data and measurement; implementing training; using comprehensive needs assessments; building collaborative partnerships; enhancing care continuity; and engaging patients and families.	☐ Discuss seven system practices to achieve health equity for socially at-risk populations and provide examples of each practice ☐ Discuss the use of community health workers (CHWs), a strategy for enhancing continuity of care and engaging patients in care ☐ Describe the 4 E's of implementation framework ☐ Apply the 4 E's framework to implementation of community health workers

6. **Leadership collaborative learning network:** Learning networks or collaboratives are a multi-site strategy to rapidly disseminate evidence-based practices and to develop new approaches to common problems in health care. We facilitate an ongoing, collaborative network among the

system-level leaders and representatives from community organizations that are involved with the practices' patient population. We refer to this group as the Health Equity Learning Network (HELN). All leaders participate in quarterly **content conference calls** (described above) throughout the length of the project (3 years). As noted above, these sessions are webinars that commenced with the Kickoff meeting.

7. **Coaching calls:** As each cohort enters the intervention period (see Randomization Scheme), we invite system-level leaders and practice-level leaders from the CC/Stepped Care intervention practices to participate in **coaching conference calls**. As each cohort commences intervening on patients, each system has one call with other practices from their system only, then joins the existing quarterly general coaching calls that also feature the other health systems. These coaching calls allow leaders to share implementation experiences, coach their sites in the intensive intervention arm, and receive coaching from members of the research team and the community organization leaders on how to implement and support initiatives to reduce cardiovascular health disparities. This applies to work within their systems and relationships with community organizations outside of their systems. On a quarterly basis, the coaching calls specifically focus on dashboard and data review including promoting dashboard review at practices and strategies for action planning based on data trends. The coaching calls provide a regular opportunity for system level, practice level, and community organization leaders to regularly interact and discuss implementation strategies.
8. **Minimizing potential contamination of SCP practices by system-level leaders.** System-level leaders are in leadership roles for practices randomized to both SCP and CC/Stepped Care intervention arms. **However, system-level leaders only participate in coaching calls with practice level leaders of the CC/Stepped Care practices**. Practice leaders in the CC/Stepped Care arm are invited to sit in on educational content calls as well. The coaching calls provide a unique opportunity for interaction and collaboration between system- and practice-level leadership that bolsters the implementation by system-level leaders of the strategies discussed during workshop calls. **Without additional coaching calls, the system level leaders' interaction with practice sites in the SCP arm are unlikely to change in a meaningful way from baseline**, minimizing the likelihood of contamination of the SCP sites.
9. **Duration of the intervention.**
    i. System-level and community organization leaders will participate in quarterly content conference calls for up to 4 years. Practice champions, care managers, and community health workers may join at their discretion.
    ii. System-level leaders, practice-level leaders (in the CC/Stepped Care arm only), care managers, and community health workers will participate in the coaching conference calls for at least 2 years with the option to continue participation after the 2 years.

Section 6: Interventions: Duration

Intervention durations reflect the rolling implementation of interventions at the participating health systems.

A. **HTN Dashboard-Audit/Feedback – 2-4 years**

B. **BP Measurement Training (with follow-up) – 4 years**

C. **HTN Care and Control Best Practices Training – 2.5 years**

D. **Collaborative Care Intervention – 1 year**

E. **Step up to: Community Health Worker – 1 year**

F. **Step up to: Subspecialist consultation core – 1 year**

G. **System Level Leadership Intervention – 2 years for content calls. Up to 4 years for HELN. (These overlap, but do not begin at the same time.)**

Section 7: Measurements

A. Primary Outcome Measures – BP control at 12 months and systolic BP change from baseline at 12 months

This study will evaluate outcomes based on BP measurements that are collected by primary care providers and medical assistants using automated devices, and entered into practices' EMR. Although this approach deviates from the approach used in traditional clinical trials, where a small pool of highly trained research staff measure BP, it is a prerequisite of a pragmatic study to measure outcomes as they are measured in the real world. First, the measures used in this trial will resemble those used for quality improvement purposes (e.g., HEDIS measures), as these metrics also are generated from BP measurements collected from clinical records. Thus outcomes from this study will offer a closer approximation of how studied interventions will affect measures as they are currently used (where practices have access to automated devices) for health system payment, quality reporting, and policymaking. Second, using measures from the EMR minimizes risk for intervention bias, as having study nurses obtain traditional research-quality BP measurements would require patients to interact with health care professionals outside of expected interactions. Our proposed approach minimizes risk for researcher-interaction bias. To minimize variability associated with clinical BP measurements and concerns related to technique-related bias, we will employ automated measurement devices, implement a multi-pronged approach to training practice staff at SCP and CC/Stepped Care arms of the study in a standardized BP measurement process, identify and train a "super-user" at each site to oversee and support BP measurement at each site, and train the site staff to monitor Dashboard data for terminal digit preference on a quarterly basis. Care will be taken to consistently measure outcomes at multiple time-points and across the two study conditions to reduce internal threats to validity. (See Section 6 on interventions.)

B. Other baseline measures: source and descriptions

1. **Instruments to be used for patient data collection:** Sources for patient data for this study include:
    i. **EMR**. The EMR data will be used to select potential patients for recruitment, obtain contact information for recruitment, and to assess clinical outcomes on enrolled patients. Data will be extracted just prior to recruitment and, for those enrolled, at 6-month intervals for up to 30 months of follow-up. Data elements will include BP measures, lipid levels, HbA1c and glucose levels, and other clinical measures of interest to the research team. The EMR is a valuable source of data. First, ours is a pragmatic trial, and real-world treatment decisions are made using EMR data. This will improve the value of our findings for real-world implementation. Second, these data elements are routinely collected when patients visit their provider. However, a major limitation of this data source is that unlike data collected at scheduled study visits, EMR data are only available if a patient visits their provider. We will minimize this limitation by only recruiting patients that have seen their provider within the 6 months preceding recruitment. We hope this will result in a patient sample with more complete follow up data.
    ii. **Care Manager, CHW and Specialist records.** The care managers, CHWs and specialists from the study's specialist core will maintain consistent records on each patient participant with whom they interact or whose case they review. The data collected includes both quantitative and qualitative data. This information is entered in a study database. For the care managers and CHWs, three and fifteen visits, respectively, will also be audio recorded and assessed for use of motivational interviewing strategies. These data will be used in assessing both clinical and patient-centered outcomes.
    iii. **Telephone surveys**. Our trained staff of recruiter/interviewers complete an interview with each participant at baseline, 6-, 12-, 18-, and 24-months. These data will be used to

assess patient-centered outcomes, including Patient Activation Measure (PAM-13), health-related quality of life, medication adherence, patient satisfaction, and patient reported adverse events. When assessing patient reported outcomes, one needs to ask patients directly about their experiences. The validated instruments (see response to IR-4 below) are designed to accurately gather information about each patient's experience as part of this study, and our analysis plan will allow us to assess how this changes over time. The limitations of using telephone surveys are the length of the surveys (each of the surveys takes between 45 and 90 minutes to complete) and survey fatigue on the part of the participant.

iv. **Claims data**.

2. **Instruments to be used for provider/staff data collection:** We are using limited surveys of providers and staff involved directly in the intervention (CMA super-users, practice champions, system level leaders, care managers, and community health workers) to collect knowledge and attitudes. Attitudes surveys will be no longer than ~15 minutes in average length. Baseline is defined as the time of enrollment of patients at the practice where the respondent works. For the comparison arm, respondents will be the same except there are no Care Managers. System- and practice-level leadership surveys will assess attitudes toward the interventions. Baseline is defined as the time of enrollment.

