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PEERS AND TECHNOLOGY FOR ADHERENCE, ACCESS, ACCOUNT-ABILITY, AND ANALYTICS (PT4A)

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CONTENTS

CONTENTS

STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonization Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and study site staff who are responsible for the conduct, management, or oversight of the study have completed Human Subjects Protection and ICH GCP Training.

PROTOCOL SYNOPSIS

Title:	Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) – A Qualitative Study
Grant Number:	1R56HL150036
Study Description:	The overall objective of this project is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on improving medication adherence for hypertension control. The central hypothesis is that peer delivery of medications integrated with HIT (PT4A) will be effective in improving hypertension medication adherence, contributing to improved blood pressure among patients with uncontrolled hypertension in western Kenya. This application will focus on the critical formative components of the overall implementation research objective, and we propose the following specific aims: Aim 1 will identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy (individual, family, clinician, health system, and environment), using qualitative methods. Aim 2: We will then use a human-centered design approach to refine the PT4A intervention using the findings from Aim 1. Sub-Aim 2.1 will evaluate the intervention for acceptability and appropriateness by use of a survey tool with patients, peers, and clinical staff. In Sub-Aim 2.2, we will then conduct a pilot of the intervention and conduct a survey questionnaire with patients, peers, and clinical staff to evaluate feasibility. We will evaluate impact on systolic blood pressure, medication adherence, and fidelity of implementation. We will also create a retrospective comparator (control) group of CDM patients, through querying AMRS, matched by sex, age, location and initial blood pressure level. We will then use their recorded blood pressure over a comparable period of upto 1 year and to allow for comparison to the blood pressure changes observed in the patients enrolled in the PT4A program to help understand the magnitude and variance of the intervention effects.
Objectives*:	The overall objective of this proposal is to utilize transdisciplinary, translational implementation research, guided by the PRECEDE-PROCEED framework, to address the challenge of hypertension medication non-adherence in low-resource settings.
Endpoints*:	The primary adherence outcome is the pill count adherence ratio, which is the proportion of prescribed doses taken over a 1-month time period, assessed at the end of the pilot. The primary implementation outcome is fidelity, measured as quantity and quality of intervention delivery as intended, comprised of three components: confirmed medication delivery documented by patient e-signature, peer completion of the HIT form, and quality of data entry into the HIT form.

Study Population:	Approximately 146 individuals will participate in this study. The number is approximate because for focus group discussions, the number of participants can range from 6-10. Aim 1: • Focus group discussions (approximately 96 participants): Participants will be patients with hypertension who are currently enrolled in the AMPATH CDM program, and at least 18 years of age from the counties of Bungoma, Trans Nzoia, and Uasin Gishu in Western Kenya. Clinical staff in the AMPATH CDM program and community leaders from the counties will also participate. (12 total FGDs, 6-10 participants each) • Key informant interviews (4 participants): Participants will be County Executive Committee representatives for health from the three Counties included in the study and the Ministry of Health head for non-communicable diseases (NCDs). Aim 2: • Human Centered Design Team (20 participants): Participants will be individuals representing the following stakeholder groups: research team members, clinicians, pharmacists, peers, patients with hypertension, representatives from the informatics team, and other relevant staff members involved in hypertension care Aim 2.1: • Use of Survey tools adapted from acceptability and appropriateness measures (39 participants): • Participants will be patients (as described above), peer navigators, and clinical staff (as described above). Aim 2.2: • Pilot (up to 100 participants): Participants will be patients who are currently enrolled in the AMPATH CDM program, and at least 18 years of age from the counties of Bungoma, Trans Nzoia, and Uasin Gishu in Western Kenya. • Retrospective comparator group: AMRS records of up to 100 patients who will serve as a control group matched by sex, age, location and initial blood pressure level
Phase* or Stage:	N/A
Description of Sites/Facilities Enrolling Participants:	AMPATH catchment area in three counties of western Kenya: Bungoma, Trans Nzoia, and Uasin Gishu.

Description of Study Intervention/Experimental Manipulation:	Peer delivery of medications: We will adopt a novel approach of extending beyond the use of peer support in the clinical setting and implement door-to-door peer delivery of medications within patients' communities Health Information Technology (HIT) Platform: To support peer delivery, we will use a HIT platform that performs 4 core functions: 1) tailored counseling strategies through decision support; 2) teleconsultation support for clinician-peer-patient interactions; 3) tracking medication refills to enhance accountability of the peer delivery process; and 4) analytics to improve medication supply chain by generating patient-level drug consumption data. This is an innovative use of HIT to accomplish these functions to support medication adherence.
Study Duration*:	Up to 1 year
Participant Duration:	Up to 1 year

A. SIGNIFICANCE

Hypertension – Global Burden and Unmet Needs. Elevated blood pressure (BP) is the leading risk factor of death globally.[1,2] The global burden of hypertension is increasing,[3,4] disproportionately so in low- and middle-income countries (LMICs).[5-8] While BP control reduces cardiovascular disease (CVD) and death,[9-11] treatment and control rates remain suboptimal both in the U.S. and LMICs.[5-7,12] The economic burden of hypertension is staggering, in terms of both direct health costs and indirect impact on employment and productivity.[13-16] Despite many evidence-based interventions to manage hypertension, substantial implementation gaps persist.[17]

Medication Adherence. Adherence is defined as "the process by which patients take their medications as prescribed," and is often divided into three phases: initiation, implementation, and persistence.[18] Adherence to hypertension medication reduces congestive heart failure,[19] CVD risk,[20] CVD events,[21,22] and mortality.[21-24] Despite increased medication costs, adherence can lead to net decrease in both health care utilization and cost in hypertensive patients.[25] Given the clinical and economic benefits of adherence, improvements in hypertension medication adherence will improve BP control and reduce CVD risk and mortality.[26] However, in low-resource settings worldwide, nearly 60% of hypertension patients report non-adherence to antihypertensive medications—both suboptimal implementation (i.e. day-to-day medication-taking behavior) and non-persistence (i.e. premature discontinuation), leading to poor BP control and increased hospitalization and mortality.[27-33]

Multi-Level Barriers Impacting Adherence. Barriers to adherence to hypertension medications are complex and multi-level.[32,34-37] At the macro-level (e.g. health systems and communities), challenges include reduced medication availability,[38] low affordability,[38] inadequate insurance coverage,[32] transportation,[39,40] and distance to health facilities.[41,42] At the micro-level (e.g. individual patients and providers), barriers include provider training,[43] poor patient-provider relationships,[44-46] patient missing doses,[40] real and perceived adverse effects,[47] and psychological factors.[40,48] Therefore, there is a need to develop and evaluate rigorous implementation strategies that address the multi-level barriers impacting medication adherence.

Peer Delivery of Medications. Peers are lay individuals with shared disease experience who provide practical, social, emotional, and motivational assistance to patients.[49] Peer support can improve chronic disease medication adherence; however, most studies have occurred in clinical settings.[50-52] To date, door-to-door peer delivery of hypertension medications to patients in order to improve adherence has not been evaluated.

Health Information Technology (HIT). The use of HIT, such as electronic medical record systems, mobile health (mHealth) approaches, and electronic prescribing, can enhance medication adherence.[53-55] In LMICs, HIT has demonstrated beneficial impact on clinical care processes for chronic diseases, and can enhance peer support networks for non-communicable disease (NCD) care.[56-58] However, it is not well known if HIT, combined with peer delivery, can enhance adherence to antihypertensive medications and improve BP control.[58,59]

Rigor of Prior Research. As described above, a large evidence base has clearly documented that medication adherence is associated with improved BP and CVD outcomes. However, micro- and macro-level barriers to hypertension medication adherence lead to suboptimal BP control and adverse CVD outcomes. While peer support and HIT have separately shown promise with respect to improving medication adherence, there remain gaps in the literature that will be addressed by our proposed project to combine peer delivery and HIT to address multiple barriers, thereby improving hypertension medication adherence, ultimately contributing to improved BP among patients with uncontrolled hypertension in western Kenya.

Relevance to the U.S. The burden of hypertension in the U.S. is substantial,[60] and the challenges for population subgroups (health facility access, transportation, and opportunity cost of lost work) are similar to those in Kenya.[61] Despite efforts to improve adherence, gaps remain leading to morbidity, mortality, and costs.[62] Hence, we aim to produce generalizable knowledge relevant to the U.S. In fact, our team and colleagues have previously translated research learnings from Kenya into impactful interventions for U.S. communities.[63-65]

Implementation Science Training and Capacity Building. Capacity building has been a longstanding priority for our team and is fundamental to this project.[66-73] We are therefore purposely involving a relatively junior Kenyan sub-award investigator with more experienced U.S.-based Multiple Principal Investigators. In addition to this experiential learning, we will leverage didactic training activities, as we have previously done.[74,75] This human resource investment will ensure future implementation research related to hypertension and other NCDs.

B. INNOVATION

Human-Centered Implementation Research. Human-centered design (HCD) is a creative approach to problem-solving, a process whereby stakeholders are engaged in all phases: inspiration (identify the challenge), ideation (design, test and refine solutions) and implementation (maximize impact).[76,77] Our team has previously utilized HCD in the context of NCD care and prevention, and we have previously proposed an approach termed "human-centered implementation research".[78-81] Using this approach is pioneering and could provide a model for co-creation and participatory design that could be relevant worldwide.

Peer Delivery of Medications. We will adopt a novel approach of extending beyond the use of peer support in the clinical setting and implement door-to-door peer delivery of medications within patients' communities.

Health Information Technology (HIT) Platform. To support peer delivery, we will use a HIT platform that performs 4 core functions: 1) *tailored counseling strategies* through decision support; 2) *teleconsultation* support for clinician-peer-patient interactions; 3) tracking medication refills to enhance *accountability of the peer delivery process*; and 4) *analytics to improve medication supply chain* by generating patient-level drug consumption data. This is an innovative use of HIT to accomplish these functions to support medication adherence.

C. APPROACH

Setting. The proposed study will take place in western Kenya at the Academic Model Providing Access to Healthcare (AMPATH) program, an academic partnership between Moi University College of Health Sciences (MUCHS), Moi Teaching and Referral Hospital (MTRH), and a consortium of North American universities.[82] AMPATH has established an HIV care program that has enrolled over 200,000 patients in a catchment population of 4 million.[82,83] In 2011, AMPATH was designated as a Center of Excellence for Cardiovascular and Pulmonary Disease Research by the NHLBI.[67,84] At the same time, AMPATH also established a Chronic Disease Management (CDM) Program in collaboration with the Ministry of Health (MOH).[85] We have a Memorandum of Understanding with the Kenya MOH to provide care for NCDs and to develop and evaluate innovative approaches to NCD management including hypertension.

The CDM Program has enrolled over 40,000 patients with hypertension. Our team has conducted several NIH-funded implementation research studies targeting various elements of the NCD care delivery system: nurse management of hypertension (K01TW009218), linkage/retention to hypertension care (U01HL114200), group medical visits and microfinance for NCDs (R01HL125487), and strengthening referral networks for hypertension (U01HL138636). In addition, we have implemented a network of revolving fund pharmacies (RFPs) to ensure a reliable supply of medicines for hypertension and other NCDs across all levels of the health system, including 60 health facilities where availability of medications for hypertension is now 95-99%.[35,86-88]

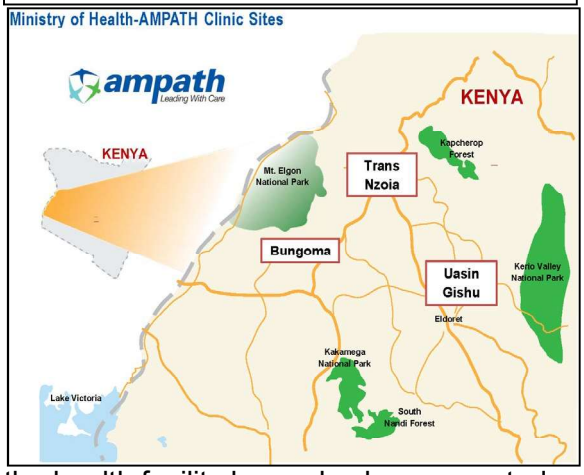
AMPATH has used the AMPATH Medical Records System (AMRS), a customized version of OpenMRS, since 2005.[89] In 2016, AMPATH developed a software program called "Point-of-Care" (AMRS-POC), which we started using in CDM clinics for hypertension management in 2017. We have developed software modules for the following clinical functions: 1) historical patient data review (patient dashboard); 2) real-time clinical data entry (customized interactive forms with skip logic); 3) decision support tailored to the type and training of clinician (e.g. when to escalate hypertension therapy); 4) health facility management (scheduling, follow-up of patients missing clinic visits, generating administrative reports); and 5) data visualization (quality indicators). AMPATH has invested in a Wi-Fi network and solar power system to ensure network access and server connectivity for each health facility. Our current system is being

implemented in over 30 health facilities serving a patient population of nearly 100,000 patients, and has been used for more than 1 million clinical encounters. We have developed and implemented a HIT-based home glucose monitoring program that has led to significant improvements in glycemic control.[90] We have also implemented real-time interactive HIT for oncology, enabling specialists at the referral hospital to co-manage patients with clinicians from remote health facilities. Finally, we are developing a personal health record platform to support asynchronous telemedicine. The proposed HIT component of this study builds upon this established infrastructure.

Preliminary Data.

Suboptimal Medication Adherence. Adherence to hypertension medications is suboptimal in western Kenya, and there remain gaps to improve patient-level access and medication refill rates. Preliminary analysis of data from participants in the BIGPIC trial (R01HL125487) indicates that nearly 50% of patients with hypertension and/or diabetes reported suboptimal adherence, similar to other countries in Africa.[37] Due to limited cash supply, patients often choose to fill only a part of their prescription on the day of the clinic visit, and are expected to return for refills. AMPATH pharmacy data indicate that as the prescription duration increases, fewer patients fill the prescription for the entire period: 43% filled their 60-day prescription, and only 21% filled their 90-day prescription. The remaining patients required a return visit to refill their prescriptions. However, missed refills are frequent; in fact, 62% of hypertensive patients in this region reported having missed or skipped a refill, while 64% reported having run out of medication before the next refill date. Pharmacy program data confirm this self-report; a recent audit indicated that only 24% of individuals who were due to return to clinic for a prescription refill actually did so.

Figure 1. Study sites in western Kenya



Impact of Adherence on BP. Suboptimal adherence in our catchment is associated with worse BP outcomes: individuals reporting having missed doses of medications had an average systolic BP (SBP) of 157 mmHg compared to 134 mmHg among those with perfect adherence. Those who had run out of medications and missed refills also had higher SBP levels (unpublished data).

Factors Impacting Adherence. For hypertension patients in Kenya, unaffordability of care, low availability of providers, poor access to health facilities, and inadequate social support are all barriers to hypertension care and medication adherence.[42,91] Cost of transport and distance to the health facility have also been reported as significant barriers. Preliminary analysis of BIGPIC trial data indicates that time taken to reach the health facility is significantly associated with a missed prescription;[79] round-trip estimates average approximately 90-120 minutes. In addition, patients spend nearly two hours at the health facility when attending a hypertension clinic, or even just for a medication refill. We have previously reported that the clinician-patient encounter averages less than 10 minutes,[92] indicating long wait times and therefore time lost from work. To supplement the substantive preliminary data summarized above, we propose to conduct a more thorough assessment of the various factors that might impact successful implementation of the PT4A strategy.

