Evaluating a service model for management of hypertension and diabetes among low- and middle-income patients enrolled on M-TIBA in Nairobi, Kenya

Research Protocol

Investigators and Institutional Affiliations

African Population and Health Research Center (APHRC)

- Catherine Kyobutungi, PhD, Principal Investigator
- Gershim Asiki, PhD Co-Principal Investigator
- Herrmann Dounfet, PhD Co-Principal Investigator
- Peter Otieno MPH Co-Investigator

Other collaborators

Marleeen Hendriks, PhD, Co- Principal Investigator (Joep Lange Institute, Amsterdam)
Judith Van Andel, PhD, Co-Investigator (Joep Lange Institute, Amsterdam)
Angela Siteyi, Co-Investigator (Pharmaccess, Kenya)
Rebecca Rayburn-Reeves, Co-investigator (Center for Advanced Hindsight, Duke University, United States),

Funding sources:

Sanofi through PharmAccess

Boehringer Ingelheim through PharmAccess

Table of contents

Contents

List of acronyms

APHRC- African Population and Health Research Center

AHTI- Amsterdam Health Technology Institute

BP- Blood pressure

CVD- Cardiovascular disease

HBPM-Home BP monitoring

HTN- Hypertension

FGD- Focus Group Discussions

LMICs- Low- and middle- income countries

SMBG-self-monitoring of blood glucose

SMS- short message service (text message)

SOP – Standard operating procedures

SSA- Sub-Saharan Africa

Abstract

Background: Both hypertension (HTN) and diabetes represent two major risk factors for atherosclerotic cardiovascular diseases (CVD), the number one cause of death globally[1]. Despite the clear evidence that lowering blood pressure (BP) and blood sugar through lifestyle changes and drug treatment can greatly reduce the risk of CVD), HTN-control (defined as the proportion of people who reach their target for BP lowering) and diabetes control (defined as HbA1c<7%) is still poor.

Objective: aim to develop, implement and evaluate a model that improves BP and blood sugar control for patients and streamlines and partly finances the provision of hypertension and diabetes care for healthcare providers while potentially reducing cost and improving access to quality care

Methodology: The core of the model is the interaction between M-TIBA (a mobile health platform for financial inclusion in healthcare that enables people to save, send, receive and pay money for medical treatment through a mobile health wallet on their phone) and mobile phone application (Afya-pap) for patients and a patient tracker for healthcare providers, which will improve access and allow for home-based measuring and monitoring of BP and blood sugar in both low and middle socio economic status populations in Nairobi, Kenya. The project will test the acceptability of the mobile application and feasibility of integrating the mHealth model into clinical care, including the effectiveness in controlling BP and blood sugar respectively when patients receive regular text messages encouraging them to take measurments at home or using a mini-tracker calendar. For the text messaging behavioural intervention patients will be randomized to reminders on blood pressure measurements in three arms (daily, weekly and no messages), and two arms for blood sugar measurments (weekly and no messages). Three surveys (baseline, midline and endline-6 months apart) will be conducted to estimate the proportion of patients with blood pressure and blood sugar controlled. The mini-tracker behavioural intervention will be conducted among patients and evaluated through one-group pre-post design. Cost-effectiveness of the intervention will also be evaluated.

Duration and budget: The project will be undertaken for 2 years. Interviews will be conducted with healthcare providers and the patients. The total budget will be 151,688 USD

Conclusion: The outcomes of this project will inform the integration of the mHealth based service model into the daily routine of the participating clinics. This generation of real-time clinical data, will ensure easy translation into clinical practice, and will facilitate rapid scale-up.

I. Introduction and Background

Hypertension and diabetes represent two major risk factors for atherosclerotic cardiovascular disease (CVD). CVD is the number one cause of death globally[1]. An estimated 17.7 million people died from CVD in 2012, with men and women affected almost equally, in total representing 31% of all global deaths[1]. Low- and middle-income countries (LMIC) are disproportionately affected with over 80% of global CVD deaths[1]. One of the most important risk factors for CVD is an elevated BP or hypertension (HTN). Worldwide there are at least 1.1 billion people who suffer from a persistently elevated BP or HTN[2]. Despite the clear evidence that lowering BP through lifestyle changes and drug treatment can greatly reduce the risk of CVD[3], HTN-control (defined as the proportion of people who reach their target for BP lowering) is still poor; globally, only around 13% of people with hypertension have their BP at target level[4].

Hypertension care in low-income countries: poor access, low quality of care

Hypertension is the leading risk factor for CVD and chronic kidney disease worldwide with estimated burden of 1.13 billion adults in 2015, an increase from 594 million in 1975 [2 5]. The increase is largely driven by the rise in low-income and middle-income countries (LMICs)[6]. A major challenge in the LMICs is the low level of awareness of hypertension and poor BP control with some countries such as Ecuador reporting only 0.3% of patients controlling hypertension [7]. Studies conducted in sub-Saharan Africa indicate a rising prevalence of HTN in both rural and urban populations. In South Africa the risk of death from HTN was estimated to have risen by 25% in less than a decade, while in Tanzania HTN prevalence increased from 25.4% to 41.1% among men and 27.2% to 38.7% among women in both rural and urban populations between 1987 and 1998. [8,9] Population based studies in Kenya have revealed a HTN prevalence ranging from 11% to 30% [10-12]. A study in the urban slums of Nairobi, Kenya showed that only 19.5% of the hypertensive patients were aware about their HTN, and only about half of those who were aware had started treatment and HTN control among all patients was less than 3% [10]. The World Health Organization estimates that there is a 50% prevalence of HTN among African adults aged 25 years and older[13]. In LMICs HTN care is often not available, not accessible, or not affordable, resulting in low treatment coverage[14]. In sub-Saharan Africa (SSA) less than 18% of people in need of HTN treatment use antihypertensive drugs[14]. Of the people who are using antihypertensive drugs, only 7% reach their targeted BP-level[14]. Similar to high-income countries, HTN care is mainly provided at the primary care level in healthcare facilities. However, healthcare systems are overburdened with competing health priorities such as HIV, and suffer from a lack of qualified health care professionals and a lack of essential supplies and medication. Infrastructures to monitor patients over time are not available with poor registration of patient's disease courses. Even when care is available, the travel distance to health clinics and the costs of care limit treatment accessibility for patients. For example, in many countries in sub Saharan Africa (SSA), over 50% of patients' total healthcare expenditures are paid out-of-pocket[15].

Annual treatment of HTN in SSA is estimated to range between $38 - $170 per person [16] despite 43% of people living on less than $1.9 per day[17]. Lifelong treatment for HTN is therefore unaffordable for the majority of the (usually uninsured) population. Even when patients have access to high-quality care, psychological and behavioral barriers contribute to the low rates of BP control described above[18]. To achieve BP control, patients must create new routines and behaviors around taking medication once or more times a day, visiting clinics more frequently, potentially monitoring their BP, changing

their diets and exercising more. However, creating new habits can be difficult and requires environmental changes, high levels of motivation, or strong self-regulation. Creating habits that do not occur on a regular daily basis may be especially difficult because it is more difficult for them to become automatic[3].

Diabetes care in low-income countries: poor access, low quality of care

Though less common than HTN, diabetes mellitus is an increasing major risk factor for CVDs with an estimated burden of 366 million people globally and is projected to increase by 92% in 2030 in low-income countries, followed by lower-middle income countries (57%), upper- middle income countries (46%) and finally higher income countries (25%) [19]. The prevalence of diabetes in both rural and urban Kenya was found to be 4% [20] but 5% in the urban slums of Nairobi, doubling to 10% among those aged 45-54 years; only 10% had ever measured their blood sugar [21]. Another study conducted at the Kenyatta national referral hospital in Nairobi showed that 50% of diabetic patients also had HTN only 30% of the diabetic patients in care achieved the desired glycemic control of HbA1c <7% [22].

Behavioral challenges in management of hypertension and diabetes

Habit formation around health behaviors is also difficult because of the psychological distortion of medical information. For example, research on the 'ostrich effect'[23] finds that patients may be motivated to ignore certain health information if it is psychologically threatening. Thus, a patient may fail to take medication as directed because the action reminds them of their disease, which is unpleasant. Finally, humans are susceptible to cognitive biases [24] that lead to less rational behavior, such as hyperbolic discounting, where short-term costs and benefits are disproportionately valued relative to long-term costs and benefits. Patients may also have a difficult time understanding cause and effect relationships between behaviors and bodily changes[25], leading to false beliefs about the speed with which BP control is achieved or the impact of missing a medication dosage on subsequent BP levels and longer term health outcomes. Together, patients' motivations, cognitions, and environments are unlikely to produce the optimal behaviors required for long-term BP control.

