Pilot trial of a Community Health Worker Intervention to Improve Heart Failure Care in Rural Haiti

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1 List of Abbreviations

Abbreviation	Abbreviation definition
CFIR	Consolidated Framework for Implementation Research
CHW	Community Health Workers
CVD	Cardiovascular Disease
HF	Heart Failure
HUM	Hôpital-Universitaire de Mirebalais
KCCQ	Kansas City Cardiomyopathy Questionnaire
LMIC	Low-and-Middle-Income-Country
NCD	Noncommunicable Disease
NYHA Class	New York Heart Association Functional Classification
PIH	Partners In Health
ZL	Zanmi Lasante

2 Protocol Summary

Title:	Pilot trial of a Community Health Worker Intervention for Heart Failure Patients in Rural Haiti
Population:	This study will be conducted in rural Haiti. We will recruit 60 adult Heart Failure (HF) patients, age > 18 years, who live in the communes of Mirebalais, Boucan Carre, and Cange, Haiti, and either: 1. Were hospitalized >48 hours, discharged from HUM, without a prior clinic visit, 2. Are established patients with prior clinic visits at HUM Six experienced Community Health Workers (CHWs) who work in the Commune of Mirebalais, Belladere, and Cange will be recruited and trained to conduct the intervention.
Intervention:	A Community Health Worker intervention designed to improve linkage to care for HF patients in rural Haiti in the 30- and 90-days following discharge. We will compare linkage to care with a comparison group of patients retrospectively identified from the medical record. The comparison group will not receive any intervention.
Objectives:	The primary study objective is to assess the implementation of the CHW intervention through the following outcomes:

	acceptability, appropriateness, feasibility, fidelity of the intervention. The secondary study objective is to assess the effectiveness of the implementation in improving linkage to care, rates of retention and readmission, HF symptoms, and mortality rate.
Design/Methodology:	A reference group of 30 HF patients will be recruited and followed without participating in the intervention. Twelve experienced CHWs will be trained to conduct the linkage to care intervention. 30 additional HF patients will be recruited to participate in the linkage to care intervention and will participate in follow up visits and phone calls with the CHWs. Implementation and effectiveness outcomes will be assessed through EMR review, surveys, validated symptom-severity tools, and semi-structured interviews with patients, CHWs, and nurses/doctors.
Total Study Duration:	24 months
Subject Participation Duration:	3 months

3 Background/Rationale & Purpose

3.1 Background Information

Cardiovascular disease burden is growing in LMICs, with nearly 80% of all CVD deaths occurring in these settings (1). In Haiti, about 25% of all deaths are caused by CVD. Heart failure (HF) in particular accounts for 14% of all global disability adjusted life years due to CVD (2). In Haiti, HF is the leading cause of adult internal medicine hospitalizations, accounting for 20-40% of adult non-surgical admissions (3,4). While ischemic heart disease is the main cause of HF in high income countries, in LMIC the main causes are cardiomyopathy, rheumatic heart disease, and hypertension (3-5). HUM is a public-sector referral academic hospital in rural Haiti co-managed by the Ministry of Health and non-governmental organizations PIH and ZL. At 300 beds, HUM is the largest regional facility, providing primary care for 185,000 people and serving as a referral hospital for 3 million people. Preliminary studies show that 392 of 1049 (37%) of internal medicine hospitalizations over a 12-month period were for heart failure at HUM, with an additional 10-15 patients discharged directly from the emergency room to follow-up in outpatient clinic.

After acute hospitalizations, successful management of chronic heart failure requires linkage to outpatient care and retention along the care cascade. The care cascade is a useful conceptualization of clinical processes necessary to achieve desired clinical outcomes, and has been used in HIV (6,7), diabetes (8), and rheumatic heart disease (9). Studies of HIV care adherence have shown that poor linkage to care is associated with poor treatment adherence, more complications, and increased mortality (7). Improving linkage to care can improve clinical outcomes. However, patients must make difficult choices when deciding about their health care, choosing between going to work or to the clinic, paying for medications or for food. Understanding barriers to linkage will help guide future interventions. This study will be conducted in compliance with the protocol, applicable regulatory requirements, and BMC /BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

Evidence-based interventions to improve linkage and outcomes for HF patients requires input from stakeholders: patients, CHWs, healthcare staff, and health system administrators.

Here we will assess a CHW intervention designed to improve linkage to care for HF patients. This intervention was systematically adapted for use in rural Haiti in a prior study using the ADAPT-ITT framework. The ADAPT-ITT framework provides 8 sequential phases to adapt interventions and programs to new target audiences: Assessment, Decisions, Administration, Production, Topical Experts, Integration, Training staff, Testing (10). The ADAPT-ITT framework has been applied successfully to the adaptation of several interventions for HIV among under-resourced communities leading to randomized clinical trials (10-14). With the first six steps of the ADAPT-ITT framework completed in a prior study, this protocol outlines the training and testing of the adapted CHW intervention.

In addition to assessing the feasibility, appropriateness, and acceptability of the adapted intervention through participants' feedback, we will assess its efficacy in improving HF outcomes. The proposed intervention is targeted at both the patient domain – through improved peer support – and health system domain – by improving health system navigation.

4 Objectives

4.1 Study Objectives

The primary study objective is to assess the implementation of the CHW intervention among key stakeholders including CHWs, HF patients, and healthcare providers at HUM. The outcomes and corresponding methods used to assess the primary study objective are as follows:

Primary Outcomes: implementation	**Definition**	**Method**

Acceptability	Perception among stakeholders that intervention is agreeable	• Semi-structured interviews (CHW, patients, administrators), • satisfaction survey (CHW, patients)
Appropriateness	Ability of intervention to meet local needs	• Semi-structured interviews (CHW, patients, administrators), • survey
Feasibility	Extent the intervention is able to be carried out	• Semi-structured interviews (CHW, patients)
Fidelity	Degree to which intervention components are implemented as intended	• Semi-structured interviews (CHW, patients), • CHW home visit checklist (CHW)

The secondary study objective is to assess the effectiveness of the CHW intervention in improving HF outcomes and linkage-to-care for patients in the 90 days following discharge.