Results from Peer and HIT Involvement in Care Delivery. We have successfully used peers in the AMPATH program to provide adherence counseling and psychosocial support for patients with HIV.[93,94] We have also delivered portable group-based NCD care, peer support, and medications in remote, patient-centered locations for several years, with improvements in retention in

Table 1: Investigator expertise in proposed work	
Domain	Investigators
Hypertension management in LMICs	**Vedanthan, Pastakia, Njuguna,** Tran, Laktabai, Manji
Systems improvement in NCD care	**Vedanthan, Pastakia, Njuguna,** Tran, Laktabai, Manji
NCD-related implementation science	**Vedanthan, Pastakia, Njuguna,** Njuguna, Genberg
Peer-based care for hypertension	**Vedanthan, Pastakia, Njuguna,** Tran
Health IT for NCD care	**Vedanthan, Pastakia, Njuguna,** Dick
Expanding access to medications	**Vedanthan, Pastakia, Njuguna,** Tran, Manji
Medication adherence research	Schoenthaler, Genberg
Qualitative research	Schoenthaler, Wachira, Genberg
Epidemiology	**Vedanthan,** Genberg
Spatial analysis	Duncan
Biostatistics and transportability analysis	Troxel, Mwangi
Cost effectiveness and decision analysis	Finkelstein

care, BP, and A1c.[79,95,96] Our program of peer delivery of HIV medications, begun over one year ago, has grown by nearly 20%, with 97% of medications delivered on time. We also have implemented a pilot program of peer delivery of medications for hypertension and diabetes, with improvement in adherence and a nearly 6-mmHg reduction in SBP. We have also shown that HIT strategies can integrate and coordinate care across the health system for HIV, diabetes, and hypertension.[85,97-100]

Summary of Preliminary Data and Remaining Gaps. As described above, the current proposal is an extension of established work, building upon a solid foundation of several years and iterations of peer- and HIT-based strategies. However, there remain implementation gaps, as well as gaps in the rigor of prior research, to be addressed. We hypothesize that our proposed strategy, **p**eers and **t**echnology for **a**dherence, **a**ccess, **a**ccountability, and **a**nalytics (**PT4A**), will help to address some of the remaining gaps we have identified in our prior research. As an initial step, further formative research is required prior to full-scale implementation and evaluation of this strategy to improve medication adherence and blood pressure. We will conduct this project in the AMPATH catchment area in three counties of western Kenya: Bungoma, Trans Nzoia, and Uasin Gishu (Figure 1).

Study Team. Our proposal builds upon longstanding institutional partnerships that comprise the AMPATH Consortium, which have laid the groundwork for clinical care and research in CVD.[67,82,84,85,101-103] Both **Dr. Vedanthan (contact PI) and Dr. Pastakia (MPI) have successfully collaborated for several years with each other and with investigators from MUCHS and MTRH, as well as members of the current study team, to establish robust structures for chronic disease research and clinical care in western Kenya.**[67,68,79,85,91,99,104-109] Each collaborator adds specific value to this proposal (Table 1). Critically, we have secured strong high-level political support from the Head of the Division of NCDs at the MOH. In addition, the AMPATH Executive Director of Care is supportive of this application. The head of the AMPATH Population Health Program, Dr. Laktabai, as well as the head of the AMPATH RFP program, Imran Manji, are co-investigators. This key program and government leadership support provide a strong foundation that positions us to successfully carry out our proposed research and produce lessons and insights that can have impact worldwide.

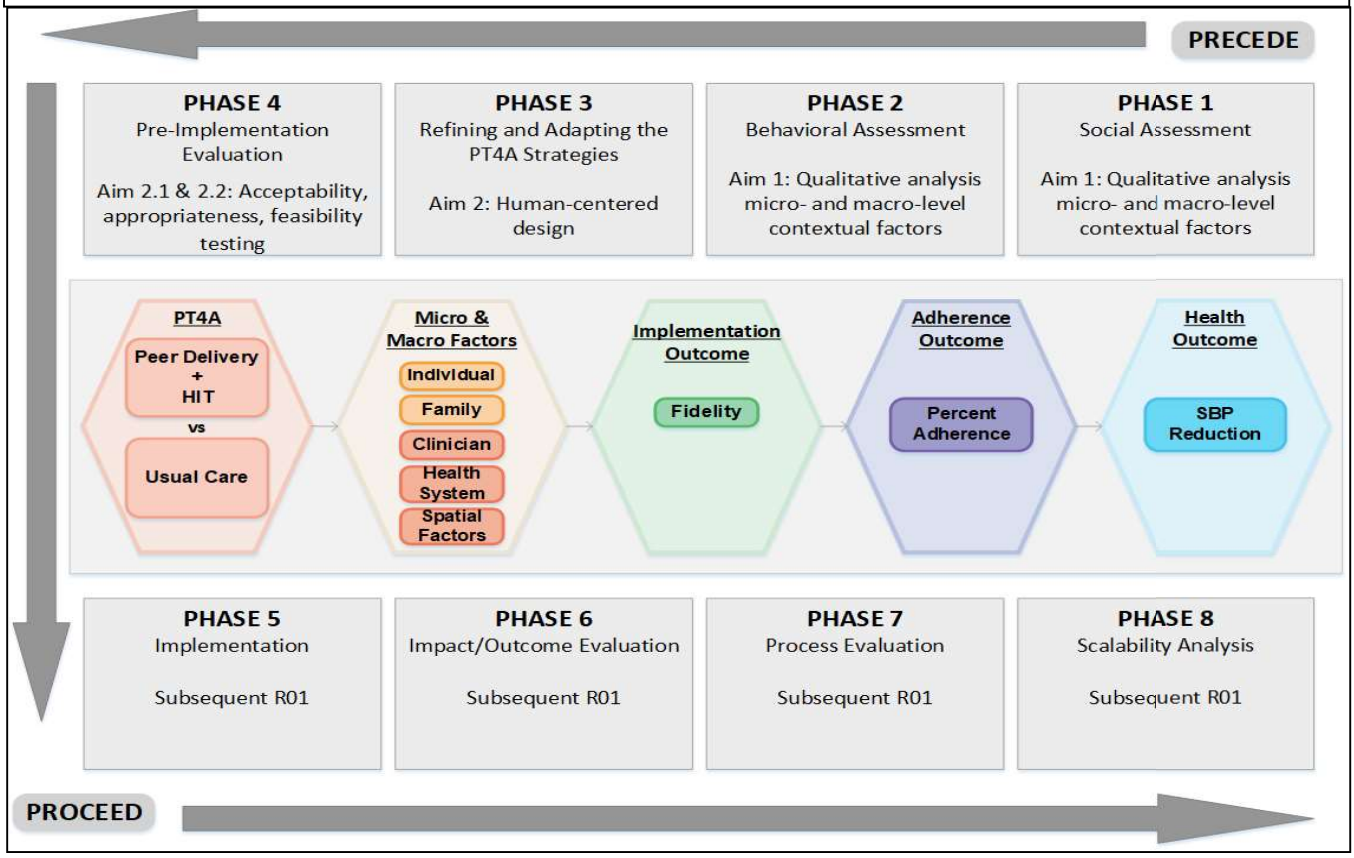
International Advisory Committee. Our goal is to make the PT4A strategy relevant for health systems in low-resource settings worldwide. We will therefore create an International Advisory Committee consisting of peers, researchers, clinicians, administrators, and policy makers from around the world. Twice a year, the committee will discuss by teleconference how to tailor the strategy for the Kenyan context as well as in other low-resource settings, and how to adapt, implement, and evaluate the PT4A strategy in other contexts.

Stakeholder Engagement. We will collaborate with key stakeholders throughout the proposed project. At the **conception** stage, we have aligned our proposal to address a key national priority: curbing NCDs while addressing the shortage of human resources for health.[110] We have also already secured input and support for this proposal from the MOH NCD leadership. At the **design** phase, we have engaged key program leaders both informally and formally as

investigators on this proposal, leveraging their experience with NCD care, peer-based care, and NCD medication adherence, thus ensuring our proposed strategy is aligned with program and policy priorities.[83] We will engage patients, communities, clinicians and health program leaders as we **conduct** our qualitative research and human-centered design-based strategy refinement. AMPATH's Community Strategy Initiative routinely engages existing community-based governance structures to gather input and feedback on community-based initiatives. In addition, the AMPATH research program has a long history of engaging and informing community stakeholders of research interventions.[79,108,111-121] finally, we will conduct regular **dissemination** of our program experiences, successes, and challenges to key stakeholders to co-create solutions and promote receptivity for future wider implementation.

Overall Implementation Research Framework. The PRECEDE-PROCEED framework provides a conceptual framework for assessment of an implementation challenge, design of a responsive strategy, and implementation and evaluation of that strategy (Figure 2). [122-124] We

Figure 2. PRECEDE-PROCEED Implementation Research Framework



chose to use PRECEDE-PROCEED as our overall implementation research framework because of its participatory nature, multi-pronged assessment of the multi-level factors that affect adherence, and multiple evaluation components. In addition, PRECEDE-PROCEED is appropriate for a hybrid type 2 implementation research trial,[125] where we will have a dual focus to assess effectiveness of the strategy in improving medication adherence and BP, while also evaluating the fidelity of our implementation strategy. We are currently using PRECEDE-PROCEED in another NIH-funded study,[126] while others have successfully used this framework to develop strategies to promote cardiovascular health in low-income populations.[127] Phases 1 and 2 are simultaneous with our baseline contextual assessment (Aim 1). Phase 3 aligns with the HCD

process (Aim 2). Phase 4 aligns with the acceptability, appropriateness, and feasibility testing. Phases 5 to 8 will encompass the subsequent planned R01 grant application. Phase 5 will be the implementation of the cluster randomized trial comparing the PT4A strategy to usual care. Phase 6 will align with our impact and outcome evaluation to determine the overall impact as well as the impact of spatial factors on strategy effect, respectively. The Phase 7 process evaluation will be implemented simultaneous with Phase 5, and Phase 8 is our planned scalability and adaptability evaluation.

Conceptual Model for Adherence Behavior. We will use the capability, opportunity, and motivation model for behavior change (COM-B)[128] as our conceptual model for medication adherence behavior. The COM-B model provides a solid foundation to comprehensively understand the multi-level determinants of adherence, and develop our strategy targeting improved adherence (Table 2). We chose the COM-B model due to its versatility at addressing a variety of behavior change challenges, its applicability in low-resource settings, and its comprehensiveness in recognizing interactions among multiple determinants of the same problem.[106,129-133]

We hypothesize that the PT4A strategy will address determinants of hypertension medication adherence at the micro- and macro-levels, leading to changes in patient activation, improvement in adherence, and reduction of BP. Peer-based delivery of medications will reduce both direct costs (e.g. transport) and opportunity costs (e.g. time lost, time off economic activity) associated with acquiring medication refills. Secondly, peer delivery will provide a platform for peer-patient interaction that can be leveraged to provide adherence counseling and psychosocial support. Through the interaction, peers may help address medication-related concerns (e.g. perceived and real adverse effects), improve patient activation (e.g. coaching patients to raise concerns and questions with clinicians), and provide psychosocial support. HIT will augment peer roles through the decision support system, teleconsultation functionality, and provision of patient-specific adherence summaries for targeted counseling. The HIT platform will also provide enhanced supply chain analytics in order to optimize availability of medications at the rural dispensing facilities.

Table 2: COM-B constructs, determinants of medication adherence, and proposed PT4A intervention components

COM-B Construct		Determinant of Adherence	PT4A Intervention Components
Capability	Physical (Micro)	• How and when to take medicines • Pill burden	Peer: adherence counseling HIT: decision support and targeted counseling
	Psychological (Micro)	• Individual knowledge about medicines, hypertension and adherence necessity • Understanding the relationship between adherence and clinical outcomes	Peer: adherence counseling HIT: decision support and targeted counseling
Opportunity	Social (Macro)	• Social norms about hypertension and treatment • Social support for adherence	Peer: psychosocial support
	Physical (Macro)	• Time, ease, and cost of transport to acquire refill • Availability and price of medications • Opportunity cost of acquiring refill	Peer: medication delivery Peer: psychosocial support HIT: teleconsultation HIT: supply chain analytics
Motivation	Reflective (Micro)	• Individual barriers and facilitators of adherence • Individual beliefs about hypertension and medicines • Patient activation in his/her care	Peer: adherence counseling Peer: psychosocial support Peer: health coaching HIT: decision support and targeted counseling
	Automatic (Micro)	• Habits/Medication routines • Emotional response to disease and medicines	Peer: adherence counseling Peer: psychosocial support HIT: decision support and targeted counseling

Aim 1: Identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy.

We will use qualitative research methods to conduct a thorough baseline contextual assessment of barriers and facilitators for implementing PT4A.

Participants: We will conduct focus group discussions (FGDs) of 6-10 participants each among four different groups in each county

: individuals with hypertension (men and women separately), clinical staff, and community members (12 total FGDs). Purposive sampling will be used to select study participants in order to sample a diversity of stakeholders. For individuals with hypertension, diversity of age and distance from the nearest health facility will be targeted. In addition, we will conduct four key informant interviews (KIIs): one each with the County Executive Committee representative or the county health director for medical services in each of the three counties where we will conduct our study, and one with the head of the division of NCDs at the MOH.

Methodology: *Focus Group Discussions:* Clinical staff will be recruited by identifying staff who care for patients with hypertension. Patients will be recruited from the health facilities participating in the study. We will work with the AMPATH leadership to identify local community members. FGD guides will be created specific to each target group, based on the COM-B constructs listed above (Table 1). Additionally, the FGDs of the clinical staff will assess organizational readiness for change (change efficacy, change commitment, and organizational context)[134] to implement a new multi-level strategy. Each guide will be pilot-tested on three individuals (male, female, and clinician) and revised accordingly. A trained moderator will lead each FGD and facilitate the discussion,[135] with an observer and a note-taker present. Each FGD will last approximately 60 to 90 minutes and will be audio-recorded. We will encourage interactions between and among group members[136] employing participatory techniques that elicit emotional elements and promote group interactions.[137-139] After each FGD, the facilitators will conduct a debriefing session to summarize findings, compare impressions, identify procedural problems, and develop plans for future FGDs

Key Informant Interviews (KIIs): The four key informants will be approached and recruited in collaboration with AMPATH CDM who have existing relationships with policymakers at both the national and county level. A trained research assistant will conduct each of the KIIs. Each KII will last approximately 30-45 minutes and will be audio-recorded. We will prepare and pilot-test an interview guide in a similar manner as above and revise it accordingly. In addition to asking about facilitators, barriers and contextual factors that may impact the strategy, the KIIs will also assess governmental readiness for change to implementing a new multi-level strategy.[134] For all qualitative sessions, a transport allowance and refreshments will be provided to participants.

Focus Group Discussions and Key Informant Interviews will be conducted in-person by the Principal Investigator (PI), Dr. Rajesh Vedanthan, or designated research team members, assisted by an interpreter. The study team will adhere to the COVID-19 regulations during the interviews including social distancing, wearing masks throughout the interviews, as well as sanitize and ensuring proper aeration. During the interview, the investigators will ask questions regarding incorporating health IT and peer delivery for improving medication adherence and control of blood pressure among hypertensive patients in PT4A participating communities.