Poor diet consisting of high salt and sugar intake, high saturated and trans-fatty intake, and low fruit and vegetable consumptionand is a key risk factor for development and control of hypertension. [26] Available evidence suggests that the early uncomplicated stage of hypertension can be controlled by lifestyle modifications particularly reduced salt intake. Among those on treatment salt reduction has a role in controlling BP as well. However, achieving sustained dietary changes among patients on treatment is a challenge. A randomized controlled trial conducted in an American population showed showed a distinctive benefit of diet rich in vegetables and fruits and low in salt on blood pressure reduction among African Americans [27.] This confirmed earlier findings that Afriacans are more sensitive to the blood pressure lowering effect of salt reduction in diet[28]. Dietary salt intake reduction can thus modify the effect of antihypertensive therapy, can facilitate blood pressure reduction in hypertensive patients receiving medical therapy, and may represent a simple cost-saving mediator to reduce cardiovascular morbidity and mortality. Diet is also a cornerstone in the management of patients with diabetes. A systematic review and metaanalysis showed that adherence to a mediterranean diet is associated with a reduced risk of type 2 diabetes mellitus[29]. Rapid urbanization in has been largely associated with dietary transition in African countries as it leads to changes in the social and physical environments that people inhabit, shifting food habits and practices, with increased consumption unhealthy diets including energy-dense and nutrient-poor diets[30]. There is a rise in supermakets in urban Kenya including small towns which has led to increase the

consumption of processed foods at the expense of unprocessed foods due to lower prices of processed foods that are high in calorie content[31].This could potentially lead to challenges in controlling hypertension and diabetes among patients on treatment.

Challenges of access to medicines for hypertension and diabetes

Lack of access to essential medicines is one of the major health system challenges affecting the control of HTN and diabetes mellitus. Currently, essential medicines needed for treating these diseases are not readily available in the public sector in low-income and middle-income countries [32,33]. The higher costs of medications in the private sector are unaffordable to the majority of the patients who have to meet these expenses out of pocket payments. This situation is made worse by the long-term treatment and co-morbidities which impose a life-time financial burden on poor households. A study in Malawi estimated that a 1-month course of medication for a patient with HTN could cost as much as 18-days' daily wage [32]. In Kenya, public Health facilities offer HTN and diabetes mellitus treatment only at the sub-county and county referral hospital levels and most patients have to pay user fees to access medicines. These high treatment costs inevitably impact on the success of long term treatment. A great proportion of patients are lost to follow-up and many who attend their visits adhere less to treatment due to the high economic burden of purchasing drugs. Deficient procurement and distribution process of essential drugs for treatment of HTN and diabetes leads to frequent stock-outs of medications, thus affecting compliance of patients to medications and control of BP. Preliminary findings from a recent survey conducted by the African Population and Health Research Center (APHRC) among 10 health facilities in Nairobi and Machakos counties showed that only 10% of health facilities stocked a beta-blocker antihypensive always, 40% had atleast one type of calcium channel blocker always, 50% had at least a diuretic and only 40% had an oral hypoglycemic drug and 10% had insulin always available for diabetes mellitus (unpublished). The financing of the available medication at health facilities (which is less than 50%) was mainly from government (86.9%), out-of-pocket (11.1%), and National Health Insurance (2.0%)-unpublished. From this analysis, more than 50% of all medications for HTN and diabetes is undocumented and is likely to be out-of pocket payments over the counter in pharmacies or remained unfunded.

II. Problem Statement

Cardiovascular diseases are becoming an increasing global problem with clinic-based ineffective and unsustainable care. Low, middle and high income countries across the globe are facing a rising number of patients in need of effective HTN treatment as their populations' age, urban migration leads to sedentary lifestyles and there is a mounting adoption of western lifestyles[34]. Concurrently, these Individual patients confront inherent behavioral barriers to the adoption of changes necessary in the adequate treatment of hypertensive disease. Research findings from an intervention conducted in the Nairobi slums, showed that there was poor patient retention in care as well as poor monitoring and BP control[35]. A study conducted at the Kenyatta national referral hospital in Nairobi showed that 50% of diabetic patients also had HTN only 30% of the diabetic patients in care achieved the desired glycemic control of HbA1c <7%[22]. This combined with the socioeconomic disadvantages, impedes the progress towards achieving reduced BP and diabetes control in the low income populations. The current model of clinic-based care brings poor results, is very costly and thereby difficult to sustain. There is an urgent requirement for cheaper and more effective care to achieve effective HTN and diabetes treatments to large populations in need. Our study aims to improve BP and diabetes control for patients in such populations and streamline the provision of HTN care for healthcare providers with the potential to reduce cost and improve quality of care and access.

III. Review of Literature

Opportunities for better hypertension and diabetes care

Building on previous research on home-based hypertension and diabetes care

Home BP monitoring (HBPM) or self-monitoring of blood glucose (SMBG) is a form of care in which patients measure their BP or blood sugar themselves at home. The BP or blood sugar measurements can be recorded by the patient to show to the health professional during a regular visit. Alternatively, the recordings can be directly transmitted electronically to the clinic using mobile applications. Research has shown that there is more control by patients measuring their BP or blood sugar at home compared to healthcare settings[36,37]. From systematic reviews done, measuring of the BP involves the patient recording the measurements in a book and relaying this to the doctor during their clinic visit. Home-based BP monitoring has been shown to decrease the risk of 'white coat HTN (elevated BP measurements when in a medical setting) prevalence by 15-20%[38,39] and 'masked HTN' (Elevated BP measurements outside a medical setting) by prevalence 10-15%[40] and offer a superior prediction of CVD when compared to office-based measurements [41]. Home-based BP measurement has also been shown to increase patients' awareness[42], decrease therapeutic inertia, and eventually reduce BP[43]. Also, self-titration of antihypertensive drugs by patients has been shown to lead to better control of BP when compared to titration by doctors[42,44]. Furthermore, behavioral interventions have strong promise to increase a patient's adherence to treatment recommendations[45]. Self-monitoring of blood sugar (SMBG) among diabetic patients has also been shown to be effective in glycemic control[46]. A systematic review and a meta-analysis of six randomized controlled trials evaluated the effects of SMBG in patients with type 2 diabetes and showed a statistically significant decrease of 0.39% in HbA_{1c} compared with the control groups[47].

There are many promising ongoing initiatives to improve HTN and diabetes care that hold strong opportunity for improvement. A recent meta-analysis of 23 randomized controlled studies showed that HBPT leads to improved HTN control compared to usual office care[48]. Due to expenditure for new equipment and technology, overall healthcare costs of HBPT where higher than standard office care[49]. Similarly, real time SMBG was shown to be more effective than intermittent monitoring[49,50].

As telemonitoring technologies become cheaper in the future because of further development, opportunities for real time HBPM and SMBG for will increase and thus better control of BP and blood sugar [48].

Existing opportunities have not yet led to better care

Despite these promising approaches, most interventions have not led to a radical improvement in existing HTN and diabetes care and most have only been tested as add-ons to usual clinic-based care, thereby increasing the bureaucratic burden on doctors and patients. In home-based BP studies, physicians and nurses face numerous practical obstacles such as the use of illegible handwritten logbooks or patients who fail to report their BPs, thereby limiting the implementation of home-based BP studies in actual clinical practice [51]. Modern technologies enabling automatic transmission of clinical data from patient to healthcare professionals have been developed to tackle these problems [44,52,53], yet experience with these technologies is limited and many of them are difficult to use.

Existing interventions have also not sufficiently incorporated lessons from behavioral science to change patient behaviors in a meaningful way[49]. When compared with psychological and behavioral factors, awareness and comprehension of one's disease is not a strong predictor of adherence[54]. Contextual reminders or alerts, or integration of medication into existing routines, has been shown to effectively increase medication adherence, in contrast to interventions focused only on communicating information[55,56]. Furthermore, the existing interventions only address a single aspect of care delivery (e.g. home-based measurement of BP by patients instead of office-based measurement by doctors) and do not replace the existing care system.

There is a great opportunity to capitalize on new technologies that integrate successful interventions while at the same time reduce the burden on the health care system. Mobile technology has recognized potential to integrate evidence-based clinical and behavioral interventions, target patients directly in their everyday life and reduce the workload on physicians by (partly) automating care and by shifting management from doctors to patients. We believe that successfully combining home-based self-measurement of BP and diabetes, self-titration of drugs and targeted behavioral interventions in a mobile application could lead to improved care with better treatment outcomes at lower costs.

IV. Research Objectives

General objective

The aim is to develop, implement and evaluate a technologically driven model that improves access to care and self management of hypertension and diabetes at home among low and middle income patients in Nairobi, Kenya.

Specific objectives

1. To assess the acceptability of, and feasibility of implementing a combination of technology driven financing and home based management model of care for diabetes and HTN
2. To evaluate the effectiveness of home based monitoring model of care for HTN and diabetes on BP and blood sugar control
3. To evaluate the cost-effectiveness of scaling up the home based monitoring & financing model

V. Conceptual Framework and Operationalization

Description of the MHealth care model

The core of the model is the interaction between mobile phone applications: M-TIBA allowing patients to receive financial support for their care, Afya Pap or Measure-App, a self-management service for patients and a patient tracker for healthcare providers, which allows for home-based measuring and monitoring of BP and blood sugar. Figure 1 shows the initial care model for home measurement of BP that will be developed and tested in this protocol. Home measurement of blood sugar will follow the same principle.