Secondary Outcomes: effectiveness	**Definition**	**Method**
Linkage	30-day clinic visit attendance	EMR Review, follow up phone call, home visits
Retention	90-day clinic visit attendance	
Readmission	Rehospitalization	
Symptoms	Patient-reported symptoms	
Mortality	Death	

4.2 Study Outcome Measures

4.2.1 Primary Outcome Measures

Primary Outcomes: implementation	**Measure**
Acceptability	Acceptability of training, home visits, complexity, components, education delivered, self-care suggestions, job/decision aids by patients, CHWs, and nurses/doctors.
Appropriateness	Satisfaction that the innovation meets local needs, assessed in patients, CHWs, and nurses/doctors
Feasibility	Percent of CHWs invited to participate in intervention, start and complete training Number of patients eligible and consented to study
Fidelity	Qualitative rating for each component of the intervention

	Number of intervention components delivered, % of scheduled visits completed, % of visits completed with all home visit checklist items completed

4.2.2 Secondary Outcome Measures

Secondary Outcomes: effectiveness	**Measure**
Linkage	Percent of patients that complete 30 day follow up visit
Retention	Percent of patients that complete 90 day follow up visit
Readmission	Rate of rehospitalization at HUM or other facility measured over 90 days following discharge
Symptoms	NYHA class, EuroQol level, KCCQ score
Mortality	Mortality rate measured over 90 days following discharge

5 Study Design

This is a clinical trial involving the training of 6 CHWs in a linkage-to-care intervention and the testing of the intervention on 30 HF patients. In a prior study, the ADAPT-ITT framework was used to adapt a CHW-based intervention for post-discharge HF patients in Haiti. This study represents the last two phases of the ADAPT-ITT framework: Training and Testing.

The standard of care in Haiti at HUM for patients discharged with heart failure is to notify patients of a follow-up visit at the hospital/clinic – usually about 7 days after discharge. Patients are also given about 30 days of medications at discharge. It is entirely the patient's responsibility to return to the hospital/clinic for the follow-up appointments. If a patient does not return for a follow-up appointment, there are no systems to track this missed visit, or to trigger active attempts to contact patients. For patients who come back to their scheduled 7-day visit, there is generally a 14-day visit followed by a 28-day visit.

We will recruit 12 CHWs. These CHWs are existing staff members whose catchment areas are in communes of Mirebalais, Boucan Carre, and Cange. Participation in the study will include training to care for HF patients at discharge, agreement to perform the expected activities including home visit and phone calls to patients, and to participate in the post-intervention evaluation. Informed consent will be obtained from CHWs at the time of recruitment. The CHWs will be trained in the intervention. The study patient population will include adult HF patients (≥18 years of age), who live in the catchment areas of the trained CHWs, and are either (1) hospitalized for more than 48 hours, with anticipated discharge from HUM, within 1-3 days, or (2) are established patients with prior clinic visits at HUM. Patients will be recruited for study participation shortly before discharge. A historical reference group of 30 HF patients will be

identified and will not participate in the follow up care intervention. The reference group will be identified through review of the medical record. We will request a waiver of consent for to extract and analyze the medical records. All reference group participants will have been discharged from the hospital prior to the beginning of the intervention.

The intervention will include study visits in the form of home visits and phone calls performed by CHWs during which they will remind patients about upcoming visits, ensure patient has sufficient medications, review medication schedule and provide education as needed.

To assess acceptability, fidelity, and appropriateness of the intervention, a semi-structured group interview will be conducted with the 12 CHWs to assess their perceptions and experience in delivering the intervention. An additional group interview with 6 other stakeholders, including CHW nurse supervisors, clinic nurses, doctors, and administrators to assess the implementation from their perspectives. A satisfaction survey will be administered to CHWs, patients, and stakeholders to assess appropriateness of intervention.

Effectiveness of the intervention will be assessed through chart review and follow up visits and will follow rehospitalization, death, HF-related symptoms, and linkage to care.

6 Potential Risks and Benefits

6.1 Risks

There are minimal risks to participation in this study. Participants may experience mild anxiety during the interviews as they will be aware they are being recorded. We will be clear with the participants that they may refuse to answer any question or withdraw from the study at any time. Each patient will be assigned a unique patient identifier.

A breach of confidentiality is also a potential risk because the names of patients and CHWs will be used during the implementation interviews. We will protect confidentiality by storing all research-related data (audio recordings, transcripts, consent forms) in either a locked cabinet at the study site (paper documents) and a password protected folder on Boston Medical Center Box.com (digital data). All other clinical data will be recorded on paper forms, then entered into REDCap forms. REDCap is an online, encrypted, password protected, HIPAA-compliant secure database. Only the Haitian research team including the Haitian PI and research coordinator will have access to the master key. A coded dataset will be exported for statistical analysis.

6.2 Potential Benefits

Participants may directly benefit from the more intensive follow-up care provided by the CHWs during the intervention. The study results will also inform ongoing clinical activities and lead to future improvements in linkage to care, benefitting patients with similar conditions.

6.3 Analysis of Risks in Relation to Benefits

The risks of participation are minimal and temporary. Some participants may directly benefit. The findings will benefit science and future patients with similar conditions by leading to healthcare system improvements.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

Patient inclusion criteria:

- Adult HF patients (age ≥18 years)
- Living in communes of Mirebalais, Boucan Carre, and Cange
- And either
  - Hospitalized >48 hours at HUM
  - Anticipated discharged from HUM within 1-3 days
  - OR
  - Are established patients with prior clinic visits at HUM

Historical patient reference group inclusion criteria:

- Adult HF patients (age ≥18 years)
- Hospitalized >48 hours at HUM
- Discharged from HUM within the 12 months preceding the intervention
- Living in Mirebalais Commune

Community Health Worker inclusion criteria

- adults (≥18 years)
- working in Mirebalais

Healthcare staff (provider/administrator) inclusion criteria

- Hospital leadership involved in supervision of clinical care programs (i.e. Chief Executive Officer, Chief Medical Officer, Chief Operations Officer, Chief Nursing Officer, etc.)
- Leaders of the Community Health Department – including the nurse Director of Community Health, and Community Health Worker Supervisors.
- Healthcare providers at HUM involved in the care of patients with heart failure (i.e. internal medicine physicians, inpatient hospital nurses, outpatient clinic physicians, outpatient clinic nurses, etc.)

7.2 Subject Exclusion Criteria

None

8 Study Intervention

The study intervention is a follow up care program for Heart Failure patients carried out by trained Community Health Workers in rural Haiti. The intervention will begin upon discharge from HUM. Patients will first be assigned to a CHW living in their area. Within the first week after discharge, the CHW will perform 1 home visit and 1 phone call. During the home visit, CHWs will remind patients about upcoming visits, ensure patient has sufficient medications, review medication schedule and provide education. If a patient does not come to their regularly scheduled 1-week visit, the CHW will contact them again for a future visit. Home visits may take between 30-60 minutes and phone calls will be 5-10 minutes. CHWs will perform these activities to support linkage to clinic care for the first 30 days after hospital discharge.