Outcomes and Analysis: All FGDs and KII audio-recordings will be transcribed and translated into English by the research team, and all translated interviews will be double-checked for accuracy. We will perform content analysis of the transcripts and notes using NVIVO software.[140] Specific quotations, group interactions, and observations will be assigned codes based on content. Two co-Is will code two transcripts independently, after which they will compare codes, arrive at consensus, and develop a coding list with definitions for the remaining transcripts. In order to assess inter-coder reliability, we will randomly select 10% of transcribed pages to be coded by two co-Is, and the Kappa-statistic will be calculated. Discrepancies will be adjudicated by a third qualitative research co-I. We will then search the remaining transcripts for the following deductive (*a priori*) codes: (a) perception of adherence to hypertension medication; (b) perception of HIT; (c) perceptions regarding the role of social support; (d) perception of peer delivery; and (e) factors that may impact the success of the PT4A strategy. Significant inductive

(emerging) codes will also be identified, assessing for differences by sex. Coded items will be grouped into a hierarchical, branching structure in which broad concepts are first identified. Then themes and interpretive ideas emerging from those constructs are labeled using constant comparison techniques, and subsequently synthesized using matrices structured by the main themes of the analysis.[141,142] Findings from the FGDs and KIIs will inform the HCD strategy refinement (Sub-Aim 1.1).

Limitations and Alternative Strategies: We may have trouble recruiting for the FGDs. To mitigate this, we will adhere to the principles of community engagement as described above, and hold sensitization sessions among potential participants. Given our success recruiting for similar research recently,[91,109] we do not anticipate that this will be a significant issue. It is also possible to assess for these factors using a more quantitative approach. However, using the proposed type of qualitative methods, our team has successfully uncovered novel factors that have informed and impacted the implementation of previous strategies.[91,143,144] It is possible that we will identify factors that are not aligned with the planned components of the PT4A strategy; in this scenario, we will incorporate those factors into the human-centered design approach described in Aim 2.

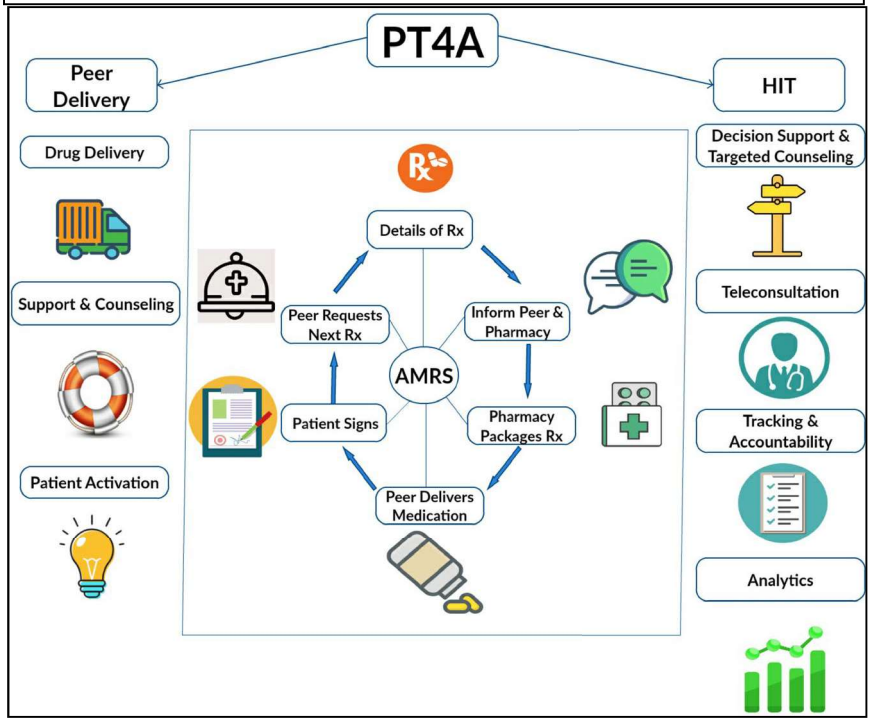
Aim 2: Use a human-centered design approach to refine and adapt the PT4A strategy (*to be implemented following completion of Aim 1 activities)*

We will pursue a participatory, iterative design process[122,123,145] and assemble a human centered design (HCD) team consisting of individuals representing stakeholder groups: research team, clinicians, pharmacists, peers, and patients with hypertension, informatics staff, and other providers involved in hypertension care. The design process will involve three phases: brainstorming, conceptualization, and creation. During brainstorming, the facilitator will review relevant information on adherence to hypertension medications, findings from Aim 1, and the PT4A prototype core principles and characteristics. In the conceptualization phase, the team will evaluate advantages and disadvantages of ideas resulting from brainstorming, and arrive at consensus regarding importance, feasibility, and congruence to the PT4A strategy goals,[146,147] in order to more concretely refine the strategy. In the creation phase, we will develop the refined PT4A strategy. Educational (for patients) and training (for peers) materials will be developed in English, Kiswahili, and other local languages as appropriate, using standard approaches to translation and back-translation.

Core components of the PT4A strategy will include a HIT component and a peer delivery component. Prototype characteristics of each are described as follows (Figure 3).

Health Information Technology: All of the HIT components will build upon, and be aligned with, the AMPATH Informatics infrastructure that has been established. We are working with leadership of the AMPATH Informatics program to ensure full alignment. Our PT4A intervention will augment AMRS to support peer-based delivery in four ways: 1) decision support and tailored adherence counselling: provide a patient-level and historical adherence summary that includes pill count, self-report, and clinical data synced with AMRS to generate tailored adherence counselling; 2) teleconsultation: facilitate teleconsultation via text or phone call between peers and clinicians; 3) tracking and accountability: provide timely prompts to peers when refills are near due, and capture participant signature to confirm receipt of medications to improve accountability; and 4) analytics:

Figure 3. Summary of the PT4A components



patient-level medication use analytics to predict future stock requirements for pharmacy supply chain. The specific design and implementation of the above will be iteratively improved via the participatory design process, as described in Sub-Aim 1.1. Each peer will be equipped with a tablet loaded with the AMRS-POC software and specific encounter forms and other features associated with the HIT component of the PT4A intervention. A Programmer will be hired as part of the Research staff, in coordination with the AMPATH informatics Program and approval by the Moi Research and Sponsored Projects Office and they will provide technical support and training for the peers.

Peer Delivery: This component will involve trained and paid peer-delivery agents who will cover a prescribed catchment area associated with each health facility in the intervention arm. Peers will play three roles: 1) Drug delivery: peers will deliver medication refills to the patient at a convenient location and time. Upon enrollment, clinical data from the AMRS, including the participant's current prescription and the next refill date, will be sent by AMRS to the pharmacy staff, in order for them to package the medication. Each patient's prescriptions will be individually packed in standard manufacturer-issued blister packs, which will be packaged in single-seal bags to prevent pilferage. A prompt will also be sent by AMRS to the peer, who will confirm with the patient delivery details (which drugs, quantity, location, date, and time for delivery). The peer will pick up the medication package from the pharmacy at the health facility and then deliver the medication to the patient, who will confirm receipt by digitally signing on the HIT tool. The peer will then request the next installment of medications from the pharmacy (via AMRS), accounting for any pills that the patient did not consume and are remaining in the blister pack. The peer will continue this cycle of medication delivery until the patient returns to the health facility for a follow-up clinic visit, when a new prescription will be issued by the clinician to the patient. The peer will then start a new prescription refill cycle for the patient. 2) Psychosocial support and adherence counseling: leveraging the peer-patient relationship,[148] and using the HIT-generated adherence data, the peer will provide adherence counseling and psychosocial support to patients at the time of medication delivery to address individual-level adherence barriers and any new issues that may have been discovered during Aim 1 activities. Peers will be trained in motivational interviewing, health coaching, and psychosocial support.[149] 3) Enhance patient activation: peers will use health coaching strategies to address concerns regarding medications, hypertension and other NCDs, and relationship with clinicians, thereby enhancing patient activation. Training, mentorship, supervision and monitoring of clinicians and peers on clinical content will be performed by the clinician investigators on the study who are qualified to do so,

complemented by the standard CDM training that is organized by CDM leadership and clinicians. Research assistant led training and supervision of peers will be limited to research related SOPs and other research content.

Sub Aim 2.1: Evaluate The Intervention For Acceptability And Appropriateness.

This will be implemented following completion of Aim 2 activities and analysis

Sub Aim 2.2: Conduct A Pilot of the Intervention and Evaluate Feasibility.

We will also conduct a pilot of the strategy for up to 1-year and conduct further FGDs to evaluate feasibility. We will select three pilot health facilities, one from each county. We will hire one peer delivery agent per facility, train them in core roles and responsibilities, and equip them with tablets. Each peer will be stationed at a specific health facility and will be able to communicate directly with the clinicians, pharmacy staff, and patients. To maintain patient confidentiality, all research staff and peers will receive study specific training on the need to at all times maintain participant confidentiality, in addition to receiving training in good clinical practice (GCP) and human subjects' protection (HSP) training. The HIT platform builds on the AMPATH OpenMRS system which encompasses patient data protection measures such as restricted access to authorized users only, which will further maintain patient confidentiality. We will recruit up to 100 patients from among these three facilities, targeting an equal number per county. In case there is a report of an adverse reaction to medications or new symptom by the participant to the peer during the pilot phase of the study, all peer navigators will be guided by a decision support system built into the HIT that will require the prompt notification of one of the two local pharmacist investigators in the study, as well as the patient's clinician. The peer will contact directly both the pharmacist investigator(s) and the appropriate clinician. Swift action will be taken based on the advisement of the clinician. Inclusion criteria will include age greater than 18 years, and currently enrolled in the AMPATH CDM program. Exclusion criteria will include acute illness requiring immediate medical attention, terminal illness, or inability to provide informed consent.

Table 3: Acceptability, Appropriateness, and Feasibility of the PT4A Intervention

	Outcomes
Acceptability	• Satisfaction with the proposed intervention design • Expressed interest or intention to participate
Appropriateness	• Perceived relevance of intervention to address adherence • Perceived fit within existing community and clinical infrastructure
Feasibility	• Anticipated success of implementing intervention in this setting • Perceived ease of implementing the intervention

We will collect data through a survey on process and implementation measures such as completeness of the peer delivery, satisfaction of the patients, patient activation, and fidelity of delivery strategy. We will conduct FGDs with patients and clinicians then conduct KII (Key informant interviews) with the peer delivery agents, focusing on contextual issues impacting implementation, suggestions for modifications, and concepts of feasibility (Table 3).The target group size for the FGDs is 6-10 participants but If there are insufficient numbers, we will accommodate a smaller size. FGD transcripts, data management, and analysis will be performed as described above. We have used this approach previously with success.[80,91,112,150]

We will evaluate the impact of the pilot on absolute mean change in SBP and medication adherence from baseline to up to 1 year. The primary adherence outcome is the pill count adherence ratio,[151] which is the proportion of prescribed doses taken over a 1-month time period, assessed at the end of the pilot. The primary implementation outcome is fidelity, measured as quantity and quality of intervention delivery as intended,[152] comprised of three components: confirmed medication delivery documented by patient e-signature, peer completion of the HIT form, and quality of data entry into the HIT form.

We will also create a retrospective comparator group of CDM patients, by querying AMRS, matched by sex, age, location and by initial blood pressure level. We will use their recorded blood pressure over time and compare the 3, month, 6 month and 1 year change in blood pressure to those of the patients receiving the PT4A intervention to evaluate the magnitude and variance of the intervention effects.

Rigor and Reproducibility

In addition to the rigorous study design described above, as well as the consideration of relevant biological variables including sex, we will create a data archive that will contain raw study data (no personal identifiers). This will be available to other investigators upon formal request made to the AMPATH Research Manager, following the publication of the primary analyses of the project, and after the data have been appropriately checked, cleaned and de-identified. The archive will reside on a server for which appropriate firewalls and other forms of data protection will be installed for maximum security. Prospective users will complete an application for use of the data, which will include queries about the users' project hypotheses and proposed analyses. All NIH regulations and restrictions as well as HIPAA Security Rules regarding personal health information will be observed.

Study Procedures, Materials, and Potential Risks

Aim 1: Qualitative data will not contain any patient identifiers. These data include transcripts of FGDs and KIIs, and observation notes. FGDs and KIIs will be digitally audio-recorded and uploaded with a coded identification number (no identifying names) as an audio file to an electronically secure database on a password-protected computer. These research data will be stored in a password-protected electronically secure database on a password-protected computer that will be known only to key research team members and the Study Coordinator. Once uploaded to the electronically secure database, the data will be deleted from the digital recording device. Any documents containing identifying information and consent documentation will be separated and added to the site's secure storage locker. Electronically captured data will transfer to the research database at the time of entry into the handheld device through a secure connection tunnel. All data on mobile devices will be encrypted and stored on the device's internal memory. All paper data collection forms will be reviewed by the Study Coordinator and Data Manager for completeness. Once validated, any sheets containing directly identifiable information and consent documentation will be separated and added to the site's secure storage locker. The remaining, de-identified pages will then be placed in a separate storage locker prior to data entry. Only key investigators and study personnel will have access to individually identifiable private information about human subjects. Transcription of the audio files will occur in Kenya. These transcripts will also be stored in an electronically secure database on a password-protected computer.

Aim 2, Sub-Aim 2.1 and Sub-Aim 2.2: All clinical patient-level data will be entered into the AMPATH Medical Record System (AMRS) as per AMPATH's standard operating procedures. A separate, password-protected research database will retrieve data from AMRS via access that will be controlled through user authentication. All data collected on paper forms will be transferred to the password-protected REDCap research database hosted by Moi University, using double data entry. Electronically captured data will be collected using the REDCap Mobile App, which enables offline data collection, then transferred to the password-protected REDCap research database through a secure connection tunnel. All data on mobile devices will be encrypted and stored on the device's internal memory. All paper data collection forms will be reviewed by the Study Coordinator and Data Manager for completeness and the presence of prespecified "danger" values. Once validated, any sheets containing directly identifiable information and consent documentation will be separated and added to the site's secure storage locker. The remaining, de-identified pages will then be placed in a separate storage locker prior to data entry. Only key investigators and study personnel will have access to individually identifiable

private information about human subjects. Qualitative data will be collected and handled in the same manner as Aim 1 above.

All research activities will be performed by CITI-certified research staff members. All data will be stored on dedicated, password-protected computers. Any data stored on portable media will be PGP-encrypted, in order to ensure security of the data. Paper forms will be stored for the duration of the study, and for one year following in order to allow verification of any data as needed for reporting and publication purposes. The paper forms will then be shredded. The electronic data with a coded identification number only (and no identifying names) may be kept indefinitely, in a secure manner as described above. Many of the questions used in this study carry a minimal risk of harm. Some of the questions in the focus group discussions, and interviews may be personal and may be considered sensitive or embarrassing. However, the project personnel will take measures to ensure that each subject's confidential information is secure and cannot be linked back to one's identity by anyone not involved in the study. Furthermore, there could be personal psychological stress related to a newly diagnosed health condition.