   We conducted short interviews with system-level leaders to assess system values prior to the active intervention and will conduct interviews with leaders after the active intervention is complete. We conduct exit interviews with CMs and CHWs departing from the study to learn more about their experiences executing the study protocol and administer CM and CHW characteristic surveys, within 12 months of the first CM visit and 6 months of the first CHW visit, to measure CM and CHW attributes. We also conducted 30-minute in-person or telephone directed interviews with CMs. The interview focuses on assessing CMs' involvement with the RICH LIFE subspecialist core as a CM on the project. The interviews will be conducted by two study team members. The interview will be audiotaped based on each CM's permission. Finally, there are frequent qualitative check-ins with CHWs and CMs to assess program utility and progress (based on the RE-AIM framework, described further below).

3. **Instrument to be used for practice-level data collection**
   i. We are using a data collection sheet to collect characteristics of practices. We are asking practice administrators to fill out this instrument. Baseline is at the time of enrollment.
   ii. We will collect common EMR metrics for all practices from the networks' central offices.

4. **Description of all data elements of interest:** Study variables, including validated measures important to patients and families, are listed in Tables 13 and 14. We will also request utilization and prescription-fill data from claims from insurers.

C. Subsequent measures: source and description

1. Table 13 gives details on how instruments used at baseline will be followed up.
2. Each patient receives two years of intervention and variable periods of post-intervention monitoring for sustainment of outcomes through year 4 and the first two quarters of year 5. In order to minimize data collection burden on patients and providers, sustainability (post-intervention) measurements will be limited to EMR extraction and claims data analyses only.
3. To correctly assess and report on participants' death across both study arms, we will be applying for National Death Index (NDI) data from the Centers for Disease Control and Prevention (CDC). We will request cause of death but we will not perform follow-back investigations, in other words, we

will not contact participants' next-of-kin. We will summarize (aggregate) data and compare across intervention arms in both reports (to PCORI and the Data and Safety Monitoring Board) and as a peer reviewed scientific journal article. The NDI data will be used to identify deaths in study participants who are lost to follow-up.

Based on the requirements of the CDC's National Death Index process, we will transmit participant data using the CDC's sFTP site and upload a password protected WinZip file. The password will be communicated to the appropriate person through email. The study biostatistician, Kathryn Carson will prepare the file and upload it.

Per the CDC's guidelines, we will include participant first and last name and month and year of birth on approximately 588 participants. It will be all participants who have not yet completed their 24 month follow-up. For those that we already know are deceased, we want to confirm their dates of death.

National Death Index data would be stored in the Johns Hopkins Enterprise data center. We will destroy NDI data by September 2023 in accordance to CDC requirements. We will submit the required data disposition form to the CDC by September 2023.

4. Follow-up interviews are conducted by study staff by phone. In cases where a patient cannot complete follow-up interviews due to limited phone minutes, we will mail a paper version of follow-up interviews with a return envelope.

Table 13: Study Measures (Patient)

	Baseline	Follow-Up
Patient-Level Variables	**Sources**	
Biomedical/Clinical Outcomes*		
Systolic and diastolic BP, BP control (<140/90)[28,131]	EMR	EMR
Hyperlipidemia control[132]		
Glycemic control[133]		
Global Framingham Risk Score[134]		
Chronic Kidney Disease (Estimated Glomerular Filtration Rate or eGFR)		
Urine microalbumin (per National Kidney Foundation K/DOQI clinical practice guidelines 2000)		
National Death Index Data		CDC
Patient-Reported Outcomes		
PROMIS Global Scale	Telephone Interview	Telephone Interview
Patient activation (Patient Activation Measure, PAM-13)[139,140]		
Medication adherence (Medication Adherence Scale, 4-item)[137]		
Physical Activity (The Framingham Heart Study (FHS). Physical Activity Questionnaire)		
Fruit and Vegetable Intake (Diabetes Self-care Activities Measure)		
Tobacco or cigarette use (National Health Interview Survey)[141]		
Stroke-free status (Questionnaire for Verifying Stroke-Free Status)		
Hypertension Knowledge, Attitudes and Perceptions		
Patient Health Questionnaire Depression (PHQ-8)		
Perceived Stress Scale		
Adverse Events (patient reported)		
Social Network Analysis (SNA)	N/A	
Patient attainment of self-defined goals (e.g., BP, weight, diet, exercise, medication adherence)+	N/A	
Patient-Reported Experiences of Care		
Resource Use (Chronic Illness Resources Survey)[138]	Telephone Interview	Telephone Interview
Patient Assessment of Care for Chronic Conditions (PACIC-Plus)		
AHRQ Care Coordination Quality Measure for Primary Care (CCQM-PC)		
CAHPS Items from Health Literacy Subset		
Satisfaction and Trust		
CollaboRATE	N/A	
Perceived usefulness of CHW (CHW Evaluation Questionnaire)[107]	N/A	
Biomedical Covariates		

Body mass index	EMR	EMR
Healthcare and Prescription Drug Utilization		
Healthcare insurance status	Telephone Interview	Telephone Interview
Hospitalizations, ED use, 30-day Readmissions	Claims	Claims
Prescription refills and medication possession ratios for relevant medications		
Social and Demographic Measures		
Age, Gender, Ethnicity/Race, Primary Language, Employment, Insurance, Income, Wealth, Disability*[141,148]	Telephone Interview	Telephone Interview
Health Literacy (CHEW)		N/A
Subjective Numeracy (Three-Item Subjective Numeracy Scale)		
Life Events		
Everyday Discrimination		
Community Stressors: Violence		
Community Stressors: Total Victimization		
Community Stressors: Disorder		
Adverse Childhood Experience (ACE) Questionnaire		
Emotional support (PROMIS Social Functioning Scale)[149]	N/A	Telephone Interview
Informational support (PROMIS Social Functioning Scale)[149]		
Instrumental support (PROMIS Social Functioning Scale)[149]		
Family composition and spillover		

Abbreviations: CHW, Community Health Worker; PHQ, Patient Health Questionnaire.
**Collected at baseline only +Collected for patients in CC/Stepped Care only*

Table 13: Study Measures (Provider, Practice, and System Levels)

	Baseline	Follow-Up
Provider and Staff Level Variables	**Sources**	
Age, Gender, Race/Ethnicity, Education, Professional Role, Years of Experience	Online Survey	Online Survey
Cultural competence, Patient-centeredness (PPOS)[152,153]		
Perceptions of practice quality improvement capacity,[154] patient-centeredness,[155] cultural competency and barriers to addressing health disparities,[156] teamwork[157]		
Provider and staff knowledge assessments		
Practice Level Variables		
Number and types of clinicians and staff, practice type (private, FQHC); resources	Survey	
Patient-level outcomes averaged across all patients from the site	EMR, Interview	EMR Telephone
System-Level Variables		
System values, priorities, and capacity for change, leader attitudes	Survey, In-person interviews	Survey, In-person interviews