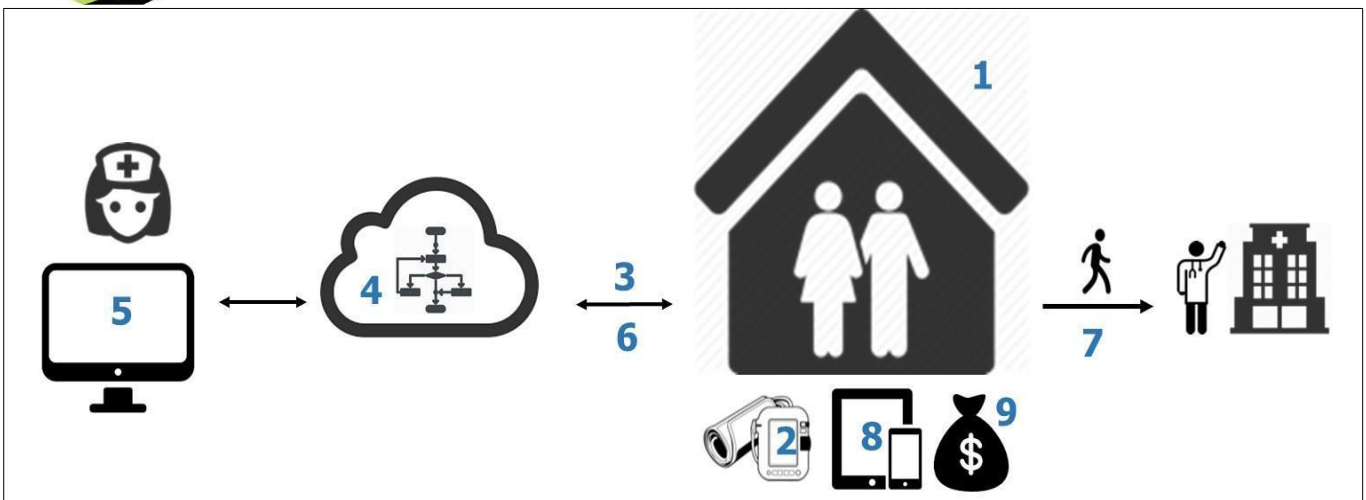

Figure 1. model for m-BP care. 1) Patients measure blood pressure (BP) at home. 2) BP-data are transmitted from the BP-device via bluetooth to the mobile device (smart phone or tablet) of the patient. 3) The application transfers the data to a data-cloud. 4) BP-data will be entered in a digital guideline-algorithm. 5) BP-data with corresponding treatment proposal will appear on the dashboard of the clinician for approval. 6) treatment feedback is given to the patient via the application. 7) Only if BP-values warrant a consultation of a clinician, patients are asked to visit the clinic. 8) During the whole process behavioral incentives appear at the mobile application to increase adherence of the patient. 9) Data on health care exchange and claim handling in real time through M-TIBA.

Figure 1: Care model for home measurement of blood pressure

Patients with HTN or diabetes will measure their BP or blood sugar at home. After each measurement, the measurement data will be automatically transferred into the application. In order to increase adherence to monitoring and treatment, behavioral interventions will be integrated into the application. The application will be designed based on evidence-based behavioral principles aimed at promoting monitoring and medication adherence. By doing this, the application will help patients understand how to create habits and the need to adhere to prescribed behaviors. It will remove barriers that would otherwise interfere with behavior change, and will lead to sustained behavior change.

AfyaPap

AfyaPap is a mobile phone application developed by United Kingdom based technology company Baobab Circle which collects subscribers' personal health data and provides them with customized education. AfyaPap is available on Google Playstore and only works on android devices. There is also an sms-based service available for non-smartphone users. It is designed to patients suffering from diabetes and HTN to manage their conditions by receiving regular personalized information essential for a healthy lifestyle including diet and physical activity. It is also designed to measure and relay information on blood glucose and BP measured at home and sent to health workers. In 2014, 500,000 subscribers enrolled into AfyaPap in Zimbabwe at its launch. In Kenya so far 3000 subscribers are using AfyaPap. AfyaPap is available in Kenya in Kiswahili and English.

Monitoring and failure journey.

In order to increase adherence to monitoring, patients receive a reminder to measure message at the time of the scheduled measurement as well as additional behavioral messages throughout the user journey. The regular weekly reminder messages rotate with other, more specific reminder messages

coming from a patient's preferred clinic (e.g., Langata Hospital) or patient group leader, in order to further motivate user engagement with Afya Pap and increase measurement entry for better monitoring of their BP or blood glucose levels.

Additional behavioral messages include patients being made aware that they have made progress, which will be particularly motivating for patients who are reluctant to continue with measuring their BP initially[59]. Once the patient starts monitoring, the application asks patients to rest and relax for a moment. This will create a pleasurable moment that becomes associated with monitoring. After monitoring, the patient receives feedback on its behavior, which will also vary with different messages at different points in the user journey. For instance, the message may ask patients to tell someone about their diagnosis and associated treatment to help them rely on social support[60]. As the patient enters more measurements into Afya Pap, they will receive feedback about their average BP and/or blood glucose levels so as to see their personal progress in managing their disease. Therefore, not only will they receive positive feedback rewarding them for entering their measurement into Afya Pap, they will see whether their most recent reading is an improvement from their average of the last four recorded readings. This specialized, more positive feedback can serve to reduce the likelihood of patients avoiding measurement input due to the ostrich effect, which is much higher in patients who begin the program with elevated BP or blood glucose levels.

When patients fail to monitor their BP as prescribed, the application will tailor the 'monitoring journey' to reflect the patient's lapse in monitoring adherence. For instance, after an X number of time of failure to measure, patients will be prompted to change their implementation intentions to create a new schedule. After further failures to monitor, patients will be prompted to forgive themselves, start fresh, and recommit. The failure journey messaging will also address psychological barriers, such as anxiety, stress, or frustration[61].

Provider monitoring of study patients (the patient tracker)

Healthcare providers will track patients enrolled using a mobile application called the tracker. The tracker will consist of an overview of the patients and their BP or blood glucose status, thereby facilitating efficient monitoring of patients through prioritization of patients that need urgent attention. Patients will be triaged according to systolic and diastolic cut-offs or HbA1c/fasting blood sugar and the provider will be alerted to patients no longer adhering to home based BP or blood sugar monitoring. In the case of a high/emergency occurrence, the nurse will inform the patient to come to the hospital for clinical intervention. The physician will also be informed and he/she will be able to advice the patient accordingly.

Connection to M-TIBA

All patients will be enrolled in M-TIBA[62,63], a mobile health platform for financial inclusion in healthcare. M-TIBA enables people to save, send, receive and pay money for medical treatment through a mobile health wallet on their phone. Funds can only be spent on health care at selected providers. If people access care at these clinics, data on diagnosis, treatment and claim handling are all visible in real-time on the platform. Through M-TIBA patients in the program will receive discounts on their visits and test for HTN or diabetes care and discounts on specific drugs for HTN and diabetes

delivered by Sanofi (the pharma partner) involved in this project. Providers are completely free to prescribe any medication in this program, and patients are expected to mainly purchase generic drugs for their disease, which will be available at a lower price than the discounted drugs in this program.

By connecting our model to M-TIBA, HTN and diabetes care can be delivered cashless, allowing for real-time insight into costs and utilization of healthcare services. Currently M-TIBA wallets do not have health insurance products so these data are only available for patients who are paying out-of-pocket. However, insurance products are planned for 2018 so if data on insured care are available at the start of the study, these data will also be used in our study. All patients will be enrolled on MTIBA and get access to the programme-benefit.

Through a programme-benefit the patients will have access to discounted prices for consultations, diagnostic tests and selected drugs. This means that when they pay for their care through MTIBA, they only pay 20% of the costs they would usually pay. Payment through MTIBA rides on My Health Funds, which is the general wallet in MTIBA. MTIBA-users can save money to My Health Funds (through their MPESA account) in preparation for their next clinic visit, but can always take this money out of the MTIBA-wallet if they need it for other purposes. By covering costs at this discount-percentage we expect the total out of pocket payments for patients in the program to go down to approximately 100-300 KSH per month (on average), which will be a significant improvement to their current costs of care. This is based on estimates of current costs of care, as objective data on actual costs of care is only sparsely available.

Mini tracker

The mini tracker will be in the form of a card including a small calendar, instructions on how to enter measurements into Afya Pap in the USSD platform, and a goal chart where patients can indicate their BP or blood glucose goal for the end of the month. The calendar will display one month's worth of days and times for which patients can indicate their measurement results after each reading. The tracker can also be adjusted to include reminders and intentions for monthly healthcare savings for some users. Once the month has ended, patients receive new cards from their patient group leader for the following month, and return their filled out cards to a PharmAccess agent to help track each group's progress over time. Various iterations of the tracker will be tested across groups in an effort to find the most effective combination of resources to help patients better adhere to their measurement (and savings) goals.