Known Potential Benefits
The benefits to the study participants are two-fold. First, the information and data collected in Aim 1 will impact the implementation of strategies which enhance the adherence to hypertension medications and we will be able to modify its implementation based on the results of the research. Thus, the results of the research have the potential to decrease the cardiovascular risk, morbidity and mortality associated with elevated blood pressure. In addition, the cluster randomized trial, multiple-criteria decision analysis, and spatial analysis results will reveal important information that will benefit the stakeholders and subjects involved in the research, as well as to other individuals not directly involved in the research. We feel strongly that the benefits of such knowledge and the potential impact on the implementation of AMPATH's chronic disease management program greatly outweigh the minimal risks of the research procedures as described in the Research Strategy.

The knowledge gained from this study will also yield a direct benefit to the communities residing in Bungoma, Trans Nzoia, and Uasin Gishu Counties due to the direct applicability of the results to program implementation. In addition, other clinical sites within the AMPATH network will also benefit from the results of this research. Finally, other resource-poor communities in low-, middle-, and high-income countries may benefit from the results and insights generated from this project.

In sum, we believe that this project involves minimal to low risk to the research subjects. Research subjects themselves stand to benefit substantially from the research activities. In addition, the benefit of the information obtained and disseminated to the study population as well as the greater population of Kenya, and its use to design scalable medication adherence interventions for chronic disease management, far outweigh the risks associated with this study. The projects expected benefits far exceed the expected risks, and therefore has a very low risk-benefit ratio.

ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Adequacy of Protection Against Risks

A. Informed Consent and Assent

The study team will consist of local personnel and individuals from western Kenya who are familiar with the region. With the support of AMPATH and community leadership, the key investigators and Study Coordinator from MTRH will approach the subjects involved in Aim 1 in-person. Written

consent will be obtained from each individual. Consent forms will standardize the description of the study and will be given to each subject. For Aim 1, activities requiring a consent form are the key informant interviews and focus group discussions. At the end of the subject's reading, the interpreter will ask the subject if s/he has any questions. Study candidates will be provided information in terms that they can fully understand, not exerting any overt or covert coercion. A consent document will be used that is written and explained in the language that the potential subject understands (Kiswahili or English). Extreme care will be taken to fully explain the benefits and risks of the research before consent is obtained. The consent forms will be written in lay terminology at approximately 6th grade level. For Aim 1, the study subjects will provide written informed consent prior to any focus group discussion or key informant interview.

For Aim 2, the clinician will invite AMPATH CDM Program patients with uncontrolled hypertension and who are eligible for the study from the health facility to enroll in the study on the day of their routine clinic visit. On that day, research team members will describe the research study and the study protocol, and ensure the patient meets eligibility criteria. For patients randomized to the PT4A intervention arm, participants of will be informed the Health Information Technology (HIT) functionality and the availability of peer delivery agents who can deliver the medications to them. As above, extreme care will be taken to fully explain the benefits and risks of the research study, before consent is obtained. Written informed consent will be obtained from all participants. For Aim 2, activities requiring a consent form are the human-centered design FGD and the human-centered design survey. For Aim 2.1, a consent form will be developed and implemented to obtain written informed consent to participate in the FGD. Finally, for Aim 2.2, consent forms will be developed and implemented to obtain written informed consent in the Aim 2.2 FGD and participation in the pilot study. The consent forms will be written in lay terminology at approximately 6th grade level. For FGDs, written informed consent will be obtained in the same manner as above.

Individuals will be free to refuse to participate in the study at any time during the period of the study. A refusal will not impact the health care available to the individual in any manner. Access to care will not be impacted in any manner by an individual's decision to opt out of this research project.

AMPATH's Chronic Disease Management program in western Kenya provides clinical care for diabetes and hypertension using a robust and evidence-based clinical protocol, and is available at the rural health facilities (all government of Kenya primary care facilities) in this region. This care program includes facility-based testing and counseling, referral to the nearest appropriate health facility, clinical care at the health facility, and follow-up as required. All of the nurses and clinical officers who staff the chronic disease management program at the health centers and rural dispensaries have been trained in hypertension management according to the AMPATH protocol. Both the management protocol and the chronic disease management trainings have been developed jointly with the Ministry of Health and the District Health Management Team (DHMT) (Government of Kenya). In addition to an initial training workshop, continuing medical education sessions are organized every quarter during which hypertension and other topics are covered. Refresher trainings are also planned on an annual basis in order to update and assess nurses' knowledge and practices regarding hypertension management. Finally, AMPATH has used novel and innovative smartphone technology to create a clinical decision support and record-keeping system for the clinicians at the health facilities, in order to ensure that the standard-of-care AMPATH hypertension management protocol is adhered to by the practitioners. All individuals with hypertension or suspected hypertension are provided care in these clinical settings. In addition to AMPATH CDM Program described above, clinical care is available at mission hospitals, private clinics, and referral hospitals, and every individual will be informed of

his/her option to receive care at any of these health facilities. All individuals will be able to attend any of these health facilities for care, and this will not be impacted in any manner by an individual's decision to opt out of this research project. This will be made clear during the informed consent process.

B. Protections Against Risk

The following principles and procedures for data collection will be followed at the research site in order to minimize risk and protect confidentiality:

- Data will be collected on coded forms, which do not include other personal identifiers.
- Only the tracking form will have the participant's name and identifiable information.
- Study records will be stored in locked cabinets in a locked room only accessible by key staff at MTRH in Eldoret, Kenya.
- Only the study personnel will have access to the data and the codes.
- All computerized information will be protected by access codes known only to key investigators and certain designated staff members.
- No data will be published with participant names.
- Data that are contained on a digital audio recording device will be PGP-encrypted and the only identifying information captured during the recording will be the recording of the participants' voices.
-
- All staff members will be trained to keep participants' information confidential, and will be informed of the penalty for breach of confidentiality.
- Any data accessed by NYUGSoM study personnel will be viewed and stored only on MCIT-approved computers and software.

The consent form signed by the participant will provide written assurance that all individual data collected in the study will be kept confidential to the extent provided by the Privacy Act of 1974. AMPATH will provide file security so that confidential data are not released. Specifically, participants will be informed that: (1) the only people who will know that they are research participants are members of the research team and, if appropriate, their physicians or health care providers; (2) no individual identifying information about them will be disclosed to others, except if required by law; and (3) when the results of the study are published or discussed in conferences, no information will be included that would reveal their identity. Any material that is digitally audio-recorded will be uploaded with a coded identification number (no identifying names) as an audio file to an electronically secure database The only identifying information captured during the recording will be the recording of the participants' voices. These research data will be stored in an electronically secure database protected by password that will be known only to the Principal Investigator and the Study Coordinator. Once uploaded to the electronically secure database on a password-protected computer, the data will be deleted from the digital recording device to protect confidentiality and minimize the risk of breach of confidentiality. Transcription of the audio files will occur in Kenya by trained research team members who have undergone human subjects research training certification. Transcripts will not be shared with anyone outside of the study team.

All clinical patient-level data will be entered into the AMRS as per AMPATH's standard operating procedures. A separate, password-protected research database will retrieve data from AMRS via access that will be controlled through user authentication. All data collected on paper forms will be transferred to the research database using double data entry. Electronically captured data will transfer to the research database at the time of entry into the handheld device through a secure

connection tunnel. All data on mobile devices will be encrypted and stored on the device's internal memory.

All data management will be carried out by CITI-certified research staff members, and all data will be stored on dedicated, password-protected computers. Paper forms will be stored for the duration of the study, and for one year following in order to allow verification of any data as needed for reporting and publication purposes. The paper forms will then be shredded. The electronic data with a coded identification number only
(and no identifying names) may be kept indefinitely, in a secure manner as described above. Data containing residential locations/addresses (person-identifiers) are considered highly sensitive

To prevent inadvertent disclosures and ensure subject confidentiality, data entry and document storage for materials containing directly identifiable information (i.e., coversheets) will be handled by key investigators or the Study Coordinator. The Study Coordinator will be responsible for the secure handling and storage of survey documents for the duration of research activity at the study site. Once activities have been completed, coversheets will be collected and forwarded to the AMPATH research office, where they will be stored in a secure, locked cabinet within a secure, locked room. To minimize the number of people with access to the
coversheet data, all data entry will be conducted under the direct supervision of the Study Coordinator. Once identifiable data has been entered as described, paper-based documents will be returned to secure storage. Data collected in the study will be used for research purposes only. The results of this research project will be summarized for reports and may be summarized for presentation at meetings or in publications. No individual identities will be disclosed in any of these reports or presentations. Furthermore, No data will be reported on an individual basis; all findings will be presented in aggregate form.

We recognize that "macro-level" structural and environmental factors such as cost of medicines and poorly equipped health facilities may be more important than the peer delivery and HIT intervention. However, addressing these macro-level factors is integral to the AMPATH CDM Program's operations, which have already been universally applied to all of the rural health facilities throughout the research catchment area. For instance, AMPATH has established community-based revolving fund pharmacies to ensure that there is adequate stock of the required medications in every rural health facility. The rural health facility committees described above are intimately involved with the establishment of these revolving fund pharmacies, in order to ensure community participation, ownership, and empowerment. The AMPATH pharmacy team has a pharmacy technician designated to supervise these revolving fund pharmacies and ensure accountability, proper storage and record-keeping. Likewise, the AMPATH CDM Program has equipped the rural health facilities with blood pressure machines, filing cabinets, desks, and other infrastructure to facilitate the clinical care program. In addition, the CDM program has consciously chosen to implement the clinical care program in the rural health facilities precisely because of proximity to the local communities, villages, and households. Moreover, as described above, AMPATH has developed a training curriculum jointly with the MOH and the DHMT that addresses both the theoretical and practical aspects of diabetes and hypertension management. Combined with the clinical decision support, AMRS, mentorship, and supervision described above, AMPATH is implementing comprehensive strategies to optimize the human resources dedicated to hypertension management in this region. Finally, the AMPATH Safety Net Program is actively engaged in income-generating and financial security activities for the communities of western Kenya, in order to address the economic situation confronted by those populations. We feel that AMPATH's efforts to address these macro-level factors will both address human subjects concerns, as well as support the implementation of the intervention strategy described in the grant application.

MILESTONES

The milestones to be achieved for this portion of the project are listed in Table 4, along with details of each milestone's objectives, activity, target completion date, performance goal and metric, and anticipated challenges and mitigation strategies.

Aim	Milestone	Objective	Activity	Completion Date (Month)	Performance Goal	Performance Metric	Data Source	Anticipated Challenges and Potential Mitigation
Preparatory Phase		1. Develop standard operating procedures and study protocols	Develop study protocols and standard operating procedures	M2	100% of SOPs completed	# of SOPs started, % finalized	Completed SOP document	***Challenge:*** Delays in coordinating SOPs across multiple regions ***Mitigation:*** Regular conference calls among investigators and research team members, clear and enforced deadlines
			Develop data collection tools	M2	100% of data collection tools finalized by completion date	# of data collection tools initiated, % successfully completed	Data collection tools records	***Challenge:*** Delays in creating uniform data collection tools across multiple regions ***Mitigation:*** Regular conference calls among investigators and research team members, rigorous pilot testing, consensus-building activities
			Receive IRB approval	M2	100% protocol approved by all parties by completion date	% approval received from required parties	Finalized protocol and supporting documents	***Challenge:*** Delays in receiving approval for all updated study material ***Mitigation:*** team will work with the IRBs to streamline approval process and will create a strategic plan to ensure content quality and completeness
		2. Hire and train research team	Hire and training of staff	M3 (and ongoing as new staff are hired)	100% of staff hired and trained by the target completion date	# of new staff hired and trained on relevant study methods	Sign-in sheets from trainings	***Challenge:*** Unforeseen barriers related to HR hiring policies and procedures at individual institutions ***Mitigation:*** Incorporate additional time for any additional unforeseen time barriers/institutions requirements that may delay onboarding and training of new staff, and adjust training schedule as necessary
			Obtain human subjects training certification	M3 (and ongoing as new staff are hired)	100% of staff have completed human subjects certification by target completion date	# staff that have successfully completed human subjects training	Training record log and documented CITI certifications	***Challenge :*** Human subjects research may take longer than anticipated. ***Mitigation:*** Research coordinator will create and review a training record log on a weekly basis of all research staff, and report to PI.
Aim 1 **Identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy**	**Conduct a thorough baseline contextual assessment of barriers and facilitators for implementing PT4A**	1. Conduct qualitative interviews (Focus Group Discussions and Key Informant Interviews)	Develop and conduct pre-tests of qualitative interviews and discussion guides	M2	100% of all interview and discussion guides developed; & 100% of all pre-tests conducted	# of interviews and discussion guides completed	Finalized interview and discussion guides	***Challenge:*** Delays in creating uniform interview and discussion guides across multiple regions and countries ***Mitigation:*** Regular conference calls among investigators and research team members, rigorous pilot testing, consensus-building activities
			Conduct in-depth key informant interviews and FDG's	M5	100% of all interviews conducted	# of interviews conducted	Interviews	***Challenge:*** All interviewees may not be available to be interviewed at scheduled times ***Mitigation:*** Research coordinator and research assistants to schedule all participants with backup times scheduled as necessary
			Transcribe and translate interview recordings	M5	100% of all interview recordings transcribe and translated	# of interviews conducted, translated, and transcribed	Interview transcripts	***Challenges:*** Lengthy interview recordings; multiple language translation required ***Mitigation:*** Allocate more time for transcription and translation
		2. Analyze qualitative data	Create data analysis code book	M5	100% of code books developed	# of code books developed by research team	Code books	***Challenge:*** Difficulties in creating uniform coding scheme across multiple regions ***Mitigation:*** Regular conference calls among qualitative investigators and analysts; Kappa statistic threshold
			Code and analyze qualitative data	M6	100% of transcripts coded and analyzed	# transcripts coded and analyzed	NVivo database	***Challenge:*** Difficulties in harmonizing qualitative data analysis across multiple regions ***Mitigation:*** Documenting context-specific differences that arise from the transcripts; ensure that qualitative analytic team consists of individuals representing all regions and countries
Aim 2 **Use a human-centered design approach to refine and adapt the PT4A strategy**	**Refine the peer delivery and HIT components**	1. Human-centered design process	Conduct human-centered design process	M8	100% of brainstorming, conceptualization, and creation of process completed	# of HCD sessions completed	Sign-in sheets from sessions	***Challenge:*** Difficulty assembling HCD team with adequate representation of all key stakeholders, and difficulty scheduling sufficient sessions based on stakeholder and project staff availability ***Mitigation:*** Incorporate additional time for any additional unforeseen time barriers/institutions requirements that may delay recruitment and implementations, and adjust schedule as necessary
		2. Acceptability and appropriateness testing	Conduct FGDs with patients, peers and clinical staff	M9	100% of all interviews conducted	# of interviews conducted	Interviews	***Challenge:*** All challenges from qualitative data collection from Aim 1 above will apply ***Mitigation:*** All mitigation from qualitative data collection from Aim 1 above will apply, as appropriate
			Code and analyze qualitative data	M9	100% of transcripts coded and analyzed	# transcripts coded and analyzed	NVivo database	
		3. Conduct a pilot of the intervention and evaluate feasibility.	Pilot implementation	M11	100% of pilot activities implemented	# of patients who were recruited and received pilot intervention	REDCap database	***Challenges:*** Unforeseen delays in county engagement; lower-than-anticipated enrollment ***Mitigation:*** Community-based screening events, community entry, clinician engagement, approval from clinic and regional administrators
			Feasibility Testing	M12	100% of testing activities completed	# of FGDs completed	Interviews	***Challenge:*** All challenges from qualitative data collection from Aim 1 above will apply ***Mitigation:*** All mitigation from qualitative data collection from Aim 1 above will apply, as appropriate
			Analysis	M12	100% completion of pilot data analysis	% of pilot data analysis completed	Pilot data collected on REDCap and Nvivo	***Challenge:*** Incomplete data from implementation phase ***Mitigation:*** An algorithm that factors in missing data will be developed prior to data collection
Research Products	**Publications and abstracts related to the aims**	1. Complete publications and abstracts related for Aims 1 and 2	Prepare and submit publications and abstracts for peer review to relevant journals	M8, M12	100% of planned publications and abstracts submitted for review	# of abstracts and publications submitted	All data collected and analyzed from Aim 1&2	***Challenge:*** delay in data collection and subsequent analysis, thus preventing writing initiation and completion ***Mitigation:*** incorporate additional time for completion of writing of publications
	Subsequent R01 grant submission	1. Identify target study population for subsequent R01	Rank potential study regions according to MCDA results and other factors	M7	100% of study sites selected	# of clusters and health facilities selected	MCDA results; Aim 1 results	***Challenges:*** All challenges from Aim 1 and Aim 2 Milestone activates below will apply; in addition, ranking might be subject to differential weighting. ***Mitigation:*** All mitigation strategies from Aim 1 and Aim 2 Milestone activities will apply; in addition, all investigators and relevant stakeholders if appropriate, will discuss and ultimately arrive at consensus for all study regions, study sites, and health facilities to be included in the subsequent R01
		2. Establish collaborative partners for subsequent R01	Reach out to and meet with key stakeholders for collaboration (community members, healthcare workforce, and policy makers)	M7	100% stakeholder representation reached from community members and leadership, healthcare workforce, and policy makers across all enrollment institutions	# of stakeholders engaged at each enrollment institutions	Stakeholder meetings and signed letters of engagement agreements	***Challenge:*** Difficulty of access due to the geographical location of facilities may be underestimated; stakeholders might be hesitant to collaborate ***Mitigation:*** A two-week buffer period will be provided for qualitative interviews with unforeseen access challenges; engage in community entry activities; attempt to align project objectives with interests of all stakeholder parties.
			Recruit and establish collaboration with baseline facilities	M7	100% of facilities recruited as baseline study sites	# of facilities recruited for qualitative activities	Stakeholder meetings and signed letters of engagement agreement from medical superintendents	
		3. Submit R01 Grant Application	Prepare and submit R01 grant application	M7	100% of grant submission activites completed by appropriate NIH deadline	1 R01 submitted grant	Analysis results from Aim 1 and 2 as available	***Challenge:*** delay in data collection and subsequent analysis, thus preventing possibility of completion of R01 application ***Mitigation:*** incorporate additional time for R01 grant application submission, based on NIH deadlines, if necessary