D. System-Level Leadership measures

Table 14: Provider Measures

Variable type	Items	Measurement tool	Platform
All participating providers and staff, including leaders, who receive support from the grant	Age, gender, race/ethnicity, education, professional role, years of experience	N/A (Socio-demographic information)	Self-Administered Online or paper survey
	Assessment of cultural competence and patient-centeredness	10-item instrument assessing provider satisfaction	
	Perceptions of organizational cultural competency and barriers to addressing health disparities	12 quality measures focused on healthcare disparities and culturally competent care for racial and ethnic minority populations endorsed by the National Quality Forum	
	Perceptions of teamwork	Items from a framework of validated teamwork measures	
All participating providers and staff, including leaders, supported by the grant	Pre-post training knowledge assessments	Team-developed items, in brief surveys conducted immediately before and after training modules (App. 13)	Online
Practice champions	Perceptions of system-level management	New short form to be developed by researchers	Online
System-Level	System values, priorities	Interview to be developed by researchers	Interview and Online survey
	Leaders' report of motivation, attitude toward health equity, and knowledge of quality improvement methods	New items to be developed by researchers	

1. We collected a system-level leadership interview at baseline to determine strategic priorities and readiness for change of all participating systems. We are collecting baseline and post intervention survey data from leaders to determine the effect of the system-level intervention over time on their attitudes and behaviors. We are also collecting a 3 to 5 item survey semi-annually during their intervention period from practice-level leadership regarding their impressions of system-level management and organizational commitment to health equity. Baseline for this mini-assessment is collected upon practice uptake of the intervention.
2. **The variables and instruments for measurement are listed in Table 14.** (Note: Patient-level variables such as biomedical/clinical outcomes and self-reported outcomes that are collected during the study will be triangulated with the measures below.)
3. We also use a ten-question post-webinar evaluation to assess participant's views of the educational content and interactive learning activities.

E. Measurement timeline. Patient data is collected annually by phone or in-practice. Provider/staff level data is collected at baseline and post-intervention (from only participating clinicians and staff supported by the grant) via online platforms. A leadership collaborative learning network survey to collect system-level data is administered at baseline and after the intervention period is complete. Baseline is defined as the beginning of enrollment into the study.

F. Data collection intervals

a. Survey data is collected for the SCP and CC/Stepped Care patient groups at enrollment and at 12 and 24 months.
b. EMR data is collected at 6-month intervals.

c. Adverse event data is collected from the EMR and by survey at 6-month intervals during the active intervention period.
d. Social Network Analysis (SNA) will be collected annually via phone at 6-month and 18-months.
e. Provider/ staff survey data is collected pre- and post-intervention via online survey.
f. System leader survey is conducted at pre- and post-intervention.
g. CMs and CHWs will complete the Post-Implementation Audit questions to explore the factors surrounding their perceived relationships with patients, and their integration into care teams.
h. CMs and CHWs are invited to complete characteristic surveys at baseline.

G. Number of assessments

a. Data from the EMR is collected at 6-month intervals for a maximum of 6 assessments.
b. All patients complete a maximum of 3 patient outcomes surveys.
c. Patients in the CC/Stepped Care arm have an extensive assessment that is part of developing their care plan administered at their First Intervention Visit.
d. Providers/staff supported by the grant participate in 2 assessments: one at baseline and one at the end of the study.
e. System leaders complete 2 surveys, at baseline and at the end of the study.
f. CMs and CHWs complete 1 characteristic survey and 1 training evaluation survey at baseline.

H. Intervention process measures

a. This is discussed in depth in Section 9: Quality Control and Quality Assurance and detailed measures are provided in Appendices 13, 14, and 15.

Section 8: Analysis

A. Recap of Hypothesis and Outcomes

UH3 Hypothesis: CC/Stepped Care will be more effective than SCP in improving clinical outcomes and self-management behaviors among hypertensive patients with other designated conditions.

Primary endpoint: The primary endpoint is 12 month follow-up. Analysis on the following outcomes will take place after 12 month follow-up data collection has been completed.

Primary outcomes

The primary clinical outcome of the RICH LIFE Project is the percent of patients with BP <140/90 at 12 months. The primary patient reported outcome is change from baseline in self-reported patient activation, measured by the Patient Activation Measure (PAM-13), at 12 months.

Secondary outcomes

The most important secondary clinical outcome is change from baseline in systolic BP at 12 months. Additional secondary clinical outcomes include: 1) change from baseline in diastolic BP at 12 months; 2) percent with BP<130/80 mm Hg and with BP<120/80 mm Hg at 12 months; 4) change from baseline in 10-year projected probability of a CVD event (global Framingham Risk Score) at 12 months; 5) mean change from baseline in total cholesterol, low-density lipoprotein cholesterol **(**LDL-C), and high-density lipoprotein (HDL) and change from baseline in the percent with controlled total cholesterol, LDL, and HDL at 12 months for all patients and for the subgroup with hyperlipidemia; and 6) mean change from baseline in hemoglobin A1c and change from baseline in the percent with hemoglobin A1c< 7.0 at 12 months in patients with a diagnosis of diabetes.

Patient-reported secondary outcomes include: 1) attainment of self-determined goals related to self-management behaviors (e.g., medication adherence, healthy diet, physical activity, and smoking cessation);

2) medication adherence; 3) health related quality of life; 4) depressive symptoms; 5) patient assessment of care for chronic conditions; 6) patient ratings of trust in their care teams; and 7) hypertension knowledge and attitudes. We will compare change from baseline to 12 months to determine the effect of the intervention.

Secondary endpoint and outcomes

We will assess the following outcomes after 24 month follow-up is completed to determine the durability or "late" intervention effect: 1) the percent of patients with BP <140/90 at 24 months; 2) change from baseline in self-reported patient activation, measured by the Patient Activation Measure (PAM-13), at 24 months; 3) change from baseline in systolic and diastolic BP at 24 months. We will also compare the change from 12 months to 24 months.

Table 14 lists study measures, data sources, and collection time points.

Statistical analysis plan

We will use descriptive statistics to characterize the organizations, providers, and patients, using means and standard deviations, medians and interquartile ranges, or frequencies and percentages where appropriate. Descriptive statistics of central tendency and variability will be generated for outcomes. The distributions of each continuous outcome variable will be assessed for normality, and appropriate transformations will be made if necessary. Two-sample t-tests, Wilcoxon rank-sum tests, and Fisher's exact test will be used to compare baseline demographic and practice characteristics across intervention arms.

Primary statistical analyses testing the differences in outcome (or change in outcome over time) between intervention groups will be conducted using the intention-to-treat principle. For our clinical outcomes at our primary endpoint of 12 month follow-up, we will select the EMR measure that is closest to 12 months following the baseline survey (enrollment date) for each patient as long as it is within the 6 month window.

General Approach

These analyses will utilize all available data through modeling approaches for correlated outcomes. All missing data will be assumed to be missing at random (MAR) conditioning on the observed data, and models will be adjusted for characteristics associated with missingness and key variables not balanced by the cluster randomization. In sensitivity analyses, missing data will be imputed using likelihood based longitudinal models developed under the MAR assumption. Missing data under plausible informative missing scenarios will be multiple-imputed using these likelihood based models with the mean models tuned according to the plausible informative missing scenarios. These sensitivity analyses will verify the robustness of the results derived under MAR assumption. All tests will be two-sided and significance will be set at alpha<0.05. Analyses will be conducted using SAS version 9.4 or higher (SAS Institute, Inc., Cary, NC) or Stata SE14 or higher (StataCorp, College Station, TX).