Main hypotheses:

Blood pressure

H0: Continuous monitoring of BP has no effect on BP

H0 – a) frequency of BP monitoring (daily or weekly) has no effect on BP control

H0 – b) the way BP measurements are communicated to the patient (actual or qualitative reading) has no effect on BP

Blood sugar

H0: Continuous monitoring of Blood sugar has no effect on patient blood sugar or HbA1c

H0 – a) frequency of blood sugar monitoring weekly has no effect on blood sugar control or HbA1c

H0 – b) the way blood sugar measurements are communicated to the patient (actual or qualitative reading) has no effect on blood sugar control

VI. Research questions

1. How feasible is it for a patient to measure BP daily or weekly?
2. Can continuous monitoring of BP improve HTN control?
3. Which is the preferred method of continuous monitoring, daily or weekly and what is the impact of either on HTN control?
4. What is the impact of a behavioral model on control of HTN?
5 How feasible is it for a patient to measure blood sugar weekly?
6. Can continuous monitoring of blood sugar improve blood sugar control?
7. Which is a preferred frequency of continuous measuring, and what the impact on HTN blood sugar control?
8. What is the impact of a behavioral model on control of blood sugar?
9. How can self-measurement and behavioral intervention be used to retain patients in care?

Inclusion and exclusion criteria for both hypertension and diabetes

This study will include known and new patients with essential HTN or diabetes who are receiving care at one of the study clinics and who are judged eligible to participate and who have consented to participate in the study. To recruit new patients, screening will be performed at clinics during triage for regular visits.

Inclusion criteria:

1. Patients with a new diagnosis of essential HTN (diagnosis made by treating clinician) or diagnosed with type 2 diabetes
2. Patients known to have essential HTN (diagnosis made by treating physician) or with diabetes who are already receiving medication.
3. HTN- or diabetic patients receiving treatment provided by the recruiting site
4. Adult (> 18 years old)
5. Ownership of a phone
6. Patients paying out of pocket and willing to be enrolled on M-TIBA

Exclusion criteria:

1. Patients with (suspected) secondary HTN, as described by local guidelines. This diagnosis is at discretion of the treating physician
2. HTN-patients requiring treatment (secondary, tertiary HTN care) not provided by the recruiting site
3. Patients unwilling or who refuse to give informed consent
4. Arm circumference greater than or less than the 22-42 cm for which the used cuffs are validated
5. Failure to obtain valid BP-values (e.g. cardiac arrhythmias)
6. Pregnancy
7. Patients who are judged to be unsuitable for receipt of mobile HTN or diabetes care by the treating physicians (for instance, patients with life-threatening diseases, dementia, and illiterate patients).
8. Patients who have had an acute cardiovascular event in the previous 3 months will also be excluded.

Patients excluded from the study will continue to receive the regular medical care from the health facilities including referrals for hypertensive emergencies.

VII. Study Design and Sampling Strategy

This will be a prospective cohort study with a pre-post design. It will be divided into two phases:

(i) Pilot phase

This will involve recruitment of patients on Afyapap and each patient followed for four months to assess the acceptability of and feasibility of using the service module and home based management of hypertension or diabetes. Within the cohort, we aim to test patient retention in care as primary outcome. However, secondary outcomes include the optimal frequency of home blood-pressure measurements and uptake of the behavioral intervention and patient satisfaction with the use of the applications. This pilot group will receive BP devices plus behavior intervention and measure their BP daily (to be recruited in October 2018) and followed for four months. Depending on the lessons learnt on the feasibility of scaling up, this group could be followed for one year. The lessons learnt from the pilotwill provide insights into the scale up phase.

The patients will be screened for eligibility (the inclusion and exclusion criteria is outlined above). The reasons that patients are not eligible will be recorded. If patients are eligible, they will be asked to participate in the study. If patients are eligible and unwilling to participate in the study, they will be asked to fill out a short quantitative questionnaire describing their reasons for not participating, they will however not be forced to fill in the questionnaire. In the pilot phase, 500 eligible patients with hypertension or diabetes will be enrolled consecutively on to AFya pap and will be asked to monitor their BP daily or fasting blood sugar weekly if they have diabetes. This arm also contains a behavioral intervention in the form of reminders to measure their BP prior to each prescribed measurement and is treated as a pilot arm to examine the feasibility of the study procedures in the first 4 months.

We additionally propose to pilot a behavioural intervention that entails using a mini-tracker by patients enrolled on Afyapap. The mini-tracker is a card including a small calendar, instructions on how to enter measurements into Afya Pap in the USSD platform, and a goal chart where patients can indicate their BP or blood glucose goal for the end of the month. The calendar will display one month's worth of days and times for which patients can indicate their measurement results after each reading. Every month new cards will be issued through patient group leaders while cards of their previous months are returned. Patients will also receive various reminders to measure, based on their chosen day and time of measuring during the onboarding phase. To determine the most effective source of messages on measurement adherence, we will provide reminders coming from their preferred clinic, their patient group leader, their chosen physician, or a family member of their choice. These more personalized messages serve to increase the patient's motivation to continue monitoring their blood pressure and/or blood sugar levels and to engage with the Afya pap platform.

Patients will also be assigned a patient group based on their geographic location. These groups exist to provide support to each patient through group discussions of chronic disease management, practice and information on measuring their BP or blood sugar, and social support through other patient members dealing with either HTN or Diabetes. We anticipate including approximately 1,000 Afya Pap users who are not receiving the SMS intervention and each will be followed for 6 months to test these iterations of the tracker. Based on previous research with providing calendars to help new or expectant mothers save for health insurance, we postulate that the tracker will provide a similar function for Afya Pap users and can be accomplished at a reduced cost compared to providing full annual calendars.

(ii) Scale up phase

After the learning from the pilot phase of 4 months, the subsequent enrolments will be randomized to two arms in the ratio of 1:1. Thepatients will be randomly assigned to 2 groups defined by frequency of measuring BP or blood sugar and the presence or absence of behavioral interventions. The study design is outlined in figures 2 and 3. In arm A, patients with hypertension or diabetes will be asked to monitor their BP or blood sugar weekly using a BP device or glucometer provided to them by the study team and will enter the measurements on afyapap. Patients with diabetes using smartphones will be provided with glucometers that are connected by a device that automatically relays blood sugar readings to the smartphone. Those with non-smartphones (feature phones) will use a USSD code to activate Afyapap and enter blood sugar mearurements manually. Arm A has behavioral intervention in the form of weekly SMS remiders to increase adherence to BP or blood glucose measurements. In arm B devices will also be provided for measurement of BP and blood sugar at home, however the particpants will choose when to take the measurements. There will be no SMS reminders to the participants.

Study population

The study population will be lower income and middle income adult patients with HTN or diabetes or both, recruited from selected health facilities: divided into the two arms of the intervention. The patients will be selected based on the inclusion and exclusion criteria outlined before.

Description of the steps in enrolment and follow up.

Following randomization to one of the two study arms, day 0 of the study starts with a baseline study assessment and onboarding of the patient on M-TIBA and in the self-management application. Healthcare providers or a study nurse will assist patients with installing the application on their smart phone, and instruct them in its use. During the patient set-up in the application, patients will complete a personal profile that allows for tailoring of the behavioral intervention.

Patients will then receive training in the use of a home based BP or blood sugar monitoring device. Patients will be instructed to perform weekly BP measurements (or more, if national guidelines prescribe more frequent monitoring). Once at home and using the BP monitor, patients will enter their measurement results in the application. We will set up protocols for extreme BP and blood sugar values based on best practice and national guidelines.

Study setting

The study will take place in health care clinics servicing the low and middle- income populations in Nairobi, Kiambu and Vihiga Counties in Kenya. The choice of this population is based the challenges of affording care and inability to enrol in private health insurance. But the patient population included will be those patients who have some means to afford HTN or diabetes treatment or who are not insured whose access can be enhanced through the financing model and home based management. There will be selected health facilities from Nairobi, Kiambu and Vihiga Counties in Kenya where patients will be enrolled from. The health facilities are; Langata hospital, Access Afya kwa Njenga clinic, Access Afya Taasia Clinic, Limuru Nursing Home, Kalimoni Mission Hospital, Coptic Mission Hospital, Kima Mission Hospital, Jumuia Friends Kamusinga Hospital, Mungoma Hospital and St. Marys hospital. In the event that we will not be able to get the required sample in the nine health facilities, we will recruit more facilities. These facilities are purposely selected because they have patient populations of interest to the study, as informed by the experiences of PHARMACCESS. Currently, PharmAcces is rolling out the service model for management and financing hypeternsion in three counties (Nairobi, Kiambu and Vihiga) targeting approximately 4000 patients in total. Permission will also be sought from relevant authorities including local authorities, county and sub-county to allow entry into the selected health facilities in Nairobi, Kiambu and Vihiga counties. The evaluation will be conducted in a representative sample as shown below.