TABLE 4: PT4A MILESTONES1

Timeline

	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Preparatory Phase												
Finalize protocol manuals	■	■										
Finalize standard operating procedures	■	■										
Develop data collection tools	■	■										
IRB approval		■										
Hire and train staff	■	■	■									
Aim 1												
Focus Group Discussions			■	■	■							
Key Informant Interviews				■	■							
Analysis				■	■	■						
Aim 2												
Human-Centered Design Process						■	■	■				
Sub-Aim 2.1												
Acceptability and Appropriateness Testing								■	■			
Sub-Aim 2.2												
Pilot Implementation									■	■	■	
Feasibility Testing											■	■
Analysis												■
Research Products												
Community dialogue and input		*	*	*		*		*		*		*
International Advisory Committee Meetings				x								x
International Conferences								§				§
Publications								‡				‡
R01 Grant Application							Δ					

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APPENDIX A.

PT4A AIM 2 STUDY PROTOCOL

Project Title: Human Centered Implementation Research for refining and adapting the Peers and Technology for Adherence, Access, Accountability and Analytics (PT4A) Strategy.

Abstract: Medication adherence is a much needed avenue of recourse in order to reduce cardiovascular disease (CVD) and death resulting from complications of high BP[1-4]. To address these hurdles, we hypothesize that the PT4A strategy, which has a component of peer delivery of medication and Health Information Technology**,** can be an effective implementation strategy to positively influence several micro- and macro-level factors leading to improved adherence to hypertension medications. In this study we will use the human centered design (HCD) approach to refine this proposed strategy. HCD is increasingly applied to implementation research, and it has successfully been used in previous studies[7-8]. This process starts with the people you are designing for and ends with new solutions that are tailor-made to suit their needs. It builds upon participatory action research, and our protocol includes: patients who are hypertensive, clinical teams providing care to the patients, and community members, who will provide insights on HTN management in a community setting. Initial stages usually revolve around immersion, observing, and contextual framing in which innovators immerse themselves with the problem and community. Subsequent stages may then focus on community brainstorming, modeling and prototyping, and implementation in community spaces.[9] The PT4A Strategy will undergo the following human-centered design processes: the Inspiration phase, Ideation phase, and Implementation phase. An HCD team consisting of individuals representing stakeholder groups: research team, clinicians, pharmacists, peers, patients with hypertension, informatics staff, and other providers involved in hypertension care will go through a participatory and iterative process to help in refining this implementation strategy.

In the Inspiration phase we will learn directly from the people we are designing for. In this case using qualitative research methods as described in Aim 1, we will conduct a thorough baseline contextual assessment of barriers and facilitators for implementing PT4A, and will gain a deeper understanding of the patients, community, and healthcare workers needs and opportunities for solutions. The interview questions employed participatory techniques that elicited emotional elements and promoted group interactions. [10-12]. The information that will form the guiding themes that will inform the PT4A strategy refinement include: (a) perception of adherence to hypertension medication, (b) perception of HIT, (c) perceptions regarding the role of social support, (d) perception of peer delivery, and (e) factors that may impact the success of the PT4A strategy.

We will explore insights into tangible ideas, divergence and convergence coming closer to the solution that can work best. It is the expectation that team members can have varying ideas when giving solutions but through the process we are able to get a solution that can work and is acceptable with many.

In the Ideation phase we will make sense of the information learned, identify opportunities for design, and prototype possible solutions. During this phase we will look at the actionable items around the core structure of using a peer to deliver medication and the use of the mobile device as a health information support tool.

In the Implementation phase we will bring the solution to life, and eventually, to implementation in the real world. Once the refined PT4A strategy model is developed, we will conduct o assess acceptability and appropriateness. Participants will be recruited through convenience sampling and will provide written informed consent. The initial prototype diagrams will convey key

features of the strategy to the participants and depicted use from the patient, clinician, and peer delivery agent perspectives.

PARTICIPANTS

A team consisting of individuals representing stakeholder groups (in total number 20): research team, clinicians, pharmacists, peers, patients with hypertension, informatics staff, and other providers involved in hypertension care will make up the design team. They will be recruited from across the three counties participating in the study. Participants will be reimbursed for their time, transportation and will be served a snack during design team meetings.

METHODOLOGY:

The design team (DT) will meet for a total of 6 meetings over the course of the process, in order to develop and iteratively adapt the integrated door to door peer delivery of medication and Health Information Technology (HIT) intervention.

Preliminary Activities: Baseline information will directly inform our design process. Data collected using qualitative methods that consist of key informant interviews and focus group discussions on the Micro and Macro level contextual factors (individual, family, clinician, health system) that might influence the implementation of the PT4A strategy will be presented before commencing our HCD design process; information on this process can be found in the parent study protocol.

Baseline Technology: All of the HIT components will build upon, and be aligned with, the AMPATH Informatics infrastructure that has been established.

Our PT4A intervention will augment AMRS to support peer-based intervention in four ways:

1) Decision support and tailored adherence counseling: provide a patient-level and historical adherence summary that includes pill count, self-report, and clinical data synced with AMRS to generate tailored adherence counseling;

2) Teleconsultation: facilitate teleconsultation via text or phone call between the patients and clinicians, by the help of the peer.

3) Tracking and accountability: provide timely prompts to peers when refills are near due, and capture participant signature to confirm receipt of medications to improve accountability.

4) Analytics: patient-level medication use analytics to predict future stock requirements for pharmacy supply chain. The specific design and implementation of the above will be iteratively improved via the participatory design process.

Design Process Goals: The Design Team will be asked to identify and prototype potential solutions to issues raised in the baseline needs and contextual assessment, in addition to the following 4 core elements of the integrated HIT, the door-to-door medication delivery, and peer support intervention:

Design Team Meeting #1: Inspiration

Session A:

- DT members will introduce themselves and review expectations for the design process, including the scope of work for the design team and the expected process to be followed during the design team, including the role of the research team in co-design and approval of the final intervention.
- PT4A research team members will introduce human-centered design methods through a presentation

- DT members will share their personal experiences with patient medication adherence challenges and support.

Session B:

- PT4A research team will introduce findings from Aim 1 activities; the design team will compile salient and interesting insights from the following findings: (a) perception of adherence to hypertension medication; (b) perception of HIT; (c) perceptions regarding the role of social support; (d) perception of peer delivery; and (e) factors that may impact the success of the PT4A strategy and create post-it notes
- Notes will be posted on the walls and arranged into clusters based on topics and patterns, forming central themes

Expected outcomes:

- Introduction and group logistics
- Understanding of the HCD process and definition of roles
- Creation of themes that we lead to development of insight statements.
- Start the synthesis process of ideation

Design Team Meeting #2: Brainstorming

Session A:

- DT members will engage in icebreaker activities & review previous meeting discussions.
- PT4A STUDY research team will identify themes based on summary statements from DT Meeting #1
- DT will break into small groups and create "How might we…" questions to address summary statements (i.e. *"How might peers best deliver the medication?"*)
- DT will select up to 5 HMW (How Might We) questions and post them on the wall

Session B:

- DT will break into small groups and brainstorm solutions to each problem in 15-minute rotations (i.e. *"the peers delivering medication and offering psychosocial support"*)

- PT4A team will introduce baseline core functions for the peers as follows and address HWM around the following issues to be addressed.
  1) Drug delivery: peers will deliver medication refills to the patient at a convenient location and time.
  2) Confirmation of the medicine delivery with the patient delivery details (which drugs, quantity, location, date, and time for delivery).
  3) Psychosocial support and adherence counseling: leveraging the peer-patient relationship and using the HIT-generated adherence data, the peer will provide adherence counseling and psychosocial support to patients at the time of medication delivery to

address individual-level adherence barriers and any new issues that may have been discovered during Aim 1 activities.

Beyond the above, the DT may deliberate on additional functions for the peers, or introduce sub-functions within the above

Expected outcomes:

- Creation of insight statements that will lead to how might we questions

Design Team Meeting #3: Conceptualization

Session A:

- DT members will engage in icebreaker activities & review previous meeting discussions.
- DT will discuss how might we question and propose each solution, evaluate advantages/disadvantages, and group similar ideas together
- DT will discuss the positive and negative effects of the proposed solutions.
- DT will vote to select up to 3 solution ideas for each HMW (How Might We) question
- DT will break into small groups and storyboard stakeholders' experience with this intervention using wall notes

Session B:

- DT will discuss each storyboard as a large group and select 1-2 solutions for each HMW question that will be prototyped during acceptability testing. If not already discussed, DT will address background logistics that underlie this integrated peer support intervention, including:
    - **The peer role**
        - How peers are recruited (Age, Gender, Education level)
        - Peer-patient relationship (Interpersonal skills)
        - The frequency of contact between the peer and the patients
        - The mechanism of contact with patients (SMS, phone, etc.)
        - The process of delivery of medication refills to the patient at a convenient location and time.
        - Confirmation of the medication delivery

Expected outcomes:

- Discuss the strongest solutions proposed

Design Team Meeting #4: Creation

Session A:

- DT members will engage in icebreaker activities & review previous meeting discussions
- DT members will discuss the solutions in detail and come up with models as to where we will refine the proposed intervention
- The research team will integrate selected solutions into a first-draft intervention model

Session B:

- The draft interventional model will be presented and members will be asked to provide for any additional input they may have.
- DT will present intervention model to the study investigators, AMPATH Informatics team, and other key stakeholders
- Investigators will be invited to provide input and discuss intervention features with the DT

Expected outcomes:

- Present final intervention model
- Finish creation of training materials

Throughout the process, the research team will develop training materials for providers and peers, data collection and encounter forms, and the questionnaires to be used during acceptability testing, PT4A research team members will maintain frequent and ongoing communication with the DT throughout the process. The PT4A research team and Informatics team will be responsible for ensuring that the DT proposes solutions that are compatible with existing technologic capabilities and feasible within the health system.

Outcomes and Analysis

Throughout the DT meetings, a designated scribe will take detailed notes, photographs, and audio records to capture the design process and how each idea was developed. This data will be used as descriptive indicators of our design process and group participation. The DT will submit a first-draft model of the intervention to the investigators, the research team, and AMPATH Informatics team. This model will include the basic features of the intervention, detailed descriptions of the different roles involved, and a description of the patient, peer delivery agent and provider experience in a variety of scenarios. The research team and Informatics team will be responsible for creating the prototype of this model for acceptability testing.

Subaim 2.1: Evaluate the intervention for acceptability and appropriateness

After the PT4A model prototype is created we will evaluate how applicable and workable the core components of PT4A will be more so in terms of cost, complexity, usability, and value.

Participants (targeted number of 39 in total will be enrolled), this will include representatives of the end users of our product, which includes: hypertension patients (5 per site), clinicians (5 per site), pharmacy (1 per site) and peers (6 in total). Participants will be recruited through convenience sampling within the 3 counties where we will conduct the study. Participants will be reimbursed for time and travel through PT4A funds during those sessions.

Methods:

Participants will be recruited through convenience sampling and will provide written informed consent. We will conduct surveys in three counties with a similar distribution of participants to gauge

perspectives from various stakeholders in the model; this will include patients, peers, and clinical staff. Initial prototype diagrams will be shared with the group and presented from the perspective of each type of stakeholder to fully inform them of their role within the model. A structured questionnaire will be used to elicit constructive feedback from the group.

Outcomes and Analysis:
Statistical Analysis will include descriptive statistics of outcomes of interest including:
1) Satisfaction with the proposed intervention design, 2) perceived appropriateness, 3) fit within existing community and clinical infrastructures, 4) perceived positive or negative effects, 5) expressed interest or intention to participate, 6) perceived relevance to address adherence to medication, 7) barriers to implementation within existing community and clinical infrastructure, 8) ease of implementing this intervention. At the conclusion of this analysis, the design team will meet to review these outcomes and refine the intervention model as necessary to enhance acceptability.