We will use mixed-effects regression models for continuous outcomes and Generalized Estimating Equations (GEE) analysis for dichotomous outcomes. For mixed-effects regression modeling, we will assume an unstructured correlation structure for longitudinal analyses of outcomes with repeated measurements over time, employ random effects to address clustering by practices, include appropriate covariate adjustment in the fixed effects, and use robust estimates for statistical inferences. The GEE approach is robust to outcome correlation misspecification, so we will just assume an exchangeable correlation structure for the outcomes, include appropriate covariates in the mean model, and use robust estimates for statistical inferences. We will use mixed-effects regression models under the MAR assumption as the basis to conduct multiple imputation for missing BP data or other outcomes as appropriate. In sensitivity analyses evaluating potential impacts under sensible informative missing

(NMAR) scenarios, we will preserve the mixed-effects regression based variance-covariance estimates, and manipulate the mean model under each informative missing scenario to carry out multiple imputation. Missing binary outcomes (e.g., controlled BP or lipids) will be derived based on multiple-imputed continuous values using appropriate observed data likelihood models as described.

Statistical analysis plan for primary outcomes

For the primary clinical outcome of BP control at 12 months we will model the binary variable BP controlled (yes/no) at 12 months using GEE with a logit link on the intervention arm indicator (CC/Stepped Care arm vs. SCP arm). Additional covariates will be included as appropriate as described previously, including appropriate cluster level characteristics and variables associated with occurrence of missing data. With correctly specified mean model, the GEE is robust to misspecification of correlation structure so the statistical inferences will account for outcome correlation due to patients clustering within practice and be valid under MCAR. The regression coefficient for the intervention arm indicator estimates the log-odds ratio of BP control at 12 months for the CC/Stepped Care arm to the SCP arm. Multiple imputation of missing BP outcomes will be carried out to impute the missing BP control outcomes to produce proper inferences under MAR and to conduct sensitive analyses under NMAR scenarios.

For the primary patient-reported outcome of change from baseline in PAM-13 score at 12 months, we will model the baseline and 12-month PAM-13 measurements using a mixed-effects linear regression model, with the intervention arm indicator (CC/Stepped Care arm vs. SCP arm), 12-month time indicator, and the cross-product term of intervention by time interaction as the fixed mean effects, the practice indicator as a random effect, and additional covariates included as fixed effects as appropriate as described previously. The fixed effect regression coefficient for the cross-product term of intervention by time estimates the mean difference of 12 month change in PAM-13 between arms.

Statistical Analysis Plan for Secondary Outcomes

For the outcomes of systolic and diastolic BP measures at 12 months, we will select the blood pressure measure that is closest to 12 months of follow-up for each patient as long as it is within the 6-month window (either direction). We will model the baseline and 12-month BP measurements using a mixed-effects linear regression model, with the intervention arm indicator (CC/Stepped Care arm vs. SCP arm), 12-month time indicator, and the cross-product term of intervention by time interaction as the fixed mean effects, the practice indicator as a random effect, and adjusting for additional covariates as fixed effects as described previously. The random effect for the cluster ID will be used to capture the outcome correlation for patients nested within the cluster. The fixed effect regression coefficient for the cross-product term of intervention by time estimates the mean difference of 12 month change in BPs between arms.

For the other secondary measures, e.g., laboratory measures of hemoglobin A1c and lipids, we will use methods similar to the assessment of 12 month outcomes for blood pressure, i.e., select the within window measure in the EMR closest to 12 months after baseline and use mixed-effects linear regression or GEE models to assess the outcomes while controlling for outcome clustering within practice.

Subgroup and Exploratory Analyses

Durability of intervention effect at 24 months

For the important clinical outcome of BP control we will model the binary variable BP controlled (yes/no) at 12 and 24 months together using GEE with a logit link, and with the intervention arm indicator (CC/Stepped Care arm vs. SCP arm), the follow-up visit indicator (24 months vs. 12 months), and the interaction term of these two binary indicators as the main predictors for the mean model. Additional covariates will be included as appropriate as described previously. Multiple imputation of missing BP outcomes will be carried out to impute the missing BP control outcomes to produce proper inferences under MAR and to conduct sensitive analyses under NMAR scenarios.

For the durability outcomes of change in blood pressure and Patient Activation at 24 months, we will derive the statistical inference from mixed-effects models utilizing all outcome measures available from the 3 study time points. The regression coefficients of the arm by 24-month visit cross-product interaction term from the corresponding models estimate the difference in change in systolic BP as well as the difference in change in PAM-13 at 24 months from baseline between the intervention and the control arm, respectively. Estimates contrasting the 24 months change to the 12 months change from the modeling results will allow us to assess the durability or late effect of the intervention.

Subgroup Analyses

Patients, clinics, and health systems will be keen to know if the interventions have differential effects on different subpopulations. The pre-specified subgroup analyses include analyses by race and ethnicity. Specifically, we will compare outcomes among non-Hispanic African Americans and Hispanics to non-Hispanic whites. The analysis plan for testing heterogeneity of treatment effects is that using the full dataset, we will compare each disadvantaged subgroup (and the combined disadvantaged groups) to the presumed-advantaged group. We will test interactions of these with the intervention effect. We targeted enrolling approximately 21 patients in each race/ethnicity category per clinic to maximize power; however, these analyses will be exploratory and are not powered to detect specific differences among the subgroups.

Exploratory analysis will also be conducted to test for differential intervention effects across clinics. For this analysis clinic-indicator dummy variables and their interaction with intervention arm will be included in the GEE and mixed effects models.

For the CC/Stepped Care arm, exploratory analysis will be conducted to determine which parts of the intervention, e.g., number of CM and CHW contacts, were more successful in improving BP control and reducing systolic BP, or if there was an overall "dose" effect.

Power calculation

We aim to recruit a total of n=1,890 unique patients. We planned for 20% random attrition which would yield an analytic sample of 1,500 (effective size of 50 patients per practice).[104,105] A review of cluster-randomized trials in primary care found a median intracluster correlation coefficient (ICC) of 0.04, with an interquartile range of -0.02 to 0.21.[164] Assuming a 5% ICC, 15 clusters of 50 patients per intervention arm and a two-sided alpha of 0.05, we will have 80% power to detect a difference in proportion of patients with BP controlled of 11-13% (depending on whether the proportion controlled in the SCP arm is 50%-70%). With the same assumptions and sample size, using a two-sample t-test, we will be able to detect an effect size of 0.278. Operationalizing this for the primary and important secondary outcomes, we anticipate that for PAM-13, estimating a SD=10.0,[165] we would be able to detect a mean difference of 2.78 between the CC/Stepped Care and SCP arms; for systolic BP, estimating a SD=19.5 mm Hg,[153] we could detect a mean difference of 5.42 mm Hg between the CC/Stepped Care and SCP arms.

Design Considerations:

Participants will be considered to be enrolled at the time they are given their randomization assignment, which will occur at the end of the baseline interview. Data from all enrolled participants will be analyzed as intent-to-treat.

Missing Data

For the Patient Survey (telephone interview) data: To limit missing data at baseline, we are not considering the patient to be enrolled in the study until they complete the baseline survey. We make the participant fully aware of the time involved to complete the survey prior to beginning. We also give the participant the option to complete the survey in more than one telephone call. Our interviewers are trained to encourage the participant to complete the entire survey. Though the participant may choose not to answer some of the questions, we are requiring that they answer at least 10 items of the PAM-13 since this is a primary outcome. Participant data entered into REDCap will be reviewed weekly by the data manager for completeness. If data were inadvertently missing (the participant did not refuse to answer), the interviewer will be asked to re-contact the participant to obtain these data. If there are patterns of missing data across interviewers, we will work to identify why this is occurring and modify training, as necessary, to correct the issue. We are using the scheduling system within REDCap to track when participants are due for follow-up telephone surveys. Additionally, if patients are still being seen at the participating health system, we will have access to updated telephone numbers and addresses. We have tried to minimize study participant burden and follow-up interviews should take less time to complete than the baseline. We will seek to replace dropout patients with others from the same clinic when these occur early in the intervention period. A dropout is defined as any participant who, after completing the baseline survey and receiving their randomization assignment, states that s/he wants to withdraw from the study and receive no further contact from the study team. If this occurs within two (2) months of the date of randomization, we will attempt to recruit an additional patient from the same practice.