9 Study Procedures

CHW Training

CHW nurse supervisors at ZL will train CHWs to conduct the intervention. Doctors and nurses who care for HF patients will also participate in the training of CHWs. CHWs are assigned to care for patients within their Communal Section. 12 total CHWs (out of the ~100 total CHWs) will be purposively selected for the pilot intervention: one from each Communal Section within the local HUM catchment area. Historically, about 1 day is needed to train CHWs in additional basic tasks. We will reimburse transportation expenses for training. The CHWs will receive printed visual job aids to use during home visits and home visit/phone call checklists to remind them of study activities.

Participant Recruitment

- Intervention Patient participants
    - 1. Hospitalized patients will be recruited by the research coordinator from the HUM wards. The research coordinator will work with treating clinicians to identify patients who meet the inclusion criteria, including those who are within a few days of discharge. The research coordinator will then review the medical record to assess if the patient is possibly eligible for the study – including reviewing address information to ensure the patient lives in the intervention areas. The treating clinician will then introduce the research coordinator. The research coordinator will then introduce the study to the patient and ensures the patient meets the inclusion criteria, including address. Informed consent is obtained at this stage. The data evaluated during the screening period will be retained only in Haiti. No data during the screening period will be transmitted to Boston University.
    - 2. Established patients with prior clinic visits will be recruited by the research coordinator from the HUM clinic. Clinic staff including nurses and doctors will notify the research coordinator of upcoming clinic appointments with patients.

The research coordinator will then review the medical record to assess if the patient is possibly eligible for the study – including reviewing address information to ensure the patient lives in the intervention areas. The treating clinician will then introduce the research coordinator. The research coordinator will then introduce the study to the patient and ensures the patient meets the inclusion criteria, including address. Informed consent is obtained at this stage. The data evaluated during the screening period will be retained only in Haiti. No data during the screening period will be transmitted to Boston University.

- Historical reference patient participants will be identified by retrospective review of routinely collected medical records.
- CHWs will be recruited purposively. We will work with the CHW supervisor to select CHWs who live in the communes of Mirebalais, Boucan Carre, and Cange. The CHW supervisor will suggest which CHWs to recruit. We will then review the study procedures and expectations with the CHW. If a CHW declines to participate, we will work with the CHW supervisor to suggest another CHW who lives in the same communal section.
- Healthcare staff. We will purposively approach the key healthcare providers and administrators listed in the inclusion criteria above to participate in this study. We will recruit staff after the intervention such that we can ask their opinions of the intervention implementation.

Consent Process

- Intervention Patient participants: During recruitment by the research coordinator in the hospital, informed consent will be obtained from the study participant. The objectives, activities, and risks of the study will be explained, using the informed consent form in Haitian Creole. The research coordinator is fluent in Haitian Creole. Participants will have up to 24 hours to decide about participation. Patients will be asked to sign the consent form. A blank copy will be given the patient. The signed copy will be stored at the study site in a locked cabinet.
- Historical reference patient participants: Waiver of informed consent. We will be reviewing existing medical records without direct contact with the study subject.
- CHWs: At the time of recruitment, informed consent will be obtained from the CHWs. This will be done at the hospital. Participants will have up to 24 hours to decide about participation. A blank copy will be given the CHW. The signed copy will be stored at the study site in a locked cabinet.
- Healthcare staff. At the time of recruitment, informed consent will be obtained from the healthcare staff by the research coordinator. This will be done at the hospital. Participants will have up to 24 hours to decide about participation. A blank copy will be given the healthcare staff member. The signed copy will be stored at the study site in a locked cabinet.

Intervention Implementation

Patients will be assessed for eligibility, recruited for study participation, and consented by study staff prior to discharge from HUM. Within 1-2 days of discharge, one of the 12 CHWs recruited for this study

is assigned to the HF patient based on the patient's address (communal section). This will be carried out by the NCD nurse after being notified by the internal medicine staff. If, after assignment to a CHW, a patient moves away from the communal section, they can be re-assigned to a different CHW if they are still in Mirebalais commune. If they move outside of Mirebalais commune, they will be withdrawn from the study.

At discharge, a follow up visit is scheduled in 7 days. Follow up visit date is communicated to the patient at the time of discharge. Patient will be given 30 days of medicines. The study visits are described below:

Visit Schedule	Type of Visit	Category of encounter	Content of Visit
Between discharge (day 0) and 7-day visit	Home visit by CHW	*Research Intervention (intervention group only)*	• Home visit will last about 1 hour • Education on medication adherence • Upcoming appointment reminder • Symptom counseling/assess for danger symptoms to watch for • Complete CHW task checklist
Day 6 (+/- 2 days)	Phone Call by CHW	*Research Intervention (intervention group only)*	• Phone call will last about 5-10 minutes • Appointment reminder • Complete CHW task checklist
Day 7 (-/+ 2 days)	Clinic visit by patient	*Clinical, routine care*	For patients who come to clinic on Day 7: • An evaluation is performed 7 days after discharge by an internist. • Patient is enrolled in the NCD program by the NCD Nurse: primarily those living in the Central Plateau and those living outside the ZL catchment area that refuse to be transferred to another non ZL facility • Next visit scheduled in 7 days (day 14 after discharge): ○ If patient is stable: next visit with NCD GP. ○ If patient not stable: next visit with HUM Internist
		Research Intervention (intervention group only)	For patients who do NOT come to clinic on Day 7: • NCD nurse schedules a visit for day 14 • NCD nurse notifies the CHW supervisor and assigned CHW of a missed visit and the new day 14 scheduled visit. • CHW does home visit with patient to notify them of 14-day visit by either phone call or home visit.

Day 14 (-/+ 2 days)	Clinic Visit by patient	*Clinical*	• Visit attendance • HF Symptoms • Vital Status
		Research Intervention (intervention group only)	For patients who do NOT come to clinic on Day 14: • NCD nurse schedules a visit for day 28 • NCD nurse notifies the CHW of a missed visit and the new day 28 scheduled visit. • CHW does home visit with patient to notify them of 28-day visit by either phone call or home visit.
Day 28 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	**1-month Clinic encounter** • Visit attendance • HF Symptoms • Vital Status
Between day 37 and 44	Home Visit or phone call by Research Assistant	*Research outcome assessment (both intervention and reference groups)*	**1-month Research encounter (about 1 hour)** • Satisfaction Survey • Acceptability interview • Vital Status • Assess whether patient attended another clinic for HF care • HF Symptoms • Assess for rehospitalization since last study visit • Semi-structured interview for appropriateness, acceptability, feasibility, fidelity
Day 60 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	• Visit attendance • HF Symptoms • Vital Status
Day 90 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	**3-month Clinic encounter** • Visit attendance • HF Symptoms • Vital Status
Between days 97-104 (-/+ 2 days)	Phone call or home visit by Research Assistant	*Research outcome assessment (both intervention and reference groups)*	**3-month Research Encounter (about 1 hour)** • Satisfaction Survey • Acceptability interview • Vital Status • Assess whether patient attended another clinic for HF care • HF Symptoms • Assess for rehospitalization since last study visit • Semi-structured interview for appropriateness, acceptability, feasibility, fidelity

Data Collection

From CHWs:

1. Home visit/phone call checklists: To be completed for all interactions between the CHW and intervention patients, and collected each month. Normally, all CHWs in general in the HUM catchment area meet during monthly meetings at HUM. At the monthly meetings, CHW supervisors collect monthly reports from the CHWs and provide ongoing refresher training, or training on new content as needed.
2. At the end of the intervention, a semi-structured group interview will be conducted with the 12 CHWs to assess their perceptions and experience in delivering the intervention. CHWs will be consented prior to the group interview.