Design Team Meeting #5: Iteration 1

Session A:
- DT members will engage in icebreaker activities and review the last meeting discussions
- The PT4A research team will present and discuss findings from acceptability and appropriateness testing
- DT will group issues raised from the interview surveys into themes and propose intervention updates

Session B:
- DT will create an updated intervention model and submit this to the study investigators, research team, and Informatics team
- DT will be divided into two groups and participate in FGDs to evaluate their experience during the HCD process

Subaim 2.2: Conduct a pilot of the intervention and evaluate feasibility

Participants:
Three health facilities will participate in the pilot (one from each county involved in the study). One peer delivery agent will be hired per facility and will be in close contact with clinicians, pharmacy staff, and patients at each health facility. The study will include all who are involved in the care for these patients and we target to enroll a total of up to 100 patients in this phase. ~~Ten patients per facility.~~

Inclusion criteria
- Greater than 18 years of age.
- Currently enrolled in an AMPATH CDM Program

Exclusion criteria
- Acute illness requiring immediate medical attention
- Terminal illness
- Inability to provide informed consent

Methods:

The pilot study will be conducted over a 3-month period. Peers will be paid through the PT4A funds. After recruitment and hiring, they will be on-boarded through a week-long training that will cover: i) basic training on hypertension care, ii) use of the PT4A HIT tool to ensure proper documentation of medication pick-up, medication delivery, and peer-patient encounter documentation; iii) providing psychosocial support for hypertensive patients aimed at supporting medication adherence and promoting patient activation. Peers will use the AMRS system (peers will have access to a tablet with access to the HIT/AMRS system, and technological support will be provided by research and the Ampath informatics team) to request a prescription for a patient in the provider catchment. The AMRS system will send the prescription from the healthcare provider to the pharmacy that covers that network. The pharmacy will prepare individually sealed blister bags in individual single seal bags to lower pilferage. Once packaging is complete, the AMRS system will send a message to the peer with the name, date/time of delivery, location, type of drug, and quantity to ensure the right medication is picked up at the right time. The peer will pick up the prescription and then deliver the medication to the patient, confirming receipt by getting a signature from the patient on the HIT tool. The peer will then request the next installment of medications through the AMRS system, taking into account any pills not consumed (remaining in the blister pack). This cycle will repeat until the patient has to see the clinician again, where the clinician will provide a new prescription. During these deliveries, peers will leverage adherence data to support patients and address any barriers to medication adherence. The overall goal of this psychosocial support will be increasing patient activation.

Outcomes and Analysis:

We will collect data on implementation such as completeness of the peer delivery, satisfaction of the patients, patient activation, and fidelity of delivery strategy. Patient satisfaction will be measured through a survey adapted from the AIDS Clinical Research Trials Group tool used extensively throughout Kenya and in the Harambee study[13]. Patient activation will be measured through the Patient Activation Measure assessment developed by Insignia Health. Fidelity will be measured as quantity and quality of intervention delivery as intended, comprised of three components: confirmed medication delivery documented by patient e-signature, peer completion of the HIT form, and quality of data entry into the HIT form, which will be assessed by checking for completeness, accuracy and coherent filling of the responses. Completeness of delivery will include these metrics of fidelity in addition to other quality assurance measures centering on medication packaging as well which will be done by the research assistant as the study goes on. We will also conduct surveys with patients, clinicians, and peer delivery agents, focusing on contextual issues impacting implementation, suggestions for modifications, and concepts of feasibility, that is, if the process of delivery and counseling has been successful or not successful in all the settings and the perceived ease of implementing the intervention. We will also evaluate the impact of the pilot on absolute mean change in SBP and medication adherence. The primary adherence outcome is the pill count adherence ratio, which is the proportion of prescribed doses taken over a 1-month time period, assessed at the end of the pilot.

Design Team Meeting #6: Iteration II

Session A:

- DT members will engage in icebreaker activities and review previous discussions
- PT4A research team will present and discuss findings from pilot study
- DT will group issues raised in FGDs and from study investigators into themes and propose intervention updates

Session B:

- DT will create a final intervention model and submit this to the study investigators, research team, and Informatics team
- The research team will conduct individual surveys with DT members to evaluate their experience during the HCD process

The research team and Informatics team will be responsible for creating the final intervention model that will be used for more widespread implementation.

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APPENDIX B. STUDY INTERVIEW QUESTIONNAIRES

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Acceptability of Intervention Measure (AIM) for Patients Living with Hypertension

Study ID:	Date:
Age:	Gender:
1. Education/ Elimu □ No formal education/ Hakuna elimu rasmi □Primary/ Shule ya Msingi □Secondary/ Shule ya Upili □Beyond secondary/ Zaidi ya Shule ya Upili maalum □Special training e.g Trade. Insert Mafunzo kwa mfano biashara	
2. What is your main source of income?/ Chanzo chako kikuu cha mapato ni nini? □Farming/ Ukulima □Business/Trade/Biashara □Teacher/ Uwaalimu □Health worker/ Mfanyakazi wa afya □Other/s (Insert): Ingine	
3. What is your estimated monthly income in KES?/ Je! Mapato yako ya kila mwezi yanakadiriwa ngapi □KES? <1,000 □1,000-2,999 □3,000-4,999 □5,000-9,999 □>10,000	
4. **How long have you been living with hypertension/pressure in months? Umeishi kwa muda gani na shinikizo la damu / shinikizo (kwa miezi)** □<6 months/ Miezi sita □Between 6 months – 1year/ Kati ya miezi sita na mwaka □Between 1-2 years/ Kati ya mwaka mmoja na mbili?□>2 years/ Zaidi ya miaka mbili?	
5**. Where do you mainly seek treatment for hypertension/pressure?/ Unapata wapi mati-babu ya shinikizo la damu** □Health facility/ Kituo cha afya □Pharmacy (over the counter medication) Duka la dawa □Herbalist / Mtaalam wa mimea (juu ya dawa ya kaunta) □Not yet sought care/ Bado sijatafuta huduma □Other specify/ Nyingine taja	
6. About how long would it take to get from your home to the nearest chemist/pharmacy if you walked to them? Je! Itachukua muda gani kutoka nyumbani kwako kwenda kwa duka la dawa lilokaribu ukitembea? □Less than 15 minutes/ Chini ya dakika 15 □16-30 minutes/ Dakika 16-30 □31 minutes to an hour/ dakika 31 hadi saa moja □More than one hour/ Zaidi ya saa moja	
7. **About how long would it take to get from your home to the nearest healthcare facility if you walked to them?/** Je! Itachukua muda gani kutoka nyumbani kwako kwenda kituo cha huduma ya afya kilicho karibu ikiwa utatembea kuelekea huko? □Less than 15 minutes/ Chini ya dakika 15 □16-30 minutes/ Dakika 16-30	

□31 minutes to an hour/ dakika 31 hadi saa moja □More than one hour/ Zaidi ya saa moja

Instructions to Study Personnel: *Read all questions aloud to the patient and record answers on questionnaire form.*

You were selected to take part in this survey because we value the knowledge you have on our topic of discussion. I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel.

There is a plan to start a project that will support people living with hypertension/pressure at the community level. The purpose of the project is to assist these individuals take hypertension/pressure medication their as required through a peer-led project. A peer will be someone who is living with hypertension/pressure in the community and has been successful in managing their hypertension. The peer will be responsible for a number of things:

- *Deliver hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Provide psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Record the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician where the individuals living with hypertension receive care to discuss their health progress.*
- *Whenever necessary enable a conversation (either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*
- *Insert the revised prototype*

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Complet agree
1. The HIT-Peer Delivery system meets my needs	①	②	③	④	⑤
2. The HIT-Peer Delivery system is appealing to me.	①	②	③	④	⑤
3. I like the HIT-Peer Delivery system.	①	②	③	④	⑤
4. I would like to be enrolled in the HIT-Peer Delivery system.	①	②	③	④	⑤

With this revisions to our PT4A strategy, will this prototype do the following for you.

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disa-gree	Neither agree nor dis-agree	Agree	Comple agree
The HIT-Peer Delivery system seems fitting.	①	②	③	④	⑤
The HIT-Peer Delivery system seems suita-	①	②	③	④	⑤
The HIT-Peer Delivery system seems appli- ble.	①	②	③	④	⑤
The HIT-Peer Delivery system seems like a od match.	①	②	③	④	⑤

Total Score:

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Acceptability of Intervention Measure (AIM) for Health Care Team

Study ID:	Date:
Age:	Gender:
1. What is your primary role at the facility? □MO □CO □Nurse □Other staff (specify)	
2. How long have you served as a health provider for Hypertensive patients?	
3. What is your interaction with patients living with Hypertension?	

Instructions to Study Personnel: *Read all questions aloud to the healthcare provider and record answers on questionnaire form.*

You were selected to take part in this survey because we value the knowledge you have on our topic of discussion. I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel.

There is a plan to start a project that will support people living with hypertension/pressure at the community level. The purpose of the project is to assist these individuals take hypertension/pressure medication their as required through a peer-led project. A peer will be someone who is living with hypertension/pressure in the community and has been successful in managing their hypertension. The peer will be responsible for a number of things:

- *Deliver hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Provide psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Record the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician where the individuals living with hypertension receive care to discuss their health progress.*
- *Whenever necessary enable a conversation (either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*
- *Insert the revised prototype*

	Completely disagree	Disagree	Neither agree nor disagree	Agree	C

1. The HIT-Peer Delivery system meets the patients needs	①	②	③	④	
2. The HIT-Peer Delivery system is appealing to both the patient and I healthcare provider	①	②	③	④	
3. I like the HIT-Peer Delivery system.	①	②	③	④	
4. I would like my patients enrolled in the HIT-Peer Delivery system.	①	②	③	④	

With this revisions to our PT4A strategy, will this prototype do the following for you.

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The HIT-Peer Delivery system seems fitting.	①	②	③	④	⑤
2. The HIT-Peer Delivery system seems suitable.	①	②	③	④	⑤
3. The HIT-Peer Delivery system seems applicable.	①	②	③	④	⑤
4. The HIT-Peer Delivery system seems like a good match.	①	②	③	④	⑤

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Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Acceptability of Intervention Measure (AIM) for PEERS

Study ID:	Date:
Age:	Gender:

1. Education/ Elimu

□ No formal education/ Hakuna elimu rasmi

□Primary/ Shule ya Msingi □Secondary/ Shule ya Upili

□Beyond secondary/ Zaidi ya Shule ya Upili □Special training e.g Trade. Insert Mafunzo maalum kwa mfano biashara

2. What is your main source of income?/ Chanzo chako kikuu cha mapato ni nini?

□Farming/ Ukulima □Business/Trade/Biashara □Teacher/ Uwaalimu

□Health worker/ Mfanyakazi wa afya □Other/s (Insert): Ingine

3. How long have you worked as a peer?

4. What is your estimated monthly income in KES?/ Je! Mapato yako ya kila mwezi yanakadiriwa ngapi

□**KES?**<1,000 □1,000-2,999 □3,000-4,999 □5,000-9,999 □>10,000

5. How long have you been living with hypertension/pressure in months? Umeishi kwa muda gani na shinikizo la damu / shinikizo (kwa miezi)

□<6 months/ Miezi sita □Between 6 months – 1year/ Kati ya miezi sita na mwaka

□Between 1-2 years/ Kati ya mwaka mmoja na mbili?□>2 years/ Zaidi ya miaka mbili?

6. Where do you mainly seek treatment for hypertension/pressure?/ Unapata wapi matibabu ya shinikizo la damu

□Health facility/ Kituo cha afya □Pharmacy (over the counter medication) Duka la dawa (juu ya dawa ya kaunta)

□Herbalist / Mtaalam wa mimea

□Not yet sought care/ Bado sijatafuta huduma □Other specify/ Nyingine taja

7. About how long would it take to get from your home to the nearest chemist/pharmacy if you walked to them? Je! Itachukua muda gani kutoka nyumbani kwako kwenda kwa duka la dawa li-lokaribu ukitembea?

□Less than 15 minutes/ Chini ya dakika 15 □16-30 minutes/ Dakika 16-30

□31 minutes to an hour/ dakika 31 hadi saa moja □More than one hour/ Zaidi ya saa moja

8. About how long would it take to get from your home to the nearest healthcare facility if you walked to them?/ Je! Itachukua muda gani kutoka nyumbani kwako kwenda kituo cha huduma ya afya kilicho karibu ikiwa utatembea kuelekea huko?

□Less than 15 minutes/ Chini ya dakika 15 □16-30 minutes/ Dakika 16-30

□31 minutes to an hour/ dakika 31 hadi saa moja □More than one hour/ Zaidi ya saa moja

Instructions to Study Personnel: *Read all questions aloud to the patient and record answers on questionnaire form.*

You were selected to take part in this survey because we value the knowledge you have on our topic of discussion. I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel.

There is a plan to start a project that will support people living with hypertension/pressure at the community level. The purpose of the project is to assist these individuals take hypertension/pressure medication their as required through a peer-led project. A peer will be someone who is living with hypertension/pressure in the community and has been successful in managing their hypertension. The peer will be responsible for a number of things:

- *Deliver hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Provide psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Record the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician where the individuals living with hypertension receive care to discuss their health progress.*
- *Whenever necessary enable a conversation (either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*
- *Insert the revised prototype*

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Comple agre
1. The HIT-Peer Delivery system meets my needs	①	②	③	④	⑤
2. The HIT-Peer Delivery system is appealing to me.	①	②	③	④	⑤
3. I like the HIT-Peer Delivery system.	①	②	③	④	⑤
4. I would like to be enrolled in the HIT-Peer Delivery system.	①	②	③	④	⑤

With this revisions to our PT4A strategy, will this prototype do the following for you?

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Complete agree
. The HIT-Peer Delivery system seems fitting.	①	②	③	④	⑤
. The HIT-Peer Delivery system seems suitable.	①	②	③	④	⑤
. The HIT-Peer Delivery system seems applicae.	①	②	③	④	⑤
. The HIT-Peer Delivery system seems like a ood match.	①	②	③	④	⑤

Total Score:

Subaim 2.2: Conduct a pilot of the intervention and evaluate feasibility

AIM 2.2 Study Instrument: EVALUATION OF FEASIBILITY QUESTIONNAIRE FOR PATIENTS

Hello, my name is _____. I am a research assistant for the PT4A study. I am approaching you as you have participated as a patient in the PT4A program and as such our feedback would be helpful for the program. I would like to ask you some questions to learn about your experiences with the PT4A program. I will ask you questions about your physical health, your mental health, and how you feel when you interact with a peer from the PT4A program. Your answers will help me understand what types of services people who are living with high blood pressure need to stay healthy.
.

Do you have any questions?

Ok, let's begin

Now I would like to hear about your experience with the PT4A peer delivery program. Please answer honestly and to the best of your knowledge. All responses are confidential.