Sample size calculation and recruitment

Sample size for patients with hypertension

From Van De Vijver et al. [10] 's study, we estimate that among people who are in treatment, 50% were able to achieve glycemic control. We assume that the current intervention will increase the BP control by 20% in one year of follow-up. Thus, we posit a 20% meaningful difference, and 80% power with 5% level of significance (one-sided test) to detect that difference. Since our study design is a pre-post design, we estimate the sample size following Connor's study [64]. The conservative necessary sample

size is 75 hypertensive patients per study arm. Furthermore, we assume a dropout rate of 20%, implying that the final sample size is 94 hypertensive patients to be recruited at the pre-intervention phase (baseline), and 94 hypertensive patients to be surveyed at the post-intervention phase (midline and end line) in each of the 3 selected counties. Hence for baseline, midline and end line, the total sample size required for patients with HTN is 282 (94×3) respondents at each time point. When it is not feasible to recruit the minimum number from a particular county, we will oversample in the other counties to achieve the required total sample.

Figure 2 represents the survey design and distribution of patients by study arm in each county

Figure 2 represents the survey design and distribution of hypertensive patients by study arm. Group A will receive the BP device plus behavior intervention and measure their BP daily (to be recruited from January 2019- scale up phase) and each patient followed for one year.

Group B will receive the BP device plus behavior intervention and measure their BP weekly (to be recruited from January 2019- scale up phase) and each patient followed for one year. Group C will receive the BP device no behavior intervention and measure their BP at their discretion (to be recruited from January 2019- scale up phase) and each patient followed for one year.

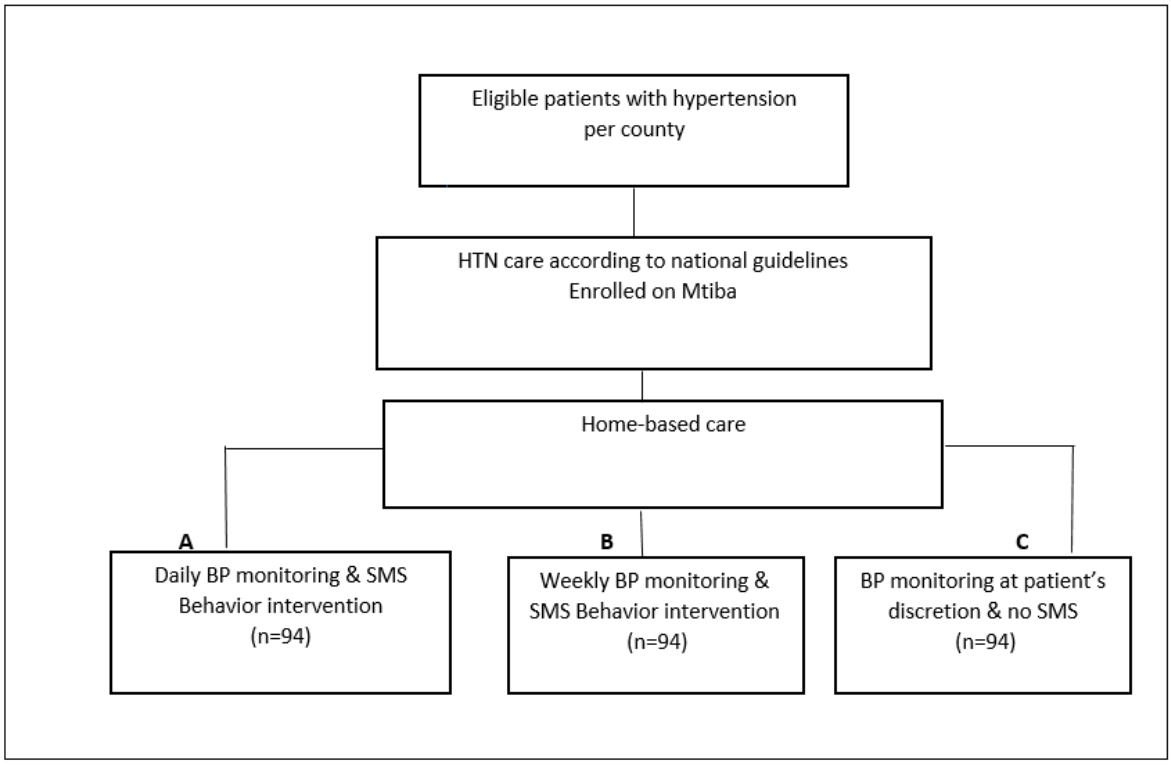

Figure 2: Patient allocation to intervention in each county

Sample size and recruitment of patients with diabetes

In reference to a study by Otieno C et al.,[22] we estimate that among patients with diabetes who are in treatment, 30% were able to achieve glycemic control. We assume that the current intervention will increase the BP control by 30% in one year of follow-up based on findings from a randomized control trial in 3 Low and Middle Income countries including Democratic Republic of Congo[65]. Thus, we posit a 30% meaningful difference, and 80% power with 5% level of significance (one-sided test) to detect that difference. Since our study design is a pre-post design, we estimate the sample size of 49 patients with diabetes per study arm. Furthermore, we assume a dropout rate of 20%, implying at baseline, midline and end line survey, 62 patients with diabetes wil be enrolled in each arm, a total 124 (62X2) in each of the 3 counties at baseline, midline and endline surveys respectively. In the event that we can not get the minimum number of patients in a particular county, we will oversample in the other counties to achieve the total number required per survey round.

Figure 3 represents the survey design and distribution of diabetic patients by study arm. Group A will receive the glucometer device plus behavior intervention and measure their blood sugar weekly (to be recruited from January 2019- scale up phase) and each patient followed for one year. Group B will receive the glucometer device no behavior intervention and measure their blood sugar at their discretion (to be recruited from January 2019- scale up phase) and each patient followed for one year.

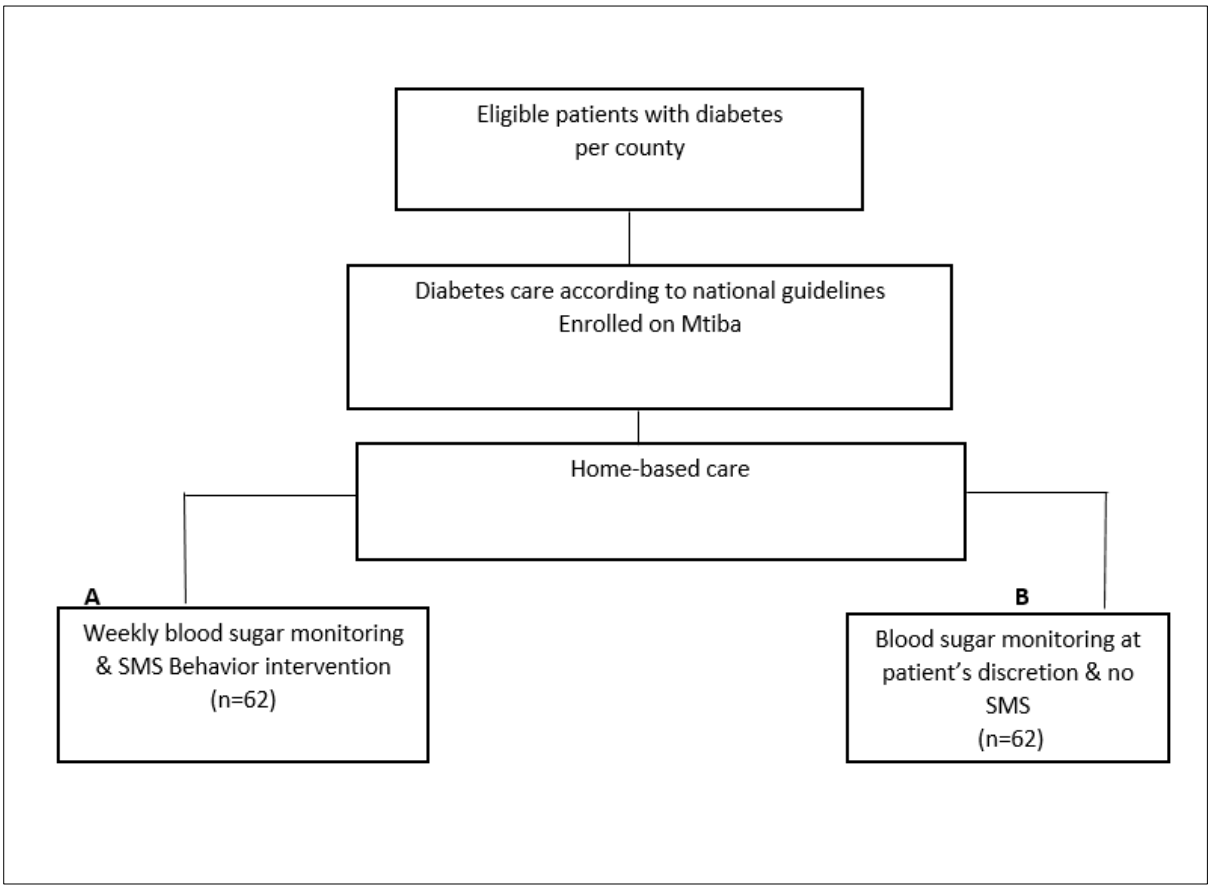

Figure 3: Distribution of diabtes patients into study arms per county

VIII. Data Collection

The study will collect data on the external validity and uptake of the intervention by collecting data on all individuals screened for the study. These data include: number of individuals screened, reasons for non-eligibility of patients identified, and reasons for non-participation of patients who are judged eligible for enrollment. As these data will be collected anonymously and at group level as opposed to at an individual level, no informed consent for screening data collection is needed.