For Outcomes data obtained from the EMR: We reviewed the data from one of our previous trials (Project ReD CHiP) (period 10/1/2010 to 10/31/2012) to estimate the percent of patients with uncontrolled blood pressure (BP) who had a follow-up visit within 13 months (to allow a one-month time window for those with annual follow-up), as well as the frequency of follow-up visits and time between the index measure (with uncontrolled BP) and the first follow-up. We found that 87.7% of the uncontrolled patients had follow-up BP recorded within 13 months. We did not check that these were established patients or that they had a PCP. Therefore, our biostatistician considered this a conservative estimate for loss to follow up: Patients willing to consent, who have a PCP, and who are not planning on leaving the clinic or moving will likely be more engaged.

Additional steps we will take to limit loss to follow-up include explaining the amount of time and type of commitments in participating in both arms, during recruitment, so that potential participants are aware of what is expected of them before they agree to participate.

We are following-up with our participants extensively.

- We are mailing letters ahead of our calls to alert them of the upcoming phone call.
- In both arms, we make a minimum of six phone call attempts to reach participant at each survey point.
- We generate weekly follow-up priority reports for data collectors to use when attempting to follow-up with patients for 6-, 12-, 18-, and 24-month surveys. These reports prioritize calling patients based on the following criteria: 1) the patient's follow-up window is closing within 6 weeks, 2) data collectors have attempted to call the patient less than 5 times, and 3) the patient has reached their follow-up due date. We send "unable to reach" letters, on a weekly basis, to patients who meet either of the following criteria: 1) the first follow-up attempt fails (failure is defined as any outcome other than contact with patient leaving a voicemail) or 2) after the data

collector leaves two consecutive voicemails. The letters request updated contact information from patients and include a pre-stamped return envelope.

- We request contact information on two persons who do not live with the patient in case the patient moves and their phone number is no longer valid. We will attempt to contact patients' alternative contacts either after the second follow-up call attempt fails or after leaving voicemails on four consecutive follow-up call attempts.
- If a participant expresses concerns about remaining a part of the study, we will discuss the concerns with the participant and attempt to resolve any barriers to their completion.
- We train interviewers on common concerns, and in staff meetings, we will review new issues that emerge.
- In the intensive intervention arm, part of the care manager's responsibilities is regular contact with the patient participants. The care manager will make numerous efforts to reach out to the participants between scheduled visits with the physician.
- If appropriate, the intensive intervention patients are assigned a community health worker to help resolve non-health related barriers to care (transportation, child care, etc.). The specific types of outreach are detailed in the care manager and CHW protocols.

As stated above, we will use observed likelihood based mixed-effects models to conduct multiple imputation for missing data. We will use robust estimates to account for statistical uncertainty. We are not using single imputation methods such as last observation carried forward.

Section 9: Quality Control and Quality Assurance

1. **Monitoring and quality control methods**: We developed process measures to monitor the uptake and quality of recruitment of study participants and fidelity to intervention components.
    a. First, together with our team of investigators, we developed a Manual of Procedures (MOP) to operationalize the study protocol, documenting procedures for screening, recruitment, and enrollment in the study and the staff roles to accomplish these tasks.
    b. During screening and recruitment, each potentially eligible patient is documented using a case report form, entered into a relational database, and tracked weekly as part of investigative research meetings to monitor the successful achievement of recruitment targets. Additionally, we monitor patient refusals to participate in order to identify any potential need for additional training of staff engaged in recruitment.
    c. To monitor the interventions, we are collecting implementation process measures. In the CC/Stepped Care intervention group, we are asking the CM to keep a log of collaborative care team communication, number of patients stepped up/referred to CHW and/or subspecialist consultation, and the categories of clinical and social issues discussed for each patient. We have prepared a meeting template form with fields that can be queried to generate reports.
    d. Use of web-based training is tracked using passive surveillance.
    e. In the CC/Stepped Care intervention group, we are asking the CHW to keep a log of collaborative care team communication, the categories of clinical and social issues discussed for each patient.
    f. We are monitoring fidelity across the interventions.
    g. For patients in the CC/Stepped Care arm, we ask each CM and CHW to obtain permission from patients to audio-record their sessions. Each CM audio-records a baseline visit, and two follow-up visits (one within the first three months of the program and one upon conclusion of the program). CMs record a different patient at each time point. Each CHW audio-records a baseline CHW visit, and two follow-up visits. CHWs record the same five patients at up to three

different time points. Members of the study team review these recording for quality assurance and training purposes.

h. CHWs are also asked to keep a brief log of contacts for each patient, including the length and location of the contact and topics discussed. Logs will be kept brief in order to minimize CHW burden and to retain the focus on delivery of care. We have used similar methods in our previous research and have found them to be acceptable and valuable to the research team in understanding the need for further communication with practices or training of interventionists.

B. **Fidelity Evaluation of Care Managers and Community Health Workers**

a. The goal of assessing fidelity for the CMs and CHWs is to monitor the *quality* of intervention delivery, which is a function of the CMs and CHWs, and the extent of patients' *receipt* of the interventions. These evaluations will support ongoing training and quality improvement efforts. We will do a pre/post initial training assessment of preparedness and confidence to carry out the actions in the study protocol. We will also reassess these ratings at 12 and 24 months. We audio record (with patient permission) three different patient visits with each CM, with one recording occurring at the FIV and two recordings occurring at a follow-up visit. We audio record (with patient permission) fifteen visits per CHW, with five audio recordings at CHW baseline and ten recordings occurring at follow-up visits, for review by members of the study team. We employ a checklist to determine whether or not key facets of the CM and CHW interventions were performed. CMs and CHWs are asked to document activities undertaken for each patient in a brief log containing such information as contact duration, contact location (face-to-face, telephonic, etc.), and the topics discussed related to the patient activation and self-management protocol. Logs are brief in order to minimize staff and provider burden and to retain the focus on delivery of care. When we consent patients to participate in the study, we notify them that a few of the sessions with the care manager and CHW may be recorded for quality assurance. CMs and CHWs also obtain written or oral consent (in the case of telephone encounters) from patients prior to audio recording patients.

b. Qualitative Process Evaluation: Glasgow *et al.'s* RE-AIM framework[166] will serve as a heuristic model for qualitatively appraising the attitudes, beliefs, and observations of CMs and CHWs in our trial. Briefly, the RE-AIM model asserts that an intervention's public health impact is a function of its reach, efficacy, adoption, implementation, and maintenance. As the primary interventionists in our trial, CMs and CHWs are well-positioned to elucidate the constellation of barriers and facilitators to implementing patient- and provider-level interventions in support of patients' chronic disease self-management. We will conduct informal, voluntary focus groups or directed interviews with CMs and CHWs at the end of the study. Our interview guide will comprise open-ended questions soliciting, amongst other possible domains, their perceptions of issues related to patients' readiness to change; social determinants of health and their subsequent impact on health-seeking behaviors; the impact of the overarching program on practice site operations relative to patients' BP management; the contextual factors affecting adoption of hypertension-focused workflows; the experience of implementing protocols and interventions; and beliefs regarding the long-term effects of the interventions on patients' well-being. We will obtain patients' perceptions about involvement in the study by incorporating open-ended questions at the end of each survey (at 12 and 24 months). These questions will ask patients about their experiences with their CM and CHW. We also inquire on the consent form whether patients are willing to be re-contacted after the 24-month interview, provided that we identify the need for additional patient feedback regarding the interventions and we have the resources to complete a small number of focus groups or in-depth interviews.

c. **Pre/Post Knowledge and Skill Assessment:** We administered a pre-test prior to the commencement of training, and a post-test at its completion. This will allow us to appraise CMs' and CHWs' existing skills and knowledge and to evaluate the extent to which they acquired new skills as a result of our training.