From intervention participants:

1. About 1 month and 3 months after discharge, the research coordinator will contact patient by phone or by home visit. The research coordinator will administer a survey and semi-structured interview.

From Healthcare staff:

1. After the follow-up period of the last enrolled intervention participant, we will review results with HUM administrators and clinicians. An additional group interview with 6 other stakeholders, including CHW nurse supervisors, clinic nurses, doctors, and administrators to assess the implementation from their perspectives (Primary study outcome: Implementation) to understand suggested changes to the intervention and barriers to dissemination.

Comparison/Reference patient group

The comparison group will be assembled from a retrospective review of routinely collected medical records. We will seek to identify 30 patients who are also discharged with heart failure and live in the same catchment area (Mirebalais commune). We will select the 30 most recently discharged patients meeting the inclusion criteria. The comparison group patients will have participated in the routine clinic visits as above (days 7, 14, and 28 after discharge) but will not receive the home visits or phone calls performed by the CHWs for the intervention group. This study does not involve the collection of biological specimens, alterations to clinical care, or additional laboratory or clinical procedures. We will identify patients from the EMR based on the inclusion criteria including the discharge diagnosis and address. We will also extract the dates of hospital discharge and dates of the first follow-up clinic visit.

Total study duration is 24 months including results analysis and manuscript preparation; and study participation for subjects is approximately 104 days (3 months + 2 weeks). See the Appendix for the schedule of events.

10 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject related to the risks of the study, including anxiety/discomfort about having home visits/phone calls, or concern about confidentiality temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

10.2 Safety Review

Both the risks listed in Section 4.1 and unknown risks will be monitored as follows:

On a weekly basis, study staff will assess for missing data, interruptions to clinical follow up care, and threats to patient privacy and confidentiality. Iterative changes will be made to minimize interruptions in clinical care, such as finding better times for survey administration. The coinvestigators will be asked about potential interruptions to care or breaches to privacy or confidentiality at regular study meetings. Adverse Events that occur during the study period will be assessed by investigators within 72 hours.

10.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus involving a fatal or life-threatening event will be reported to the IRB within 2 days of the investigator learning of the event.
- Unanticipated Problems occurring at BMC/BU Medical Campus not involving a fatal or life-threatening event will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

10.4 Stopping Rules

This study has no stopping rules.

11 Data Handling and Record Keeping

11.1 Confidentiality

This study involves an intervention where CHWs directly contact patients at their home. To facilitate these home visits, PHI will be collected and communicated to members of the intervention and study team including name, address, and phone number. Further data on the

implementation (intervention components achieved) and effectiveness (follow-up in clinic) will also be collected on paper CRFs. We will calculate derived variables from some of the PHI (such as length of stay, and # of days from hospital discharge to 1st clinic visit). The data from paper CRFs will subsequently be entered into REDCap.

At the end of data collection (after all 90-day follow-up data has been collected), a master-code will be created and separated from the rest of the analytic research data.

The mastercode will include:

- name: first, last
- date of birth
- medical record number
- telephone number
- address (locality/neighborhood – the smallest geographic unit)
- dates of hospital admission and discharge
- dates of clinic visits

Other PHI that will remain in the analytic dataset includes:

- address (communal section), for aggregate mapping

Data derived from PHI that will remain in the analytic dataset includes:

- Length of hospital stay
- # of days from discharge to 1st clinic visit

The master-code will be kept on hardcopy paper records, and within REDCap. Master-code information will be entered onto a separate data collection form in REDCap from other data. Only the PI (Dr. Kwan at BMC), and Haitian research team including the research coordinator and Haitian study co-PI (Dr. Darius Fenelon), will have access to the master key. Identifiable health information will be brought to Boston Medical Center in the United States for enrolled participants.

A coded analytic dataset will be exported for statistical analysis and will be available to other members of the BMC/BU study team. Other BMC research team members will not have access to the master-code.

Paper CRF will be stored in a locked cabinet at the study site. Coded data will be exported for analysis. The master-code will not be shared with BMC staff except for the PI Dr. Kwan.

Audio recordings will be coded with the Study ID and stored separately from the master-code. Audio recording devices and digital audio recordings will be first stored on an encrypted hard drive in a locked cabinet at the study site. Notes taken during the meetings and interviews will be recorded on the paper interview guides and stored in the locked cabinet. Audio recordings

will be uploaded to BMC Box.com for sharing with the third-party vendor for transcription/translation into English.

This study will be registered on ClinicalTrials.gov.

11.2 Source Documents

- Audio recordings – digital audio recordings will be stored on an encrypted hard drive, stored in a locked cabinet at the study site.
- Hospital paper charts – stored in medical ward and the archives room at the hospital and are pulled by trained archivists. Paper records will be reviewed by research staff in the central archives to allow for extraction of necessary data.
- Electronic medical records – access is restricted only to hospital staff using a unique login and password.
- Data generated by the methods described in the protocol will be recorded directly into the REDCap database. Paper hardcopy data collection forms will be stored in a locked cabinet accessible only to research team in Haiti.
- CHW paper data collection forms - CHW demographics, address to the level of the communal section, and work experience, intervention acceptability and satisfaction surveys. Data will be entered into REDCap. Paper hardcopy data collection forms will be stored in a locked cabinet accessible only to research team in Haiti.
- Patient paper data - patient demographics, address to the level of the communal section, clinical information, socioeconomic status, intervention acceptability and satisfaction surveys
- Web-conference recordings - stored on Boston Medical Center Box.com