1. When you receive medication and counseling from a peer, how often do the peers treat you with courtesy and respect?
- All the time
- A lot of the time
- Some of the time
- None of the time

2. When you receive medication and counseling from a peer, how often do the peers listen carefully to you?
- All the time
- A lot of the time
- Some of the time
- None of the time

3. When you receive medication and counseling from a peer, how often do the peers ask for your opinion regarding your healthcare?
- All the time
- A lot of the time
- Some of the time
- None of the time

4.When you receive medication and counseling from a peer, how often are you satisfied with the amount of time your peer spends with you?
- All the time
- A lot of the time
- Some of the time
- None of the time

Please tell me how much you agree or disagree with the following statements
5.The peers in the PT4A delivery program can be trusted to keep my medical information private and confidential. □ Strongly agree □ Agree □ Disagree □ Strongly Disagree
6.Whenever you had questions about your medications or health which you brought up to the peer, how often were you satisfied about the answers you received from the peer? □ All the time □ A lot of the time □ Some of the time □ None of the time
7. When you receive medication and counseling from a peer, how often did you get clear instructions on how to use/take the medication? □ All the time □ A lot of the time □ Some of the time □ None of the time
8. Did you feel the peer having the Mobile Device helped with record keeping for the next clinical encounter you had with your doctor? □ Strongly agree □ Agree □ Disagree □ Strongly Disagree
9. Did the Mobile Device help you have a consultation with a healthcare provider for any emerging medical issue? Yes No Do you feel that the use of the mobile device helped you to manage the arising medical issue that came up? □ Strongly agree □ Agree □ Disagree □ Strongly Disagree
10. Did the use of a peer to deliver medication has improve your health? □ Strongly agree □ Agree □ Disagree □ Strongly Disagree
11. Did the use of a peer to offer psychosocial support help you improve your quality of life? □ Strongly agree □ Agree □ Disagree

Strongly Disagree
11. Has the use of a peer to deliver medication helped you to adhere to medication and you have experienced few if no symptoms associated with Hypertension □ Strongly agree □ Agree □ Disagree Strongly Disagree

AIM 2.2 Study Instrument: EVALUATION OF DELIVERY PROCESS AND COMPLETENESS QUESTIONNAIRE FOR PATIENTS

Now I would like to hear about your feedback on the PT4A medication delivery process. Please answer honestly and to the best of your knowledge. All responses are confidential.
Successful/proper deliveries
The peers delivered the right medication as requested □ All the time □ A lot of the time □ Some of the time □ None of the time
The medication was delivered on the date expected □ All the time □ A lot of the time □ Some of the time □ None of the time
The medication was delivered at the time expected □ All the time □ A lot of the time □ Some of the time □ None of the time
Medication packaging
The medication was properly sealed during the delivery □ All the time □ A lot of the time □ Some of the time □ None of the time
The medication was properly labeled and the dosage indicated □ All the time □ A lot of the time □ Some of the time □ None of the time
The medication was properly labeled and the dosage indicated □ All the time □ A lot of the time □ Some of the time □ None of the time
The peer was able to give you instructions for medication use □ All the time

☐ A lot of the time ☐ Some of the time ☐ None of the time
The medication brand changes were clearly communicated ☐ All the time ☐ A lot of the time ☐ Some of the time ☐ None of the time
The medication payments reflected the amount of medication received ☐ All the time ☐ A lot of the time ☐ Some of the time ☐ None of the time
Total Scores

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Focus Group Discussion (FGD) Guide for Clinical Team

FGD moderator: _____

FGD note taker: _____

Date: ____/____/2022

County: _____

Start Time: _____

End Time: _____

FGD:

- **Inform the participants about the study guided by the study information sheet.**
- **Provide participants with an opportunity to ask questions.**
- **Obtain written consent from each participant privately. (2 copies per participants)**
- **Provide each participant with a copy of their signed informed consent form.**
- **Complete the demographic survey for each participant privately.**

Demographic Survey

Indicate or insert your responses as necessary				
1. Study ID:				
2. State your age (Years)				
3. Sex	Male	Female		
4. What is your primary role at the facility?	MO	CO	Nurse	Other staff (specify)
5. How long have you served as a health provider?				
6. Have you interacted with patients living with Hypertension?	Yes		No	

NB: To be completed for each participant

Summary of observations during FGD

Moderator and note taker: In the space below, please provide a summary of the FGD session you just had including both verbal and nob-verbal cues.

Focus Group Discussion Guide
Clinical Team

****

Opening Remarks

Hello. My name is _____XXX_____ and I will help guide our discussion today. Thank you for welcoming us to your community. ___XXX_____ is also present today to help take notes during our discussions. We will also be recording this session using a tape recorder (show the participants the tape recorder). This will help us capture what you say without missing out on anything. Your opinions and experiences are very important to us since it will help us understand how to develop health program to assist individuals living with hypertension in your community.

You were selected to take part in this discussion because we value your feedback regarding your experience in PT4A program I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel. You are welcome to say as much or as little as you want. I am eager to hear what you have to say. Do you have any questions about what I have said so far?

FGD rules

Before we start, I would like as to you mention some of the rules that will guide our discussion

1. There are no right or wrong answers. We expect that you will have differing points of view. Please feel free to share your point of view even if it differs from what others have said.

2. We are recording this session as we discussed, because we do not want to miss any of your comments. No names will be included in any reports. Your comments are confidential. Please speak loudly for I want to be accurate in capturing what you say.

3. Don't feel like you have to respond all the time. But if you want to follow up on something that someone has said, you want to agree, or disagree, or give an example, feel free to do that.

4. I am here to ask questions, listen, and make sure everyone has a chance to share. We're interested in hearing from each of you. So if you are talking a lot, I may ask you to give others a chance. We just want to make sure all of you have a chance to share your ideas.

5. If you have a cell phone, please put it on quiet mode.

Now let us start discussions about your perceptions about the PT4A Intervention.

A. PT4A intervention:

PT4A project was started to support people living with hypertension/pressure at the community level. The purpose of the project was to assist these individuals take hypertension/pressure medication as required through a peer-led project. This peer led project used a mobile device similar to regular mobile phone, a smart phone, or a tablet. The mobile device enabled us to deliver hypertension health services to the patients in a safe, confidential, and timely manner. The device, supported patients in treatment counseling; delivering medications to the patients; accounting for the types of medications delivered, quantity, and amount of fees the patients pays at the time of delivery (like an Mpesa transaction); and also connecting the patients with their doctor whenever they needed.. In doing so, a peer collected health information from the patients on a regular basis on this mobile device.

A peer was someone living with hypertension/pressure in the community who had been successful in managing their hypertension. The peer was responsible for a number of things:

- *Delivering hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Confirming payment of medication (Mpesa transaction) by people living with hypertension/pressure before issuing the medication.*
- *Providing psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Recording the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician, to discuss the progress of an individual living with hypertension.*
- *Whenever it was necessary, they enabled a conversation (intervention: either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*

1. What did you think about this peer-led project in supporting individuals living with hypertension in the community?
   Probe:
   - What parts of the project did you like? Why?
   - What part of the project didn't you like? Why?
   - Parts of the project that were easily carried out? Why?
   - Parts of the project that were difficult to carry out? Why?

2. What were the advantages of this kind of peer-led program?
   Probe:
   - Advantages of peers leading the delivery of health services
   - Advantages of door to door drug delivery
   - Advantages of peers providing psychological support to individuals living with hypertension at the community level
   - Advantages of peers recording health information of the individuals receiving hypertension medication at the community on the mobile device (Probe: quality of care, provider-patient communication, privacy and confidentiality)

- Advantages of doctor and the patient having a clinical meeting using a mobile device at the community level (Probe: quality of care, provider-patient communication, privacy and confidentiality)

3. What were the disadvantages of this kind of peer-led program?
   Probe:
   - Disadvantages of peers leading the delivery of health services
   - Disadvantages of door to door drug delivery
   - Disadvantages of peers providing psychological support to individuals living with hypertension at the community level
   - Disadvantages of peers recording health information of the individuals receiving hypertension medication at the community on the mobile device (Probe: quality of care, provider-patient communication, privacy and confidentiality)
   - Disadvantages of doctor and the patient having a clinical meeting using a mobile device at the community level (Probe: quality of care, provider-patient communication, privacy and confidentiality)

4. In what ways did this peer-led program affect the management of hypertension at the community level?
   Probe:
   - How did it affect medication adherence for individuals living with hypertension?
   - How did it affect follow-up of individuals living with hypertension?
   - How did it effect on how hypertension is perceived in the community?

5. In what ways did this peer-led program affect the management of hypertension at the facility level?
   Probe:
   - Positive effects (How did this program complement the efforts in clinic?)
   - Negative effects (How did this make it challenging to manage hypertension at the clinic level

6. In what ways did this peer-led affect the way care for hypertension/pressure is offered during the current COVID pandemic?

B. <u>Peers</u>

Now let us talk more specifically about the peers who delivered these health services to individuals living with hypertension at the community.

7. *What are your perception about the peers that were used to implement the PT4A intervention*
   Probe:
   - *characteristics of the peer*
   - *Qualifications/skill*
   - *Training*
   - *Integrity*

C. <u>Mobile device</u>

Now let us talk more about the mobile device used to deliver these health services to individuals living with hypertension at the community.

8. What is your perception of mobile device used by the peers to deliver the PT4A intervention?
9. What are the mobile device features that were most useful in implementing the PT4A intervention?
    Probe:
    - Type of device
    - Size of device
    - Connectivity
    - Content
    - Data flow
    - Care facilitation features

10. What were the mobile device features that were not useful in implementing the PT4A intervention?
    Probe:
    - Type of device
    - Size of device
    - Connectivity
    - Content
    - Data flow
    - Care facilitation features

11. What was your perception about the mobile payment mode used to pay for the Hypertension medications in the PT4A intervention?
12. How did the use of a mobile device impact the delivery of hypertension services at the community?

D. <u>Recommendation for improving the PT4A project</u>

We are about to end our discussion today. But before we end, we would like to hear about some of your recommendations for improving the proposed peer-led project to support individuals living with hypertension.

13. What is your perception about the uptake of this peer led project in your facility?
14. Would you recommend this peer-led project to other individuals living with HTN? Why
15. What would be your recommendation for improving this peer-led project? Probe:
    - Parts of the project that could be improved. How?
16. What would make this peer led project acceptable as part of standard care?
17. What would make this peer-led project sustainable?

E. <u>Closing</u>

We have now come to the end of our discussions today. Thank you for your time and participation. We very much appreciate your comments, discussion, and input. We plan to take into account everything that was said today as we continue to improve the services we offer to your community.

- Do you have any questions related to our discussion today?

NB: Before ending

- **Remind participants about the confidentiality of the interview.**
- **Ask if there is anything that wasn't raised that should have been that is important to know in understanding their perception about the peer-led intervention.**
- **Offer lunch stipend and provide contact information for any future questions they may have.**
- **Thank participants once again for their time.**

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study/

Study Instrument: Focus Group Discussion (FGD) Guide for Individuals living with Hypertension

FGD moderator/ Msimamizi: _____

FGD note taker/ Mchukua noti: _____

Date/ Tarehe: ____/____/2022

County/ Kaunti: _____

Category of FGD (tick)/ *Aina ya Majadiliano ya Kikundi*
[ ] Men living with hypertension / *Wanaume wanoishi na Shinikizo la damu/ Pressure*
[ ] Women living with hypertension/ *Wanawake Wanaoishi na Shinikizo la damu/ Pressure*
[ ]Community members/ Wanachama wa Jamii

Start Time/ *Saa ya Kuanza:* _____

End Time/ *Saa ya Kumaliza:* _____

FGD:

- **Inform the participants about the study guided by the study information sheet.**
- **Provide participants with an opportunity to ask questions.**
- **Obtain written consent from each participant privately. (2 copies per participants)**
- **Provide each participant with a copy of their signed informed consent form.**
- **Complete the demographic survey for each participant privately.**

Demographic Survey for Individuals Living with Hypertension

Indicate or insert your responses as necessary					
1. Study ID:/ ***Nambari ya Utafiti:***					
2. State your age (Year of Birth)/ ***Taja umri wako (Mwaka wa kuzaliwa)***					
3. Sex/ ***Jinsia***	□Male ***Kiume)***	□Female ***(Kike)***			
4. Education/ ***Elimu***	□No formal education/ ***Hakuna elimu rasmi***	□Primary/ ***Shule ya Msingi***	□Second-ary/ ***Shule ya Upili***	□Beyond second-ary/ ***Zaidi ya Shule ya Upili***	□Special training e.g Trade. *Insert* ***Mafunzo maalum kwa mfano biashara***
5. What is your main source of income***?/ Chanzo chako kikuu cha mapato ni nini?***	□Farming/ ***Ukulima***	□Busi-ness/ Trade/***Bi-ashara***	□Teacher/ ***Uwaalimu***	□Health worker/ ***Mfanyak azi wa afya***	□Other/s *(Insert):* ***In-gine***
6. What is your estimated monthly income in KES?/ ***Je! Mapato yako ya kila mwezi yanakadiriwa pesa ngapi (Kes?***	□<1,000	□1,000-2,999	□ 3,000-4,999	□ 5,000-9,999	□ >10,000
8. How long have you been living with hyperten-sion/pressure in months? ***Umeishi na shinikizo la damu / pressure (kwa miezi ngapi***	□<6 months/ ***Miezi sita***	□Between 6 months – 1year/ ***Kati ya miezi sita na mwaka?***		□Be-tween 1-2 years ***Kati ya mwaka mmoja na mbili?***	□>2 years/ ***Zaidi ya miaka mbili?***
9. Where do you mainly seek treatment for hyper-tension/pressure? / ***Unapata wapi matibabu ya shinikizo la damu/ pressure***	□Health fa-cility/ ***Kituo cha afya/ name the health facility***	□Phar-macy (over the counter medica-tion) ***Duka la dawa / dawa ya kaunta)***	□Herbalist / ***Mtaalam wa dawa za Kienyeji***	□Not yet sought care/ ***Bado sijatafut a huduma***	□Other specify/ ***Nyingine taja***

10. About how long would it take to get from your home to the nearest chemist/pharmacy if you walked to them? ***Je! Itachukua muda gani kutoka nyumbani kwako kwenda kwa duka la dawa lilokaribu ukitembea?***	□Less than 15 minutes/ ***Chini ya dakika 15***	□16-30 minutes/ ***Dakika 16-30***	□31 minutes to an hour/ ***dakika 31 hadi saa moja***	□More than one hour/ ***Zaidi ya saa moja***
11. About how long would it take to get from your home to the nearest healthcare facility if you walked to them?/***Je! Itachukua muda gani kutoka nyumbani kwako kwenda kituo cha huduma ya afya kilicho karibu ikiwa utatembea kuelekea huko?***	□Less than 15 minutes/ ***Chini ya dakika 15***	□16-30 minutes/ ***Dakika 16-30***	□31 minutes to an hour/ ***dakika 31 hadi saa moja***	□More than one hour/ ***Zaidi ya saa moja***

NB: To be completed for each participant

Summary of observations during FGD

Moderator and note taker: In the space below, please provide a summary of the FGD session you just had including both verbal and nob-verbal cues.

Focus Group Discussion Guide
Individuals living with Hypertension

****

Opening Remarks

Hello. My name is _____XXX_____ and I will help guide our discussion today.. ___XXX_____ is also present today to help take notes during our discussions. We will also be recording this session using a tape recorder (show the participants the tape recorder). This will help us capture what you say without missing out on anything. Your opinions and experiences are very important to us since it will help us understand how to develop health program to assist more people living with hypertension in your community.

You were selected to take part in this discussion because you participated in this study and we value your experiences and knowledge on our topic of discussion. I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel. You are welcome to say as much or as little as you want. I am eager to hear what you have to say. Do you have any questions about what I have said so far?

FGD rules

Before we start, I would like as to you mention some of the rules that will guide our discussion

6. There are no right or wrong answers. We expect that you will have differing points of view. Please feel free to share your point of view even if it differs from what others have said.

7. We are recording this session as we discussed, because we do not want to miss any of your comments. No names will be included in any reports. Your comments are confidential. Please speak loudly for I want to be accurate in capturing what you say.