C. Establishment of Oversight:

a. We will continue to work closely with the NIH-appointed Data and Safety Monitoring Board (DSMB) that oversees the study from design through implementation. We have budgeted funds for the co-PIs and an un-blinded statistician to travel to one, face-to-face, 2-day DSMB meeting in Washington D.C. each year of the grant. We report any protocol violations and adverse events to them.
b. The Johns Hopkins Medicine IRB oversees this trial. We have obtained approval of our study protocol, consent forms, and HIPAA waivers from the IRB, and will continue to submit revisions to them as needed. We also report any protocol violations and adverse events to them.
c. The trial has been registered at ClinicalTrials.gov. (ClinicalTrials.gov Identifier: NCT01566864)
d. Finally, we will continue to work closely with the NIH-selected Steering and Protocol Review Committees to elicit their guidance for study conduct.

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics and Design

i. **Human Subjects Involvement**:

1. *Open "Town Hall" Meetings*: Two open town hall meetings will occur during Year 1, Quarter 4 (UH2 Period) and at during the last quarter of the study period. Approximately 150 stakeholders from participating health systems (clinicians, administrators, and patients), payer groups, professional organizations, public health agencies, faith community groups, community organizations, and local government will be invited to attend the town hall meetings.
2. *Practice Orientation Meetings*: Beginning in Year 2, Quarter 2, to coincide with the start of implementation, separate practice orientation meetings will be held for each practice site.
3. *Quarterly Stakeholder Community Advisory Board Meetings*: Stakeholders will continue to participate in quarterly in-person meetings/conference calls to discuss the planning, progression, and dissemination of the proposed research.
4. *Randomized trial*: The human subjects in this phase of the proposed research are 1,890 patients with hypertension (HTN) and associated comorbidities who receive their primary healthcare at partnering health systems, as well as the clinicians and staff of each practice and leadership of the systems to which the practices belong. The research will include an average of 63 patients at each of the 30 participating practices within these health systems. As our study design is a cluster randomization of practice sites, not participants, patients will be assigned to the study condition, SCP or CC/Stepped Care intervention arm, of the practice they attend for healthcare. Patients are surveyed prior to learning the random assignment of their practice and are given information on each condition and asked if they are willing to participate, given that they may end up in either condition. Clinicians and staff will be asked their opinions about their workplace and their satisfaction with the program. Leaders will be asked about the capacity and priorities of their systems.

b. Adequacy of Protection Against Risks and Potential Benefits

i. **Education in protection of human research participants**: Education in the protection of human research participants and good clinical practice has been met by certified completion of the Johns Hopkins University School of Medicine or School of Public Health Web-based Research Compliance course, "Human Subjects Research Training" by all relevant Key Personnel. The course consists of the University of Minnesota Web modules on Informed Consent, the Consent Process, and After Informed Consent, a Johns Hopkins University School of Medicine module on local IRB requirements, and achievement of a passing score on the Johns Hopkins Knowledge Assessment module. Training in the Health Insurance Portability and Accountability Act (HIPAA) has also been met by certified completion of the Johns Hopkins University School of Medicine's Web-based HIPAA training course.

ii. **Recruitment and Informed Consent**:

1. *Recruitment for Kick-Off/Town Hall Meetings*: Identified stakeholders in the proposed research are invited to attend town hall meetings by letter/email from the Principal Investigators (PIs). Letters are sent at least two months prior to meetings to allow adequate planning time for stakeholders.
2. *Consent for Kick-Off/Town Hall Meetings*: Stakeholders electing to attend town hall meetings are notified in the invitation that their choice to attend the meetings indicates consent to participate in the discussion of research activities.

3. *Recruitment for Practice Orientation Meetings*: The system-level champions in collaboration with the PIs and relevant research work group members draft and send a written and electronic invitation for the practice orientation meetings at the practices in their organizations. Potential participants will be notified of the meeting's date, time, and location with as much advance notice as possible to provide time for proper schedule planning.
4. *Consent for Practice Orientation Meetings*: Participants electing to attend orientation meetings are notified at the meeting that their choice to attend the meeting indicates consent to participate in the discussion and research activities.
5. *Patient Recruitment for Trial*: Patients who are age 21 years or older, receiving primary care at one of the 30 participating practices, have a diagnosis of HTN, and a systolic BP of greater than or equal to 140 mm Hg in the past 6 months, will be recruited for participation in the study. Eligible patients will also have at least one additional cardiovascular risk factor including: diagnosis of diabetes mellitus, hyperlipidemia, coronary heart disease, or depression; or current tobacco smoker. Patients meeting the above criteria will be excluded from the study if they meet any of the following exclusion criteria: serious medical condition which either limits life expectancy or requires active management (e.g., certain cancers), condition which interferes with outcome measurement (e.g., diagnosis of end stage renal disease or on dialysis), pregnant or planning a pregnancy during study period, alcohol or substance use disorder if not sober/abstinent for greater than or equal to 30 days, or planning to leave the practice or move out of geographic area within 24 months. Nursing mothers would need approval from a physician. The research team will identify a listing of patients meeting the inclusion and exclusion criteria at each of the practices in the quarter prior to intervention roll-out. We obtained a HIPAA waiver to screen the EMR for potentially eligible patients. We will mail our selected sample of patients a packet that includes a letter from the practice and the study principal investigators advising them that they are eligible to participate in the study, along with a brief brochure with the study eligibility criteria, objectives, what they would be asked to do as a study participant, a copy of the Oral Consent form, and information on how to contact the study recruiters by telephone. Packets will include a self-addressed refusal post card allowing contacted patients to decline participation. If the study coordinating center does not hear from the potential participant within 10 days, trained recruiters will attempt to contact them by telephone to assess their willingness to participate in the study and complete eligibility screening, oral consent, and a baseline telephone questionnaire using a standardized telephone script. Enrolled participants in the CC/Stepped Care intervention arm will then be scheduled for the First Intervention Visit by CMs, to occur within 14 days of recruitment, whenever possible. For the intensive intervention arm providers, the health system, practice, and administrative champions will assist the research manager in the recruitment of practice providers for participation in the quality improvement and disparities in care training and subsequent follow up webinars. The champions and research manager will notify the providers that they may elect to not participate in the training by not attending the training and subsequent webinars. Attendance to the training and webinars will serve as consent for participation in this part of the intervention.
6. *Consent for Trial Participants*: Trained recruiters at a study coordinating center will contact potential participants by telephone after 10 days from mailing of recruitment packet, to assess their willingness to participate in the study and complete eligibility screening and a baseline telephone questionnaire using a standardized telephone script and oral consent process. Patients will be told if they enroll in the study, we

will obtain data from their EMR and insurance claims for the purpose of monitoring their BP and other associated medical conditions (i.e. diabetes, hyperlipidemia, coronary heart disease, smoking status, and depression). They will also be informed that we will be asking them to complete several questionnaires via telephone interview at baseline, 6, 12, 18, and 24 months to obtain information about factors associated with their HTN and other conditions, as well as their experience in the clinical programs being tested in the trial. CMs and CHWs also ask patients to provide either written or oral consent (in the case of telephone encounters) before audio-recording patient encounters.