11.3 Case Report Forms

Multiple case report forms (CRF) will serve as primary data collection instruments for the study. All data requested on the CRF will be recorded. All missing data will be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, “N/D” will be written. If the item is not applicable to the individual case, “N/A” will be written. All entries will be printed legibly in black ink. If any entry error has been made, to correct such an error, a single straight line will be drawn through the incorrect entry and the correct data will be entered above it. All such changes will be initialed and dated. There will be no erasures or white-out on CRFs. For clarification of illegible or uncertain entries, the clarification will be printed above the item, then initialed and dated. The following source data will be recorded directly on the CRFs:

- Training records:
    - Feasibility: number of CHWs recruited and trained. Some who are initially recruited may decline participation.
- Enrollment records:
    - Feasibility:
        - Number of patients enrolled who are matched with a CHW
        - Number of patients not matched to a CHW.
        - Number of patients who drop out of study before CHW visit
- Satisfaction Survey (Source: HF patients, CHWs, nurses/doctors)
    - Acceptability of intervention: acceptability of home visits, complexity, components, education received, self-care instructions, suggestions, job/decision aids
    - Appropriateness: satisfaction
- CHW Home Visit Checklist (Source: CHW Home Visit)
    - Fidelity: Did CHW perform components of intervention
- Follow Up CRF (Source: EMR, Clinic follow up visits)
    - Linkage: did patient complete 30-day clinic visit
    - Retention: did patient complete 90-day clinic visit
    - Readmission within 90 days of discharge
    - Symptoms: NYHA class, EuroQol level, KCCQ score
    - Mortality within 90 days of discharge

See the Appendix for the following CRFs: Patient CRF, CHW Home Visit Checklist, Interview guides

11.4 Study Records Retention

- Informed consent: Paper copies of study documents will be kept at the study site until the completion of the study. The paper copies will be scanned and stored electronically on the encrypted study hard drive and kept for at least 7 years. The paper copies will be destroyed at the completion of the study. Paper copies include signed informed consent forms as well as interview guides and notes
- Audio recordings: Electronic audio recordings will be stored on the encrypted study hard drive and kept for at least 7 years.
- Audio transcripts: Creole and English transcriptions of the audio recordings will be stored on the encrypted study hard drive and kept for at least 7 years.
- REDCap database: Electronic data in the database will be kept within REDCap for at least 7 years. Any data exports will be stored on the encrypted study hard drive and kept for at least 7 years.
- Master-code: will be destroyed 7 years after study completion.

12 Statistical Plan

12.1 Study Hypotheses

Implementation Hypothesis: the CHW intervention will be found acceptable, appropriate, feasible, and able to be implemented as intended when assessed by key stakeholders including CHWs, HF patients, nurses, and doctors.

Effectiveness Hypothesis: the CHW intervention will improve linkage to care, retention in follow up care, rates of readmission, recognition of HF-related symptoms, and mortality within 90 days of discharge.

12.2 Sample Size Determination

We will enroll a total of 78 participants (30 patient for the intervention, 30 patients in the historical reference group, 12 CHWs, 6 healthcare administrators)

A sample size of 30 HF patients will allow for identification of at least 97% of implementation issues (15). Even with significant dropout, 95% of implementation problems will still be identified with only 20 patients.

Effectiveness will be assessed relative to the reference group. By design, this pilot trial is not powered for effectiveness (16). The effect size will inform sample size calculations when designing a future effectiveness trial.

12.3 Statistical Methods

Recordings of the semi-structured interviews conducted with patients, CHWs, nurses, and doctors will be transcribed and translated. Analysis of the transcribed group interview data will be performed to identify themes and content. (17-19) Open coding will be used to elucidate emergent themes (17-19) in addition to predefined-codes adapted from the Consolidated Framework for Implementation Research (CFIR) patient, environment, and health system domains. (20) CFIR is a meta-theoretical framework that standardizes implementation determinants. CFIR has been used in studies from patient, provider, and system perspectives in diverse settings including Haiti. (21) Patient factors include limited time to attend clinic, low income, food insecurity, poor social support, and cultural norms. (22-25) Environment factors include transport cost. (26) Health system factors include negative experience at hospitals, medicine costs, and complex systems.

Two independent coders will assign codes to transcripts, compare results, and reconcile discrepancies through consensus with a third coder when needed. The analysis will be assisted by NVivo analytic software (QSR International, Australia), enabling aggregation of code frequency, data analysis by code segments, and creation of code matrices. Signal strength can

be quantified and also corroborated by representative narratives. Findings will be reported using the 32-item Consolidated Criteria for Reporting Qualitative Research structure (27).

This implementation trial is not powered for effectiveness but will use effect size to inform sample size of a future effectiveness study. Effectiveness outcomes shown in include 30-day linkage, 90-day retention, symptoms by NYHA Class, quality of life with EuroQol-5D (license obtained for Creole version) and Kansas City Cardiomyopathy Questionnaire (license obtained), 30- and 90-day rehospitalization, and death at 90-days. Research staff and CHWs will assess the outcomes by EMR review, phone calls, or home visit for both the pilot and reference groups. Data will be summarized using tabulation, graphical displays, and descriptive statistics including 95% confidence intervals without hypothesis testing.

