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 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.

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

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

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.

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.

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

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		