Data collection for enrolled patients will be collected from three different sources:

1. Study-specific baseline, midline and end-line patient assessments
2. Clinical and behavioral data collected from the patient and health-care provider use of the self-management application and patient tracker
3. Clinical data collected during patient and health-care provider encounters.
4. Billing data for all care-activities collected through M-TIBA

Study-specific assessments

Baseline data: Following inclusion in the study, all patients will visit a study nurse at recruitment for baseline assessment. Data collection will include a digital questionnaire with following data: demographics (age, sex), education, income, ethnicity, use of alcohol, smoking status, other CVD risk factors (physical inactivity and unhealthy diet), hours absence from work, travel costs to the clinic, adherence to drugs and medication adherence percentage (for patients already on treatment); data extraction from electronic health record if not available through digital questionnaire: co-morbidities, drug use (type, number of drugs, frequency), already receiving HTN care and physical examination done by the study nurse: height, weight, waist circumference, arm circumference, hip circumference, etc. (See questionnaire appended).

Midline and End-line data: Midline assessment will take place 6 months after enrolment of the patient and end-line assessment will take place 12 months after enrolment of the patient. In addition to the questions in the baseline questionnaire, a small module of questions on the social and economic impacts of COVID-19 on primary care has been added. The data for midline and end-line survey will be collected by telephone interviews. Since the patients enrolled in this study have BP and BG machines previously issued at the enrollment stage, they will be requested to take their BP or BG measurements at the time of the phone interview and relay the information to the interviewer via SMS texts.

Qualitative interviews: In-depth interviews and focus group discussions (FGDs) with purposively selected providers and a subset of the patients (those with the highest quartile of adherence to blood pressure or blood sugar and the lowest quartile of adherence) will provide information on provider and patient experiences with the application. The number of interviews and FGDs will be determined through saturation. Barriers and facilitators for implementation and scale-up will be explored with the program's participants (doctors, pharmacy staff, and patients). A discussion guide will be used during the FGDs/ interviews including the following topics: satisfaction with model, barriers and facilitators for implementation and scale-up, willingness to sustain and scale up the model, advantages

and disadvantages of model compared to usual care, any specific topics resulting from the intermediate data review.

Data collected through the mobile application: The primary data collected by the mobile application is the timing and frequency of BP or blood sugar measurements performed by the patients. A validated automatic BP device will be used for all measurements (OMRON Healthcare Co. Ltd.) with a cuff size adjusted to the patients arm circumference. BP will be measured according to a predefined standard operating procedure (SOP). Measurement will be after at least 2-5 minutes of rest. Three different readings will be taken, if possible on the non-dominant arm with patient well seated on a chair and the BP cuff at the level of the heart. The average of the readings will be used for analyses. Similarly, standardized fasting blood sugar measurements will be conducted.

Additional data collected by the application for patients will include patient responses to specific behavioral or monitoring requests from the mobile application, frequency and type of interactions between patients and health-care providers and health-care provider interaction with the dashboard (if automated during feasibility phase) and weight. Medication adherence will be self-reported. At this stage, changes in the treatment plan and medication changes will not be collected through the mobile application but will be collected in the patient records as part of usual care.

Potential additional data collected from health care providers through the dashboard include the frequency of visits to the clinic, frequency of interaction with the provider patient tracker, time spent in tracker, frequency of providers' calls to patients. Whether it is feasible to collect these data will depend on the stage of technological development of the system. Clinic staff will register the frequency and cause of hospital admissions and reasons for patient drop-out. Because all patients enrolled in the study will also be enrolled in M-TIBA, we will have medical costs and data for each clinic visit including diagnosis, treatment (tests and drugs) and claim amount for all patients who are paying out-of-pocket (non-insured care).

IX. Data Processing and Analysis

Quantitative outcomes: Data will be analyzed using STATA (STATA Corporation, Texas, and USA).

We will use an econometric model to evaluate the treatment effect of the home-based management of HTN. We will first utilize a t-test (for continuous outcome) and chi-squared test (for binary outcome) to assess the change in the outcome variable between each time point (baseline vs. midline, baseline vs. end line) for different groups. For our primary outcome, we will also model the probability of controlling the BPs at least 70% in a month using a regression based approach. Covariates included in the model will be a binary variable indicating pre- and post-intervention period, respondent's education, respondent's age, respondent's income, self-reported health and drinking status etc. A difference-in-difference model will also be used to estimate the treatment effect of the home-based management of HTN. The same approach will be used for blood sugar control as a secondary outcome

Cost-effectiveness analysis and business model

We will use the ingredient approach to estimate the total cost of home-based management of HTN or diabetes. The costing will be done from both the provider's and patient's perspective. The provider's

perspective represents a 'business case': how do the costs of the program compare to the gains or losses in productivity. As such it forms, in essence, an accounting exercise. Hence, we will collect the expenditures related to the BP machine, text messages (SMS), transportation, consultation with the clinicians, drugs, forgone earnings due to sickness, etc. First, we will estimate the average cost (unit cost, i.e., total expenditures incurred by one patient to adopt home-based management of HTN. A cost-effectiveness evaluation will also be carried out to estimate the cost to recruit an *additional* hypertensive patient.

Second, we will develop a net-cost model to estimate the substantial cost savings for the individual using the productivity approach. Hence, the net benefit is:

The costs avoided will be translated into monetary terms by capturing the excess of lost work hours using a survey instrument or surveillance system, transport cost and visitation to clinicians that will be saved by patients due to the intervention (avoided medical costs=pre-intervention medical care cost minus post medical care cost). The costs of the intervention will be estimated using the ingredient approach and information found in the financial report.

Data management

Qualitative data will be recorded and transcribed. Transcribed data will be saved in word format and saved in a password protected computer for storage, audio-taped interviews will also be labeled with the study identifier, rather than with names. The quantitative data collected through surveys at recruitment and during the research will contain unique numbers for each patient, the data will be collected by the health facility staff and analyzed by the research team. All study participants in this research will be assigned unique study identifiers by the health facility to protect patient data confidentiality. The data will be accessible to both APHRC and the health facilities. The data will be stored in a computerized database and all study documentation and materials (including informed consent forms) will be stored in locked file cabinets when not in use at APHRC. Only project and assigned healthcare staff will have access to the data.

Anonymized and aggregated data-insights will be shared with the pharma-partner involved in this project, of which the project-management team is partly based in Kenya and partly based in France.

X. Plan for Communicating Findings of the Study

From research evidence we know that research is most effectively disseminated using multiple vehicles, ideally with face to face interaction. So, in addition to giving feedback to study participants, we will disseminate the study findings through engagement in a dissemination workshop and share factsheets. We will also share the results with the funder. Thus, this proactive dissemination strategy offers the breadth to reach out to multiple audiences and the depth to conduct more in-depth interactive work with key audiences such health service providers to streamline provision of HTN and diabetes care for healthcare providers with the potential to reduce cost and improve quality of care.

XI. Study Limitations and Risks

This study has been designed as a cohort study in order to identify barriers to implementation of the care model on a larger scale. The major impediments to the study – that patients do not enroll or that patients download the application without using it – are also useful outcomes for the design of the overarching model. There are numerous impediments expected in implementing the program.

Site diversity. Given the difference in the target populations, it is highly likely that implementation of the study in the different populations will be unique. These differences will require individualized approaches to each field site and can complicate a future scale-up of the intervention.

Work force. Primary health clinics and general practitioner's offices are strained in high, middle and low-income settings. This study may place an unanticipated strain on these clinics making study recruitment, implementation, and follow-up difficult. We aim to minimize this burden by recruiting additional study staff.

Reduced healthcare costs: We anticipate the healthcare costs for the patients to reduce due to reduced visits to health facilities leading to reduced fees for consultation for the healthcare provider which might be counted as loss. To minimize this, we plan to provide subsidies for the healthcare costs by paying the providers a certain percentage of this lost income. This we anticipate to occur during the scaling up of the study. For now, we do not anticipate a change in the healthcare visits as the patients will still need to come in for checkups as recommended by physician, hence the subsidies will be done at a later stage after the outcomes of the feasibility study, including impact of the study on healthcare visits and patient retention in care. The amount will be a percentage of the charge for consultation per patient seen during the study.