13 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

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Appendix

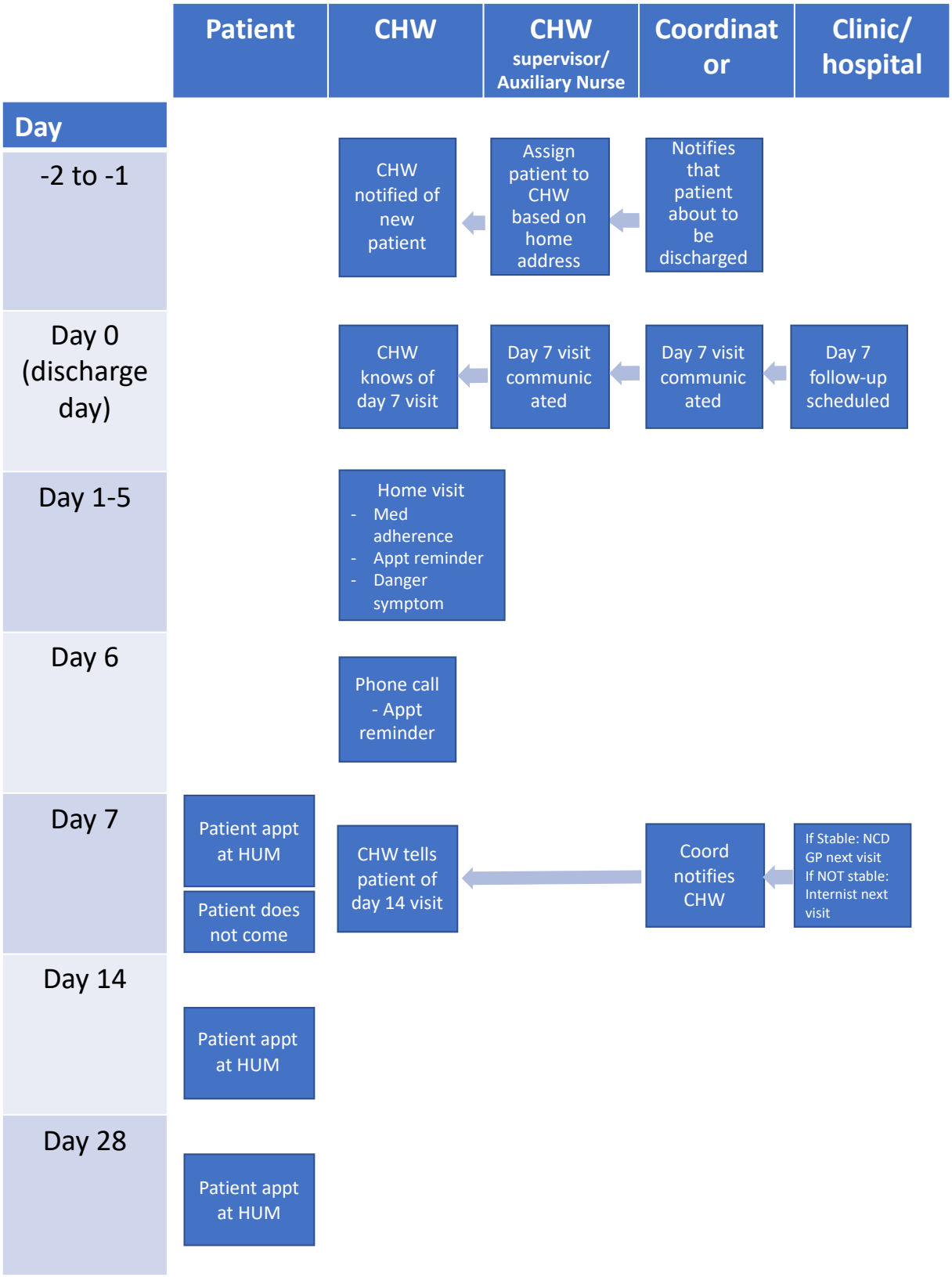
A. SCHEDULE OF EVENTS
B. SCHEMATIC OF INTERVENTION DESIGN
C. DATA COLLECTION TOOLS
D. PATIENT SATISFACTION QUESTIONNAIRE
E. DRAFT INDIVIDUAL INTERVIEW DISCUSSION GUIDE – PATIENT
F. DRAFT GROUP INTERVIEW DISCUSSION GUIDE – CHW
G. DRAFT GROUP INTERVIEW DISCUSSION GUIDE – HEALTHCARE ADMINISTRATORS

A. SCHEDULE OF EVENTS

Visit Schedule	Type of Visit	Category of encounter	Content of Visit
Between discharge (day 0) and 7-day visit	Home visit by CHW	*Research Intervention (intervention group only)*	• Home visit will last about 1 hour • Education on medication adherence • Upcoming appointment reminder • Symptom counseling/assess for danger symptoms to watch for • Complete CHW task checklist
Day 6 (+/- 2 days)	Phone Call by CHW	*Research Intervention (intervention group only)*	• Phone call will last about 5-10 minutes • Appointment reminder • Complete CHW task checklist
Day 7 (-/+ 2 days)	Clinic visit by patient	*Clinical, routine care*	For patients who come to clinic on Day 7: • An evaluation is performed 7 days after discharge by an internist. • Patient is enrolled in the NCD program by the NCD Nurse: primarily those living in the Central Plateau and those living outside the ZL catchment area that refuse to be transferred to another non ZL facility • Next visit scheduled in 7 days (day 14 after discharge): ○ If patient is stable: next visit with NCD GP. ○ If patient not stable: next visit with HUM Internist
		Research Intervention (intervention group only)	For patients who do NOT come to clinic on Day 7: • NCD nurse schedules a visit for day 14 • NCD nurse notifies the CHW supervisor and assigned CHW of a missed visit and the new day 14 scheduled visit. • CHW does home visit with patient to notify them of 14-day visit by either phone call or home visit.
Day 14 (-/+ 2 days)	Clinic Visit by patient	*Clinical*	• Visit attendance • HF Symptoms • Vital Status
		Research Intervention (intervention group only)	For patients who do NOT come to clinic on Day 14: • NCD nurse schedules a visit for day 28

			• NCD nurse notifies the CHW of a missed visit and the new day 28 scheduled visit. • CHW does home visit with patient to notify them of 28-day visit by either phone call or home visit.
Day 28 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	**1-month Clinic encounter** • Visit attendance • HF Symptoms • Vital Status
Between day 37 and 44	Home Visit or phone call by Research Assistant	*Research outcome assessment (both intervention and reference groups)*	**1-month Research encounter (about 1 hour)** • Satisfaction Survey • Acceptability interview • Vital Status • Assess whether patient attended another clinic for HF care • HF Symptoms • Assess for rehospitalization since last study visit • Semi-structured interview for appropriateness, acceptability, feasibility, fidelity
Day 60 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	• Visit attendance • HF Symptoms • Vital Status
Day 90 (-/+ 2 days)	Clinic Visit by patient	*Clinical, routine care*	**3-month Clinic encounter** • Visit attendance • HF Symptoms • Vital Status
Between days 97-104 (-/+ 2 days)	Phone call or home visit by Research Assistant	*Research outcome assessment (both intervention and reference groups)*	**3-month Research Encounter (about 1 hour)** • Satisfaction Survey • Acceptability interview • Vital Status • Assess whether patient attended another clinic for HF care • HF Symptoms • Assess for rehospitalization since last study visit • Semi-structured interview for appropriateness, acceptability, feasibility, fidelity

B. SCHEMATIC OF INTERVENTION DESIGN


Patient
CHW
CHW supervisor/ Auxiliary Nurse
Coordinator
Clinic/ hospital
Day
-2 to -1
CHW notified of new patient
Assign patient to CHW based on home address
Notifies that patient about to be discharged
Day 0 (discharge day)
CHW knows of day 7 visit
Day 7 visit communicated
Day 7 visit communicated
Day 7 follow-up scheduled
Day 1-5
Home visit
- Med adherence
- Appt reminder
- Danger symptom
Day 6
Phone call - Appt reminder
Day 7
Patient appt at HUM
Patient does not come
CHW tells patient of day 14 visit
Coord notifies CHW
If Stable: NCD GP next visit
If NOT stable: Internist next visit
Day 14
Patient appt at HUM
Day 28
Patient appt at HUM