8. Don't feel like you have to respond all the time. But if you want to follow up on something that someone has said, you want to agree, or disagree, or give an example, feel free to do that.

9. I am here to ask questions, listen, and make sure everyone has a chance to share. We're interested in hearing from each of you. So if you are talking a lot, I may ask you to give others a chance. We just want to make sure all of you have a chance to share your ideas.

10. If you have a cell phone, please put it on quiet mode.

A. PT4A intervention:

PT4A project was started to support people living with hypertension/pressure at the community level. The purpose of the project was to assist these individuals take hypertension/pressure medication as required through a peer-led project. This peer led project used a mobile device similar to regular mobile phone, a smart phone, or a tablet. The mobile device enabled us to deliver hypertension health services to the patients in a safe, confidential, and timely manner. The device, supported patients in treatment counseling; delivering medications to the patients; accounting for the types of medications delivered, quantity, and amount of fees the patients pays at the time of delivery (like an Mpesa transaction); and also connecting the patients with their doctor whenever they needed.. In doing so, a peer collected health information from the patients on a regular basis on this mobile device.

A peer was someone living with hypertension/pressure in the community who had been successful in managing their hypertension. The peer was responsible for a number of things:

- *Delivering hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Confirming payment of medication (Mpesa transaction) by people living with hypertension/pressure before issuing the medication.*
- *Providing psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Recording the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician, to discuss the progress of an individual living with hypertension.*
- *Whenever it was necessary, they enabled a conversation (intervention: either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*

I would first like to ask you questions regarding your perception and experience with the PT4A project

18. What did you think about this peer-led project in supporting you as an individual living with hypertension in the community?
    Probe:
    - What parts of the project did you like? Why?
    - What part of the project didn't you like? Why?

19. What were your experiences with peers leading the delivery of hypertension services in the community?
    Probe:
    - What did you like? Why?
    - What didn't you like? Why?

20. What were your experiences with peers delivering medication at your convenient location in the community?
    Probe:
    - What did you like? Why?
    - What didn't you like? Why?

21. What were your experiences with peers providing psychological support to you in the community?
    Probe:
    - What did you like? Why?
    - What didn't you like? Why?

22. What is your perception of peers recording your health information on a mobile device?
    Probe:
    - Privacy and confidentiality.

23. What is your perception of you and the doctor having a clinical meeting using a mobile device at the community?
    Probe:
    - Quality of care
    - Provider-patient communication
    - Privacy and confidentiality

24. What is your perception about the mobile payment mode used to pay for the Hypertension medications in the PT4A intervention?

25. What are your perceptions about the characteristics of the peers who delivered the hypertension services to your at the community?
    Probe:
    - Age
    - Gender
    - Personality
    - Academic qualification
    - Skill/Training

26. In what ways did this peer-led program affect your hypertension care?
    Probe:
    - How did it affect your medication adherence?
    - How did it affect your clinic adherence?
    - How did it affect the quality of care you received?

B. Recommendation for improving the PT4A project

We are about to end our discussion today. But before we end, we would like to hear about some of your recommendations for improving this peer-led project to support individuals living with hypertension/pressure

27. Would you recommend this peer-led project to other individuals living with HTN? Why

28. What would be your recommendation for improving this peer-led project? Probe:
    - Parts of the project that could be improved. How?

C. Closing

We have now come to the end of our discussions today. Thank you for your time and participation. We very much appreciate your comments, discussion, and input. We plan to take into account everything that was said today.
Do you have any questions related to our discussion today?

NB: Before ending

- **Remind participants about the confidentiality of the interview.**
- **Ask if there is anything that wasn't raised that should have been that is important to know in understanding their perception about the peer-led intervention.**
- **Offer lunch stipend and provide contact information for any future questions they may have.**
- **Thank participants once again for their time.**

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Key Informant Interview Guide for Peers Team.

FGD moderator: _____

FGD note taker: _____

Date: ____/____/2022

County: _____

Start Time: _____

End Time: _____

FGD:

- **Inform the participants about the study guided by the study information sheet.**
- **Provide participants with an opportunity to ask questions.**
- **Obtain written consent from each participant privately. (2 copies per participants)**
- **Provide each participant with a copy of their signed informed consent form.**
- **Complete the demographic survey for each participant privately.**

Demographic Survey

Indicate or insert your responses as necessary		
1. Study ID:		
2. State your age (Years)		
3. Sex	Male	Female
5. How long have you served as a peer?		
6. How long have you interacted with patients living with Hypertension?		

NB: To be completed for each participant

Key Informant Interview Guide
Peers Team

****

Opening Remarks

Hello. My name is _____XXX_____ and I will help guide our discussion today. Thank you for welcoming us to your community. ___XXX_____ is also present today to help take notes during our discussions. We will also be recording this session using a tape recorder (show the participants the tape recorder). This will help us capture what you say without missing out on anything. Your opinions and experiences are very important to us since it will help us understand how helpful the intervention was for patients with hypertension.

You were selected to take part in this discussion because we value your feedback regarding your experience in PT4A program. I kindly request for your honest opinions and ideas. There is no wrong or right response. You should feel free to say whatever you think and feel. You are welcome to say as much or as little as you want. I am eager to hear what you have to say. Do you have any questions about what I have said so far?

FGD rules

Before we start, I would like as to you mention some of the rules that will guide our discussion

1. There are no right or wrong answers. We expect that you will have differing points of view. Please feel free to share your point of view

2. We are recording this session as we discussed, because we do not want to miss any of your comments. No names will be included in any reports. Your comments are confidential. Please speak loudly for I want to be accurate in capturing what you say.

3. I am here to ask questions, listen, and make sure everyone has a chance to share. We're interested in hearing from each of you. So if you are talking a lot, I may ask you to give others a chance. We just want to make sure all of you have a chance to share your ideas.

4. If you have a cell phone, please put it on quiet mode.

Now let us start our discussion with talking about how the project was perceived and the impact it had on individuals living with hypertension.

<u>D. PT4A intervention:</u>
There is a plan to start a project that will support people living with hypertension/pressure at the community level. The purpose of the project is to assist these individuals take hypertension/pressure medication as required through a peer-led project. This peer led project will use a mobile device similar to regular mobile phone, a smart phone, or a tablet. The mobile device will enable us to deliver hypertension health services to the patients in a safe, confidential, and timely manner. With the device, we will support the patients in treatment counseling; delivering medications to the patients; accounting for the types of medications delivered, quantity, and amount of fees the patients pays at the time of delivery (like an Mpesa transaction); and also connecting the patients with their doctor whenever they need.. To do so, a peer will need to collect health information from the patients on a regular basis on this mobile device.
A peer will be someone who is living with hypertension/pressure in the community and has been successful in managing their hypertension. The peer will be responsible for a number of things:

- *Deliver hypertension medication to people living with hypertension/pressure at their most convenient location (door-to-door medication delivery).*
- *Confirm payment of medication (Mpesa transaction) by people living with hypertension/pressure before issuing the medication.*
- *Provide psychological support to people living with hypertension/pressure during medication delivery and whenever needed.*
- *Record the health progress of people living with hypertension/pressure in a mobile device whenever they are in contact with a person living with hypertension/pressure.*
- *Using the mobile device, communicate with a clinician, to discuss the progress of an individual living with hypertension.*
- *Whenever necessary enable a conversation (<u>intervention:</u> either audio or video) between the clinician and the patient using the mobile device at the patient's convenient location.*

I would first like to ask you questions regarding your perception and experience with the PT4A project

1. Could you kindly describe your role in the PT4A intervention?

2. What was your general perception of the PT4A intervention project?
   Probe:
   - What parts of the project did you like? Why?
   - What part of the project didn't you like? Why?
   - Parts of the project that were easily carried? What made it easy?
   - Parts of the project that were difficult to carry out? What made it difficult?

3. Now I would like you to share your experiences of the difference components of the PT4A intervention. How was your experience of;
   - Delivering HTN medication to individuals living with HTN?

- Providing psychological support to individuals living with hypertension at the community level
- Recording health information of the individuals receiving hypertension medication at the community on the mobile device (Probe: quality of care, provider-patient communication, privacy and confidentiality)
- Facilitating the doctor and the patient to have a clinical meeting using a mobile device at the community level (Probe: quality of care, provider-patient communication, privacy and confidentiality)

4. In what ways did the PT4A intervention affect the management of hypertension in the community?

   Probe:
   - How did it affect medication adherence for individuals living with hypertension?
   - How did it affect clinic adherence for individuals living with hypertension?

E. Mobile device.

Now let us talk more about the mobile device you used to deliver these health services to individuals living with hypertension at the community.

5. What was your perception about the mobile device you used as you delivered the PT4A intervention in the community
   Probe:
   - What did you like about the mobile device?
   - What didn't you like about the mobile device?
6. What mobile device features were useful in implementing the PT4A intervention?
   Probe:
   - Content
   - Data flow
   - Connectivity
7. What mobile device features were not useful in implementing the PT4A intervention?
   Probe:
   - Content
   - Data flow
   - Connectivity

8. What was your perception about the mobile payment mode used to pay for the hypertension medications in the PT4A intervention?
   Probe:
   - What did you like about the mobile payment?
   - What didn't you like about the mobile payment?

9. How did the use of a mobile device impact the delivery of hypertension services at the community?

F. Peers.

Following your experience as a peer in the PT4A project, I would now like us to talk about the qualities of a peer who would lead the delivery of PT4A intervention at the community.

10. What characteristics would be important for a peer to have if they were to lead the PT4A intervention in the community
    Probe:
    - Age
    - Gender
    - Personality
    - Academic qualification
    - Skill

11. What are your perceptions about the training you received from PT4A facilitators?
    Probe:
    - How relevant was the training in preparing you to conduct your duties as a peer in the PT4A intervention?
    - How adequate was the training in accomplishing your duties as a peer in the PT4A intervention?
    - What additional training aspects should be considered in the future for peers in the PT4A intervention?

G. Recommendation for improving the PT4A project

We are about to end our discussion today. But before we end, we would like to hear about some of your recommendations for improving the proposed peer-led project to support individuals living with hypertension.

12. What is your perception about the uptake of this peer led project in your facility?
13. Would you recommend this peer-led project to other individuals living with HTN? Why
14. What would be your recommendation for improving this peer-led project? Probe:
    - Parts of the project that could be improved. How?
15. What would make this peer led project acceptable in the community?
16. What would make this peer-led project sustainable in the community?

H. Closing

We have now come to the end of our discussions today. Thank you for your time and participation. We very much appreciate your comments, discussion, and input. We plan to take into account everything that was said today as we continue to improve the services we offer to your community.

- Do you have any questions related to our discussion today?

NB: Before ending

- **Remind participants about the confidentiality of the interview.**
- **Ask if there is anything that wasn't raised that should have been that is important to know in understanding their perception about the peer-led intervention.**

- **Offer lunch stipend and provide contact information for any future questions they may have.**
- **Thank participants once again for their time.**

Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) Study

Study Instrument: Focus Group Discussion (FGD) Guide for Design Team- Meeting 6.

FGD moderator: _____

FGD note taker: _____

Date: ____/____/2022

County: _____

Start Time: _____

End Time: _____

FGD:

- **Inform the participants about the study guided by the study information sheet.**
- **Provide participants with an opportunity to ask questions.**
- **Obtain written consent from each participant privately. (2 copies per participants)**
- **Provide each participant with a copy of their signed informed consent form.**
- **Complete the demographic survey for each participant privately.**

Demographic Survey

Indicate or insert your responses as necessary				
1. Study ID:				
2. State your age (Years)				
3. Sex	Male	Female		
4. Where are you from?	Uasin-Gishu County	Trans-Nzoia County		Bungoma County
5. Which group are you representing in the design team?	Health care Team	Patients Team	Peers Team	Other (specify)
6. How many design team meetings did you attend?				

NB: To be completed for each participant

Focus Group Discussion Guide
Design Team

Opening Remarks: Human-centered design is a creative approach to problem solving. It emphasizes issues that are important to community stakeholders rather than leadershipor administrators. This design process is focused on understanding the needs of the community, generating many ideas from different perspectives, building tangible prototypes, and iteratively improving the solution based on stakeholder feedback.

During our Design Team meetings, we worked through phases of Inspiration, Brainstorming, Conceptualization, Creation, and Iteration. Through this process, we have learned much about the human-centered design methods and how they may be used tocreate a combined health information technology (HIT) and peer support program for PT4A. We have asked you to participate today because you have been a part ofthe PT4A Design Team. The purpose of this discussion is to reflect on your experience during the design process and provide feedback to the facilitators.

FGD rules

Before we start, I would like as to you mention some of the rules that will guide our discussion

11. There are no right or wrong answers. We expect that you will have differing points of view. Please feel free to share your point of view even if it differs from what others have said.

12. We are recording this session as we discussed, because we do not want to miss any of your comments. No names will be included in any reports. Your comments are confidential. Please speak loudly for I want to be accurate in capturing what you say.

13. Don't feel like you have to respond all the time. But if you want to follow up on something that someone has said, you want to agree, or disagree, or give an example, feel free to do that.

14. I am here to ask questions, listen, and make sure everyone has a chance to share. We're interested in hearing from each of you. So if you are talking a lot, I may ask you to give others a chance. We just want to make sure all of you have a chance to share your ideas.

15. If you have a cell phone, please put it on quiet mode.

A. DESIGN TEAM EXPERIENCE

1. Reflecting back to our first meeting, what is your understanding of human-centered design?
    - Probe:
        - What were the goals of the design team?
2. Why did you volunteer to join the Design Team for PT4A?
    - Probe:
        - What were your expectations for this design process?
        - Did this design process meet your expectations? Why or whynot?

3. What have you learned during the human-centered design process?
    - Probe:
        - What have you learned about yourself?
        - What have you learned about others in this group?
        - What have you learned about your community?
        - What have you learned about the health system?
4. Do you think that you will use what you have learned during the design process in the future? Please explain.
5. Often in group discussion, some participants may speak up and express opinions more than others. To what extent did every member of the DesignTeam participate equally in discussion?
    - *Probe:*
        - How have we succeeded to encourage participation fromeveryone in the group?
        - What challenges have we faced in encouraging participation fromeveryone in the group?
        - Were the opinions of each participant considered equally?Please explain.
6. Often in group discussion, there are times when there is disagreement between participants. How were disagreements addressed on the Design Team?
    - *Probe:*
        - When disagreements occurred, did the Design Team reach aconsensus before moving on? Please explain.
7. Reflecting on our work so far, to what extent did the Design Team incorporate:feedback from the community during the design process?
8. Reflecting on our work so far, to what extent did the Design Team incorporatefeedback from the PT4A investigators during the design process?
9. How do you feel about the current intervention model?

    Probe:

    - How confident are you that it meets the original goals of ourdesign team?
    - What are your thoughts about how this intervention was received by patients?
    - What are your thoughts about how this intervention was received by providers and other health care workers?

B. RECOMMENDATION FOR IMPROVING HCD MEETINGS.

10. What would be your recommendation for improving these design team meetings?

C. CLOSING

Thank you for your time and participation. We very much appreciate your Comments, discussion, and input. We plan to consider everything that was said today as we continue to improve the services we offer to your community.

Do you have any questions related to our discussion today?