Ethical considerations

Study participants will provide written informed consent to the study nurse before inclusion in the study at the baseline assessment. All study data will be collected and stored anonymously. Ethical principles of justice, beneficence and respect for human dignity will be adhered to throughout the project activities.

Potential risks and benefits to patients

The study described in this proposal is a prospective cohort study which introduces a new mobile health application for patients and providers. The model is embedded in local HTN and diabetes guidelines and provision of HTN and diabetes care should not deviate significantly from these guidelines.

Nonetheless, the proposed intervention has specific risks associated with it. The first risk is that patients enrolled in the model will measure their BP or blood sugar very often and may have unnecessary or excessive contact with their health care providers. This could lead to rapid escalation of treatment and overtreatment of patients with the concomitant risk of hypotension and medication side effects. A second risk is that patients may suffer stress and undue concern due to the frequent monitoring of their BP despite having adequate control. A third risk is that patients will measure their BPs more frequently and could measure a very high BP at a time when they cannot easily contact the primary health clinic. This could result in an unnecessary and potentially costly visit to another health facility for the patient.

Our study has been designed to mitigate some of the risks. We will collect information on how patients perceive daily measurements during the beta-test and can adjust the protocol if needed. In addition, patients who are on daily measurement have the freedom to switch to less frequent measurement if the burden is too high. The remote monitoring of the patients by the physician will seek to reduce the situation where the patient would need to seek attention in a costly clinic, by contacting the patient in the event of a high BP and advice accordingly.

Conversely, the proposed intervention could have several benefits for patients. The first is enhanced education and awareness of their disease. The second is an improvement in the trust and reliance of the primary health care provider. The third is a potentially improved medication adherence and control of HTN, with long-term benefits in reduction of the risk of CVDs. The fourth is financial support to co-finance their care will improve access to medication and consultation visits.

The risk of a HTN emergency is very low. All patients are seen by a healthcare professional at enrollment. Patients with signs of a hypertensive emergency (very high blood pressure with signs and symptoms as defined by WHO[40]) are admitted and are not enrolled in our study until the doctor judges them suitable for home-based care (after stabilization). It is very rare that patients who are in outpatient HTN care and using drugs are developing a hypertensive crisis. Similar to usual care, patients will get clear instructions to contact the clinic when they have signs of severe hypotension or HTN. We therefore believe that the risks to the patient from the intervention are low and that the benefits to the patient can be high. Patients can discontinue use of the application at any time without consequence.

This trial has been designed as a cohort trial in order to identify barriers to implementation of the model on a larger scale. It may be possible that patients do not enroll or download the application without using it. If this is the case, the trial is designed to identify and understand the factors influencing this behavior and is thereby still useful to the overarching program. As such, the trial could still be helpful to patients even if they do not actively participate, as physicians will be informed of patients' lack of engagement and could adopt alternative strategies to engage patients in their care.

XII. Management and Organization of the Study

Catherine Kyobutungi, is the Executive Director at APHRC, she is a Medical doctor and an epidemiologist with interest in non-communicable diseases. She holds a PHD in Epidemiology from the Heidelberg University, Germany. She is the PI and will offer overall technical direction to the study and be the main contact person for any correspondence.

Project Team Members

Gershim Asiki, an Associate Research Scientist at APHRC, a medical doctor with a PhD in Epidemiology, will be the project manager and will oversee the day to day running of the project and will be the contact person for the other partners collaborating in the project.

Herrmann Dounfet, is an Associate Research Scientist, with a PhD in Health Economics will lead the health financing aspects for the study.

Caroline Wainaina and Peter Otieno, both Research officers at APHRC, will be the project coordinators and their roles will include formulation, contextualizing of data collection tools, the consent forms, participate in training, organizing of sensitization meetings, recruitment of participants and clinics, supervise data collection, management and analysis.

Other project collaborators

Angela Siteyi, a project manager at PharmAccess international and will offer expertise on the use of M-tiba and the intervention phase that will incorporate the care pathways

Judith Van Andel, a medical advisor at PharmAccess International has extensive experience and knowledge on the use of care pathways and the health pocket innovation known as M-tiba. She will offer technical assistance in the operation of the project.

Marleeen Hendriks (Joep Lange Institute, Amsterdam), is medical director and head of innovation at the Joep Lange Institute, with extensive experience on self-management of disease and financial models to provide care for HTN and diabetes in low-income settings. She will advise on study design and overall direction of the project.

Rebecca Rayburn-Reeves (Center for Advanced Hindsight, Duke University, United States) is a senior behavioral researcher at the Center for Advanced Hindsight (CAH) and the Afya Pap project lead at CAH. She has a PhD in Experimental Psychology and extensive experience in experimental design. She will advise on study design and assist in secondary data analysis.

Rachel Kahn (Center for Advanced Hindsight, Duke University, United States) is a behavioral researcher at the Center for Advanced Hindsight (CAH) with experience working on medical care research, such as ER diversion and medication adherence. She will advise on study design and assist in secondary data analysis.

Judson Bonick (Center for Advanced Hindsight, Duke University, United States) is a senior behavioral researcher at the Center for Advanced Hindsight (CAH) and the partner lead on the collaboration between CAH and JLI. He has extensive experience in designing interventions for increasing health savings in low to middle-income Kenyans utilizing mobile health platforms. He will advise on study design and assist in secondary data analysis.

Summary Budget for Phase I (budget issued in phases)

	Preparations phase (USD)	Prototype phase pilot (USD)	Scale-up phase pilot amendment (USD)	Total budget (USD)
Personnel cost	5787	23151	44009	72949
Training	1498	-	-	1499
Sensitization	1755	-	-	1755
Recruitment	-	4185	-	4185
Patient monitoring	-	14580	-	14580
Evaluation and post intervention data collection	-	3946	4143	8090
Data review workshop	-	-	-	
Operation cost	-	17938	450	18389
Meeting, mobilization and dissemination	-	7650	-	7650
Sub-total	9,041	71,451	48,604	129,096
Overhead costs	1582	12503	8505	22,592
Grand Total	10,623	83,955	57,109	151,688

Timeline of the study

The aim for this study is to dry-run all tools and data-processes by the end of August 2018 and to start including patients by September 2018. The first follow-up phase will consist of a period of 4 months to be able to closely monitor a small group of patients and optimize the study tools and evaluate uptake of the service model. After these initial four months, the study will be scaled up to three counties (Nairobi, Kiambu and Vihiga) with a total follow-up time of at least 1 year per patient. Since the recruitment may happen in most of 2019, the study period will extend to 2020.Figure 4: shows the study timeline.