C. DATA COLLECTION TOOLS

	Patient mastercode	Baseline	30-day	90-day	Note
Identifiers	x				
Contact		x			
Inpatient hospital/clinical data		X			Admit/discharge dates, echo results, lab data
Socioeconomic status		X			MPI
Clinical status/Quality of life		X	X	X	
HF knowledge		X	X	X	Self care of heart failure index
Satisfaction with care		X	X	X	
Health education experience		X	X	X	
Contact info verify			X	X	
Clinic visit attendance @ HUM or other clinics			X	X	EMR review and patient-reported
Satisfaction with CHW			X		

Form	**Variables**
Patient Mastercode	• Name • Date of birth • Medical record number • Address
Contact information	• Telephone numbers (3)
Inpatient hospital/clinical data	• Date of admission • Date of discharge •
Socioeconomic status	• Socioeconomic indicators: multidimensional poverty index ○ Death of child in the household

	○ Body mass index, weight, height ○ Education ○ Children not in school ○ Assets: telephone, radio, refrigerator, car/motorcycle ○ Living standards: water supply, toilet quality • Hardship financing ○ Borrow money to pay for healthcare ○ Sell belongings to pay for healthcare
Clinical status/quality of life	• Self-reported overall health status: poor/fair/good/excellent • HF Symptoms: Kansas City Cardiomyopathy Questionnaire • EuroQol 5D • Vital Status: alive (yes/no)
HF knowledge	• Self Care of Heart Failure Index • Have you been educated on your condition and medications for your heart failure? (yes/no) • Have you been educated about your heart failure? (yes/no)
Health education experience	• HF education Satisfaction (5-point Likert) [from patient-centered education in Uganda https://doi.org/10.1371/journal.pone.0166411] ○ Overall, how satisfied with patient education in at HUM? ○ I am satisfied that my doctor told me about my condition, the treatment options and how I can stay healthy. ○ I am satisfied that I understand the nature and causes of my health condition. ○ I am satisfied that I know the different medical treatment options available for my health condition. ○ I am satisfied that I know how to prevent further problems with my health condition. • Education material satisfaction ○ How clear is the writing and information on the educational materials? ○ How visually appealing are the educational materials? ○ How professional is the look and feel of the educational materials? ○ How likely are you to recommend the content of the educational materials to others? • HF Education delivery satisfaction (yes/no) [from patient-centered education in Uganda https://doi.org/10.1371/journal.pone.0166411] ○ Did someone sit down with you and talk about your disease? ○ Did someone use any pictures to help you explain your disease? ○ Did these pictures and explanations help you to ask questions you may have?

	○ Did reading the materials stimulate you to ask any questions of your doctor? ○ Would you talk about the materials with your family or friends?
Contact info verify	• Are the prior telephone numbers still valid? • Record telephone numbers
Clinic visit attendance @ HUM or other clinics	• Did the patient attend clinic at HUM since the last study encounter: ○ If 30-day visit, was there a clinic visit since hospital discharge? ○ If 90-day visit, was there a clinic visit since the 30-day visit? • Did the patient attend another clinic that was not HUM? • Have you been hospitalized since the last study encounter? • Satisfaction with education (5-point Likert) ○ Overall, how satisfied with the educational materials? ○ How clear is the writing and information on the educational materials? ○ How visually appealing are the educational materials? ○ How professional is the look and feel of the educational materials? ○ How likely are you to recommend the content of the educational materials to others? • Health Education experience ○ Did someone sit down with you and talk about your disease? ○ Did someone use any pictures to help you explain your disease? ○ Did these pictures and explanations help you to ask questions you may have? ○ Did reading the materials stimulate you to ask any questions of your doctor? ○ Would you talk about the materials with your family or friends?
CHW Visit Checklist	Ensure the CHW completed the following intervention steps: ▪ Provide education on importance of medication adherence • Medicines DO NOT need to be taken with food • Continue taking medicines even if they are feeling improved/well • Review how to take the medicines: # of tablets, # of times/day ▪ Remind them of their next scheduled appointment • Medication supply: Does the patient have enough medications to last until the next visit. ▪ Symptom counseling - danger symptoms to watch for: • Shortness of breath • Edema of lower limb • Cough, hemoptysis

	• Irregular heartbeat • Thoracic pain • Advise patient to make an earlier clinic visit if they have worsening of these symptoms.

D. PATIENT SATISFACTION QUESTIONNAIRE



Please rate the acceptability of the following components:	GREAT 5	GOOD 4	OK 3	FAIR 2	POOR 1
Heart Failure Program					
1. Appropriateness of being assigned a CHW after hospital discharge	5	4	3	2	1
Home Visits					
2. Acceptability of a CHW visiting you in your home within 5 days of hospital discharge	5	4	3	2	1
3. Complexity of the home visit by the CHW	5	4	3	2	1
Checklist Components					
4. Acceptability of CHW counseling for medication adherence	5	4	3	2	1
5. Perceived quality of medication adherence counseling by CHWs	5	4	3	2	1
6. Acceptability of CHW screening for medication side effects	5	4	3	2	1
7. Perceived quality of medication side effects screening by CHW	5	4	3	2	1
8. Acceptability of CHW reviewing your medication packages to assess adequate supply	5	4	3	2	1
9. Perceived quality of CHW's review of your medication packages to assess adequate supply	5	4	3	2	1
10. Acceptability of CHW screening for danger symptoms	5	4	3	2	1
11. Perceived quality of danger symptom screening by CHW	5	4	3	2	1
12. Acceptability of CHW reminding you about future appointments	5	4	3	2	1
13. Perceived quality of appointment reminders by CHW	5	4	3	2	1
14. Acceptability of CHW calling you by telephone	5	4	3	2	1
15. Perceived quality of telephone call by CHW	5	4	3	2	1
Education					
16. Acceptability of education provided by CHW	5	4	3	2	1
17. Content of education provided by the CHW	5	4	3	2	1
18. Content of self-care education provided by the CHW	5	4	3	2	1
Job Aides					
19. Availability of the job aides	5	4	3	2	1
20. Ease of use	5	4	3	2	1
21. Helpfulness of job aides	5	4	3	2	1

What do you like best about our the CHW interactions?

What do you like least about our Center the CHW interactions?

Suggestions for improvement?

E. DRAFT INDIVIDUAL INTERVIEW DISCUSSION GUIDE - PATIENT

Below are introductory talking points, sample questions, and additional probes to guide the semi-structured interview based on the Consolidated Framework for Implementation Research (CFIR) Domains. NB: the interview will not follow a set script; instead, it will use questions the same as, similar to, or closely related to the questions below based on how the interview evolves. Additional questions may be included if necessary to discuss themes or issues that emerge as relevant to the study objectives.