iii. **Protection Against Risk:** Risks and Benefits:

1. *Kick-Off/Town Hall Meetings*: The major risks for town hall meeting participants include loss of privacy or confidentiality. Meeting attendees are told they may refuse participation at any point in the study period. While meeting participants may not experience direct benefits, we inform participants that their engagement in the research process is part of a deliberate effort to improve patient care in primary settings and reduce disparity in healthcare access and outcomes.
2. *Randomized Trial*: The major risks for trial participants includes loss of privacy or confidentiality. Participants will be told that they may refuse to continue participating in the trial at any point during the study period. Participants in the SCP arm may benefit from improvement in organizational awareness of health disparities and barriers to care. We anticipate that participants in the CC/Stepped Care intervention arm will benefit both from the expanded health teams including access to subspecialists' care that was previously unavailable or difficult to obtain. We also anticipate that CC/Stepped Care intervention arm participants who are stepped up to receive a CHW will benefit from the additional support at home, opportunities to include family members and caregivers in interactions with CHWs, and navigation support for health, social services and other community-based resources. Those stepped up to subspecialist consultation will benefit from the added insight among providers in caring for complex, multi-morbid patients. Participants in the CC/Stepped Care intervention arm will receive a home BP monitor. Additionally all patient participants will be compensated for follow up interviews – $25 per interview at baseline, 12 and 24 months, and $10 for adverse events brief surveys at 6 and 18 months.

iv. **Protection Against Risk:** Procedures for Minimizing Risk:

1. *Kick-Off/Town Hall Meeting*: Specifics of participants' engagement, including expressed opinions, will not be reported to employers, families, clinicians, or any other party without participants' permission, and then only in aggregate.
2. *Randomized Trial*: For study participants, phone contacts to locate the study participant will not suggest the content of the study. All study data will be stored in locked filed cabinets and secure desktop or encrypted laptop computers at Johns Hopkins or in study assigned locked filing cabinets at the participating practice sites. Personal identifiers will be removed as soon as possible. Audiotape data will be transferred onto a secured server for coding purposes, and will be stored in locked files after identifiers are removed. A code key will be kept in a separate location. For trial participants, none of the participant information will be released to patients' families, employers, health care organizations or any other party without participants' permission.

c. **Potential Risks versus Anticipated Benefits:** Patients who participate in this study should not have any negative changes in the medical care they receive. By participating in this study, participants may not experience any direct benefits, but they will be told that they are helping us

to develop ways to improve BP control and care of diabetes, heart disease, high cholesterol, depression, and smoking, and improve cardiovascular health outcomes in patients. Patients in the CC/Stepped Care intervention arm may benefit from interactions with the expanded care team of the Collaborative Care model, including access to a CHW and subspecialist consultation.

d. **Importance of Knowledge to be Gained**:
   i. Cardiovascular disease (CVD) remains the leading cause of death in the US responsible for 1 in every 4 deaths in US.[1] Disparities in CVD risk factors are well documented even among patients seen regularly in the healthcare system. For example, the prevalence of HTN in African Americans is among the highest in the world.[6] Other groups, such as Hispanics and American Indians, also suffer disproportionately from HTN in addition to other CVD-risk factors, such as diabetes.[2,22] This study aims to determine if a clinic-based collaborative care team, including a stepped care approach to either subspecialist consultation, a CHW to deliver community based contextualized care, or both, reduces disparities in BP control rates, lowers CVD risk, and improves outcomes among patients with HTN and other common comorbid conditions when compared to standard of care health system approaches to CVD risk management, including audit and feedback and staff and provider training.
   ii. The risk to human subjects in this study is minimal with the major risk being loss of privacy and/or confidentiality. The ratio of low patient risk to anticipated knowledge to be gained about reduction of health care disparities is reasonable.

B. **Inclusion of Women and Minorities:** Women and minority patients are included in this study; women at the natural rate of their occurrence in the hypertensive population and minorities at a rate greater than their natural rate in the hypertensive population. This protocol focuses upon racial disparities in the practice and health system levels. African Americans and other minorities are more likely to have uncontrolled HTN. This study seeks to understand if a CC team model, including a CHW and subspecialty consultation (as needed) reduces disparities in BP control through locally tailored programs. Depending on the number of eligible patients at each site, we will use a sampling strategy to select adequate numbers of African Americans, Hispanics, and non-Hispanic white patients. We anticipate that African Americans and Hispanics will comprise at least 60% and women will comprise at least 50% of patient participants.

C. **Inclusion of Children**: Individuals under the age of 21 are not included in this study. This is an intervention study that focuses on practice and patient level interventions and the inclusion of community outreach to improve BP control and reduce disparities in adults. HTN and commonly occurring co-morbidities are much less common in those under the age of 21 and their self-management promotion and medication regimens would be different from the algorithms in our proposed study. Additionally, factors associated with behavior change in children are likely somewhat different than those for adults with HTN.

Section 11: Data Handling and Recordkeeping

A. **Data Handling and Recordkeeping:** Our statistician's computer is managed by the systems manager at the Johns Hopkins Institute for Clinical and Translational Research and all data are stored on a file server on the JHMI network. The server is in a secure room with controlled access, and is managed by trained staff familiar with Hopkins IT standards and practices. The server is actively monitored and access is controlled by enterprise directory so that only the authorized individuals have access. Server configuration and management follow a build and/or configuration checklist, reflecting systems administration best practices. Server backup is automated with appropriate security. The IRB protocol includes safeguards to assure the participant confidentiality in regard to all study data, including use of code numbers, not names, to identify the digital audio files, storage of digital files in a restricted, password protected study share drives and use of tablets and computers that are password protected. Any reference to names or other identifiers will be deleted from study records and will not include participant names. Access to the digital files is limited to study investigators and coders. All study personnel will have current CITI, HIPAA and COI training in human subjects protection.

B. **Data Sharing Plan and Reproducibility of Research:** After the end of the final year of funding, the biostatistician/data analyst will begin preparing a cleaned, de-identified copy of the dataset that was used in analyzing the primary outcomes of the study. First, all direct identifiers (based on HIPAA guidelines) linking variables and participants will be removed. Specific dates, such as date of birth and dates of visit, will also be removed and instead calculated variables, i.e., age, time from baseline, will be included. Variables that can be linked to an external source will also be removed. Data will be re-sorted from the original file, and new ID numbers will be assigned. The extreme values of some variables, e.g., age, BP measures, may be grouped to protect against de-identification. The dataset will be as complete as possible, while maintaining de-identification. Specifically, it may not be possible to include a variable for the practice networks because that would increase the likelihood of being able to identify specific practices, which with only approximately 60 patients enrolled at each practice, would allow for identification of specific patients based on a combination of variables, i.e., age, race, sex, diagnoses. Once the de-identified dataset is prepared it will be uploaded to an appropriate file sharing archive, such as clinicaltrials.gov.

C. **Describe the ability to reproduce potentially important findings from this research in other data sets and populations.** To ensure the generalizability of our results, we selected a large number of practices (30) in several practice networks to get a representative set of practices serving diverse populations. Practices included represent FQHCs as well as nonprofit practice networks serving higher income brackets. Our focus on disparities in CVD care requires that we work in an area with a large number of African-American and Hispanic residents in order to be able to create statistically valid comparisons by race/ethnicity. During the proposal process we went to great lengths to interview, survey, and meet with practice sites with different patient populations, and with representatives of the community and of community support agencies. We convened large groups of clinician researchers and methodologists with patient and community representatives to define the desired intervention and the methods for testing it. We believe this will render the intervention more sustainable in the real world and increase its ability to be reproduced in other settings.

Section 12: Publication Policy

We anticipate submission of at least three manuscripts related to this project, reporting: the methods of the intervention (end year 1), preliminary results (in year 4), and final results (end year 5). However, given the scope of the project, we will most likely complete several additional manuscripts. To promote replication of our intervention elsewhere and to better serve the broader population of hypertensive patients, we will make all informational materials, content, and tools produced as part of this project available to other practice networks and practices. We will also be available to consult for the implementation of this intervention upon request. Overall responsibility for manuscript and abstract generation and approval for the study should be guided by the following authorship principles.

A. **General:** Voting members of the **Publications Committee** will consist of the PIs of the study, Lisa Cooper and Jill Marsteller, who will also serve as Co-Chairs of the Publications Committee. In addition, other members of the study's Oversight Committee: Carmen Alvarez, PhD, RN; Lee Bone, RN, MPH; Romsai Boonyasai, MD, MPH; Kathryn Carson, ScM; Deidra Crews, MD, ScM; Cheryl Dennison-Himmelfarb, PhD, RN; Katie Dietz, MPH; Debra Hickman, MDiv; Chidinma Ibe, PhD; Lisa Lubomski, PhD; Edgar R. Miller, MD, PhD; Kristina Weeks, MHS; and Hsin-Chieh Yeh, PhD; will be invited to participate in the Committee for discussions of projects related to their particular workgroups. The Publications Committee will also consist of ad-hoc members who will assist with review and approval of publications. Permanent members will select ad-hoc members on a publication-by-publication basis.

B. **Principles of Disclosure and Confidentiality:** During the conduct of the research project and analyses associated with the research project, information and documents are generated that the researchers may consider confidential. Examples of such information include protected health information, intellectual property regarding conceptualization of the research design and approach to analyses as well as execution of analysis, discussion of the interpretation of results of analyses, written discussion about the content of a manuscript or publication and the manuscript or publication in its various drafts. The research group will be guided by the following principles:
    a. The research activities will be guided by a **principle of confidentiality** whereby ideas, concepts, and products developed by the research group will not be used by individual group members or shared with persons outside the group without express approval of the group;
    b. A **principle of openness among study team members** will underlie all research activities. Such openness will be protected by the principle of confidentiality;
    c. Members of the research group will disclose participation in research studies for which similar analyses are being conducted to the Co-Chairs of the publications committee;
    d. Members of the research group will take credit only for work they have actually performed or to which they have substantially contributed to the concept, design, or execution of the analyses.

C. **Types of Publications:** There are several types of publications and presentations for which approval procedures are established. These include:
    a. Major descriptions of the design and conduct of the study.
    b. Major descriptions of results addressing the main objectives of the study.
    c. Descriptions of results addressing issues other than the main objectives of the study.
    d. Descriptions of methodological developments required to meet the needs of the study.
    e. Articles to appear in proceedings of meetings for which no abstract was required.
    f. Invited presentations for which no abstract is submitted and for which there are to be no published proceedings.

g. Peer-reviewed abstracts to be presented at professional meetings, regardless of whether or not they are to be published.
h. Perspectives articles closely related to main objectives of the study.
i. Press releases or discussions with the media.
j. Lectures or other informal presentations.

The Publications Committee is responsible for resolving any uncertainties as to which category a specific presentation or publication belongs.

D. **Outline of the Preparation and Approval Process:** The basic steps for the generation and approval of publications and presentations are listed below:
   a. The lead author of the writing group or the Publications Committee designates a topic.
   b. The writing group prepares specifications for the manuscript and submits the publication form to the Communications/Publications Manager where the information will be logged and tracked. One of the co-chairs will be designated as the lead for the paper proposal.
   c. The Publications Committee will review the proposed specification for the publication, and give feedback before the writing group begins the draft.
   d. The writing group submits the completed draft publication to the Chair for review and approval.
   e. The Chair will submit the draft publication to the Publications Committee for review and for a 10-day review period.
   f. The manuscript is formally submitted to a journal or abstract selection process.

E. **Authorship, Inclusions, and Acknowledgements**
   a. All authors must make substantive contributions to the study and the writing of the abstract/manuscript to be named as an author.
   b. The person who assumed the lead responsibility for a particular publication or presentation is to be listed as the first author or preparer.
   c. The first author will indicate the likely authorship team during the proposal stage and can amend authorship near the end of the editing process. Conflicts or disputes that occur with respect to appropriate recognition of authorship will be handled using a staged process:
      i. As a first step, the conflict or dispute will be raised internally with the lead author and senior author for discussion.
      ii. If the group is unable to resolve the conflict or dispute, the matter will be discussed with the designated Publications Committee Chair for resolution.
      iii. The Chair will forward the outcomes of conflicts/disputes to the Publications Committee as they occur.
   d. Authorship on an abstract does not pre-determine authorship and authorship order on subsequent manuscript which will be based on contribution to the development of the manuscript.
   e. The phrase "**the RICH LIFE Project**" is to be included in the title and listed as a "key word" whenever possible.
   f. In all manuscripts, the following **acknowledgements** will be included:
      i. *Funding:* Research in this publication was supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health and the Patient-Centered Outcomes Research Institute (PCORI) under award number 1UH2/UH3HL130688. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the Patient-Centered Research Outcomes Institute.

ii. The Johns Hopkins School of Medicine Institutional Review Board has approved all study procedures [Protocol #CIR00025118/ IRB00085630]. The study is registered with clinicaltrials.gov [NCT01566864].
iii. The authors express their gratitude to the physicians, nurses, medical assistants, staff and patients of our partner health systems.
iv. All CAB members will be named in alphabetical order and acknowledged for their service on the Community Advisory Board.

G. Manuscript and Abstract Generation: Individuals interested in preparing a manuscript or abstract on a specific topic must **submit their proposal**, which should include suggestions for writing group members, to the Publications Committee for approval. The proposal must include a clear statement of the nature of the publication, and should, if appropriate, also include the hypotheses to be addressed and the types of statistical computations or data summarizations likely to be required, including the study variables to be used in the analyses. The Publications Committee has the responsibility for reviewing these proposals, both for appropriateness and for a priority designation. The Publications Committee also ensures that the different participating groups are appropriately represented and that appropriate recognition is provided.

H. Approval Procedures: A publication stemming from the study is submitted to the designated Chair of the Publications Committee. The Chair will send copies of the submitted manuscripts to the members of the Publications Committee for their critique during a 10-day comment period. Upon receiving the comments from the Publications Committee, three courses of action are possible:

a. If there are no comments or suggestions, the publication will be returned to the writing group.
b. If the Chair deems the Committees' suggestions to be mainly editorial in nature, she may approve the publication with a note of "conditional approval" and request that the authors incorporate suggested changes to the final version for publication. No further action is needed from the Publications Committee; or
c. If, in the Chair's judgment, critiques entail substantive changes, the Chair will note that the manuscript is "deferred", indicating that further revisions are required, authors must respond to comments, point by point, and the revised manuscript must be further reviewed by the Publications Committee before approval is granted.

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