Introduction and welcome

Study personnel facilitator will discuss the following:

- Introduction of facilitator
- Objectives of the overall study - Objectives of the interview
- Reminder of timeframe, that interviewees are not obligated to answer any questions, confidentiality (i.e. that all information will remain confidential), process of the interview, and that there are no "right" or "wrong" answers.
- Emphasis that all information discussed will remain confidential.

Acceptability of the CHW

1. For this interview, we would like to learn about your thoughts on the home visits and phone calls by the community health worker who was assigned to you.
    a) How did you feel about the community health worker visiting your home shortly after being discharged from the hospital?
    b) After asking for your permission, was it acceptable for the CHW to discuss with your family or friends about how you can keep yourself healthy?

Appropriateness of the education

2. The CHW was supposed to give you some education to help you better understand your condition and how to keep yourself healthy.
    a) What was your impression of the education?
    b) Did the education help you better understand your condition? In what way?
    c) What was your impression of the picture book (*album imaj)*?

Acceptability of medication review

3. The CHW reviewed your medication packages.
    a) How was your experience of having someone review your medications with you at your home?
    b) Did the CHW help you identify any errors in the way you were taking your medication? What corrective steps were taken?

Acceptability of appointment reminder

4. The CHW reviewed with you your scheduled appointment day. Coming to appointments can be important to maintain good health.
    a) What was your impression of having the appointment reminder?
    b) Do you think the reminder was helpful to coming to your appointment on time?

Acceptability of phone call

5. The CHW was asked to call you to remind you about an upcoming appointment.
    a) What was your impression of having a phone call by someone from the hospital/clinic?
    b) What are some of the challenges of receiving future phone calls? Do you have a consistent phone number and charge?

Wrap-up

6. Please let us know of ways we can improve the way that CHWs can help you. What other activities would be helpful for you to take care of your health?

F. DRAFT GROUP INTERVIEW DISCUSSION GUIDE - CHW

Below are introductory talking points, sample questions, and additional probes to guide the semi-structured interview based on the Consolidated Framework for Implementation Research (CFIR) Domains. NB: the interview will not follow a set script; instead, it will use questions the same as, similar to, or closely related to the questions below based on how the interview evolves. Additional questions may be included if necessary to discuss themes or issues that emerge as relevant to the study objectives.

Introduction and welcome

Study personnel facilitator will discuss the following:

- Introduction of facilitator
- Objectives of the overall study - Objectives of the interview
- Reminder of timeframe, that interviewees are not obligated to answer any questions, confidentiality (i.e. that all information will remain confidential), process of the interview, and that there are no "right" or "wrong" answers.
- Emphasis that all information discussed will remain confidential.

For this interview, we will ask you as CHWs your perception and opinion of the intervention to improve heart failure care in which you participated

Acceptability of the CHW

1. For this interview, we would like to learn about your thoughts on the home visits and phone calls by you, the community health worker.
    a) How did you feel about visiting heart failure patients at their home shortly after being discharged from the hospital?
    b) How acceptable was it for the CHW to discuss with a patient's family or friends about how the patient can keep themselves healthy?

Appropriateness of the education

2. During home visits, you were asked to deliver education to patients to help them better understand their condition and how to keep healthy.
    a) What was your impression of the education?
    b) Did you feel prepared to deliver this education
    c) What was your impression of the picture book (*album imaj)*?
    d) In what ways did you think the education helped patients. For what concepts was there still confusion after the education?

Acceptability of medication review

3. During home visits, you were asked to review medication packages with the patient.
    a) How was your experience of reviewing medication packages?
    b) Did you feel prepared to identify any errors in the way patients were taking their medication? Did you feel prepared to discuss corrective steps if there were errors?

Acceptability of appointment reminder

4. You were asked to review the future scheduled appointment day. Coming to appointments can be important to maintain good health for patients.
    a) What was your impression of delivering the appointment reminder?
    b) Do you think the reminder was helpful for patients to remember to come to appointments on time?

Acceptability of phone call

5. You were asked to call patients to remind them about an upcoming appointment.
    a) What was your impression of calling a patient by phone to remind them of their visit?
    b) What are some of the challenges of giving future phone calls? Do you have consistent access to a phone, signal, and charge?

Wrap-up

6. Please let us know of ways we can improve the way that CHWs can help patients with heart failure. What other activities would be helpful for you to do your work to help patients take care of their health?

G. DRAFT GROUP INTERVIEW DISCUSSION GUIDE – HEALTHCARE ADMINISTRATORS

Below are introductory talking points, sample questions, and additional probes to guide the semi-structured interview based on the Consolidated Framework for Implementation Research (CFIR) Domains. NB: the interview will not follow a set script; instead, it will use questions the same as, similar to, or closely related to the questions below based on how the interview evolves. Additional questions may be included if necessary to discuss themes or issues that emerge as relevant to the study objectives.

Introduction and welcome

Study personnel facilitator will discuss the following:

- Introduction of facilitator
- Objectives of the overall study - Objectives of the interview
- Reminder of timeframe, that interviewees are not obligated to answer any questions, confidentiality (i.e. that all information will remain confidential), process of the interview, and that there are no "right" or "wrong" answers.
- Emphasis that all information discussed will remain confidential.

Acceptability of the CHW

1. For this interview, we would like to learn about your thoughts on the home visits and phone calls by the community health worker who was assigned to a patient with heart failure.
    a) How did you feel about the community health worker visiting a heart failure patient at their home shortly after being discharged from the hospital?
    b) If the patient is not home, do you think it is acceptable for the CHW to discuss with a patient's family or friends about how the patient can keep themselves healthy?

Appropriateness of the education

2. The CHW was supposed to deliver some education to help patients better understand their condition and how to keep themselves healthy.
    a) What was your impression of the education?
    b) What was your impression of the picture book (*album imaj)*?

Acceptability of medication review

3. The CHW reviewed medication packages with patients.
    a) Do you think having CHWs review medications with patients at their home is useful?

Acceptability of appointment reminder

4. The CHW reviewed with the patient their upcoming scheduled appointment day. Coming to appointments can be important to maintain good health.
    a) What was your impression of CHWs reminding patients for their appointments?
    b) Do you think the reminder will be helpful for patients to come to their appointment on time?

Acceptability of phone call

5. The CHW was asked to call patients to remind them about an upcoming appointment.
    a) What was your impression of having the CHW do a phone call to patients?
    b) What are some of the challenges for patients receiving future phone calls?

Wrap-up

6. Please let us know of ways we can improve the way that CHWs can help patients with heart failure. What other activities would be helpful by CHWs to help patients take care of their health?