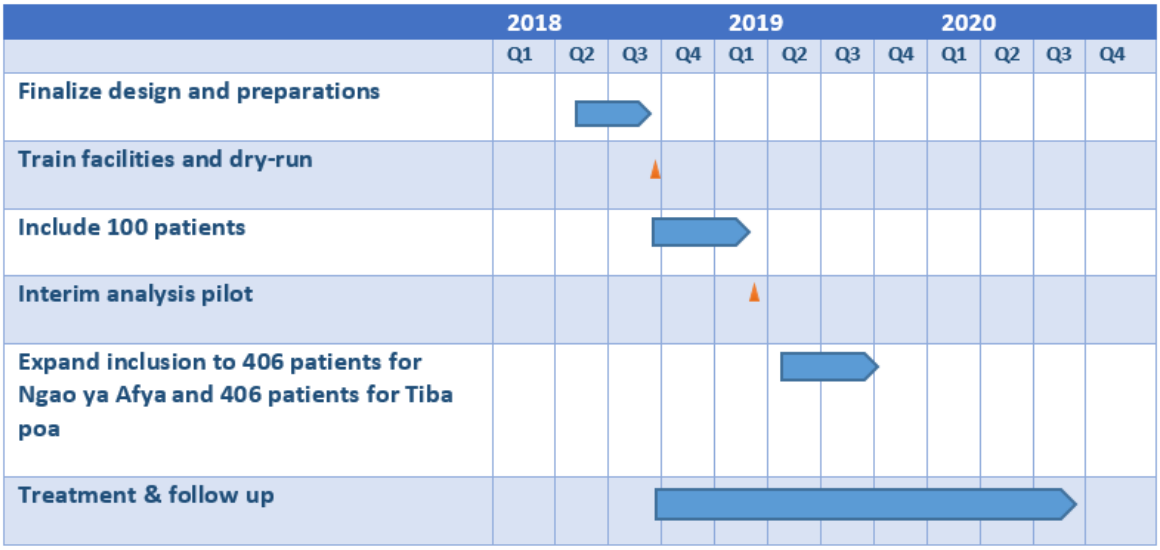

Figure 4: Timeline for the study

XIII. Appendices and References

References

1. WHO Cardiovascular diseases (CVDs). WHO (2016).
2. Zhou B, Bentham J, Di Cesare M, et al. Worldwide trends in blood pressure from 1975 to 2015: a pooled analysis of 1479 population-based measurement studies with 19· 1 million participants. *The Lancet.* 2017;389(10064):37-55.
3. Neal DT, Wood W, Quinn JM. Habits—A repeat performance. *Current Directions in Psychological Science.* 2006;15(4):198-202.
4. Chow CK, Teo KK, Rangarajan S, et al. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. *Jama.* 2013;310(9):959-968.
5. Danaei G, Lu Y, Singh GM, et al. Cardiovascular disease, chronic kidney disease, and diabetes mortality burden of cardiometabolic risk factors from 1980 to 2010: A comparative risk assessment. *Lancet Diabetes & Endocrinology.* 2014;2(8):634-647.
6. Sarki, A.M., Nduka, C.U., Stranges, S., Kandala, N.B. and Uthman, O.A., 2015. Prevalence of hypertension in low-and middle-income countries: a systematic review and meta-analysis. *Medicine*, *94*(50).
7. Anselmi M, Avanzini F, Moreíra J-M, et al. Treatment and control of arterial hypertension in a rural community in Ecuador. *The Lancet.* 2003;361(9364):1186-1187.
8. Mayosi B, Bryer A, Lambert V, et al. A statement of intent on the formation of the NCRP on cardiovascular and metabolic disease: a new initiative to fight heart disease, stroke, diabetes and obesity in South Africa. 2007.
9. Edwards R, Unwin N, Mugusi F, et al. Hypertension prevalence and care in an urban and rural area of Tanzania. *Journal of hypertension.* 2000;18(2):145-152.
10. Van de Vijver SJ, Oti SO, Agyemang C, Gomez GB, Kyobutungi C. Prevalence, awareness, treatment and control of hypertension among slum dwellers in Nairobi, Kenya. *Journal of hypertension.* 2013;31(5):1018-1024.
11. Jenson A, Omar AL, Omar MA, Rishad A, Khoshnood K. Assessment of hypertension control in a district of Mombasa, Kenya. *Global public health.* 2011;6(3):293-306.
12. Bloomfield GS, Hogan JW, Keter A, et al. Hypertension and obesity as cardiovascular risk factors among HIV seropositive patients in Western Kenya. *PloS one.* 2011;6(7):e22288.
13. WHO. WHO | Raised blood pressure. World health observatory data (World Health Organization, 2015).
14. Ataklte F, Erqou S, Kaptoge S, Taye B, Echouffo-Tcheugui JB, Kengne AP. Burden of undiagnosed hypertension in sub-saharan Africa: a systematic review and meta-analysis. *Hypertension.* 2014: HYPERTENSION AHA. 114.04394.
15. WHO. WHO | Out-of-pocket expenditure on health as a percentage of private expenditure on health (US$). WHO (2016).
16. Brouwer ED, Watkins D, Olson Z, Goett J, Nugent R, Levin C. Provider costs for prevention and treatment of cardiovascular and related conditions in low-and middle-income countries: a systematic review. *BMC Public Health.* 2015;15(1):1183.
17. World Bank. Poverty and Equity Database | Data. (2016). Available at: http://data.worldbank.org/data-catalog/poverty-and-equity-database. (Accessed: 17th January 2017).
18. Verplanken B, Wood W. Interventions to break and create consumer habits. *Journal of Public Policy & Marketing.* 2006;25(1):90-103.

19. Whiting DR, Guariguata L, Weil C, Shaw J. IDF diabetes atlas: global estimates of the prevalence of diabetes for 2011 and 2030. *Diabetes research and clinical practice.* 2011;94(3):311-321.
20. Christensen DL, Friis H, Mwaniki D, et al. Prevalence of glucose intolerance and associated risk factors in rural and urban populations of different ethnic groups in Kenya. *Diabetes research and clinical practice.* 2009;84(3):303-310.
21. Ayah R, Joshi MD, Wanjiru R, et al. A population-based survey of prevalence of diabetes and correlates in an urban slum community in Nairobi, Kenya. *BMC public health.* 2013;13(1):371.
22. Otieno C, Vaghela V, Mwendwa F, Kayima J, Ogola E. Cardiovascular risk factors in patients with type 2 diabetes mellitus in Kenya: levels of control attained at the Outpatient Diabetic Clinic of Kenyatta National Hospital, Nairobi. *East African medical journal.* 2005;82(12).
23. Webb TL, Chang BP, Benn Y. 'The Ostrich Problem': motivated avoidance or rejection of information about goal progress. *Social and Personality Psychology Compass.* 2013;7(11):794-807.
24. Tversky, A. & Kahneman, D. in Utility, Probability, and Human Decision Making 141–162 (Springer Netherlands, 1975). doi:10.1007/978-94-010-1834-0_8.
25. Hilbert M. Toward a synthesis of cognitive biases: how noisy information processing can bias human decision making. *Psychological bulletin.* 2012;138(2):211.
26. Cecchini M, Sassi F, Lauer JA, et al. Chronic Diseases: Chronic Diseases and Development 3. Tackling of unhealthy diets, physical inactivity, and obesity: health effects and cost-effectiveness. *Lancet.* 2010 Nov 11;376(9754):1775-84.
27. Appel LJ, Brands MW, Daniels SR, Karanja N, Elmer PJ, Sacks FM. Dietary approaches to prevent and treat hypertension: a scientific statement from the American Heart Association. *Hypertension.* 2006 Feb 1;47(2):296-308.
28. Frisoli TM, Schmieder RE, Grodzicki T, Messerli FH. Salt and hypertension: is salt dietary reduction worth the effort?. *The American journal of medicine*. 2012 May 1;125(5):433-9.
29. Schwingshackl L, Missbach B, König J, Hoffmann G. Adherence to a Mediterranean diet and risk of diabetes: a systematic review and meta-analysis. *Public health nutrition*. 2015 May;18(7):1292-9.
30. Vorster HH, Kruger A, Margetts BM. The nutrition transition in Africa: can it be steered into a more positive direction? *Nutrients.* 2011 Apr;3(4):429–41.
31. Rischke R, Kimenju SC, Klasen S, Qaim M. Supermarkets and food consumption patterns: the case of small towns in Kenya. Food Policy. 2015 Apr 1;52:9-21.

32 Mendis S, Fukino K, Cameron A, et al. The availability and affordability of selected essential medicines for chronic diseases in six low-and middle-income countries. *Bulletin of the world health organization.* 2007;85(4):279-288.
33. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *The lancet.* 2009;373(9659):240-249.
34. Yusuf S, Reddy S, Ôunpuu S, Anand S. Global burden of cardiovascular diseases: part I: general considerations, the epidemiologic transition, risk factors, and impact of urbanization. *Circulation.* 2001;104(22):2746-2753.
35. Oti SO, Van De Vijver S, Gomez GB, et al. Outcomes and costs of implementing a community-based intervention for hypertension in an urban slum in Kenya. *Bulletin of the World Health Organization.* 2016;94(7):501.
36. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. *Bmj.* 2004;329(7458):145.

37. Walford S, Gale E, Allison S, Tattersall R. Self-monitoring of blood-glucose: improvement of diabetic control. *The Lancet.* 1978;311(8067):732-735.
38. Obara T, Ohkubo T, Funahashi J, et al. Isolated uncontrolled hypertension at home and in the office among treated hypertensive patients from the J-HOME study. *Journal of hypertension.* 2005;23(9):1653-1660.
39. Ohkubo T, Metoki H, Imai Y. Prognostic significance of morning surge in blood pressure: which definition, which outcome? *Blood pressure monitoring.* 2008;13(3):161-162.
40. Bobrie G, Chatellier G, Genes N, et al. Cardiovascular prognosis of masked hypertension detected by blood pressure self-measurement in elderly treated hypertensive patients. *Jama.* 2004;291(11):1342-1349.
41. Sega R, Facchetti R, Bombelli M, et al. Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population: follow-up results from the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study. *Circulation.* 2005;111(14):1777-1783.
42. Parati G, Stergiou GS, Asmar R, et al. European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. *Journal of hypertension.* 2008;26(8):1505-1526.
43. Agarwal R, Bills JE, Hecht TJ, Light RP. Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control: a systematic review and meta-analysis. *Hypertension.* 2011;57(1):29-38.
44. McManus RJ, Mant J, Bray EP, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. *The Lancet.* 2010;376(9736):163-172.
45. Linn AJ, Vervloet M, van Dijk L, Smit EG, Van Weert JC. Effects of eHealth interventions on medication adherence: a systematic review of the literature. *Journal of medical Internet research.* 2011;13(4).
46. Karter AJ, Ackerson LM, Darbinian JA, et al. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry∗. *The American journal of medicine.* 2001;111(1):1-9.
47. Welschen LM, Bloemendal E, Nijpels G, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. *Diabetes care.* 2005;28(6):1510-1517.
48. Omboni S, Ferrari R. The role of telemedicine in hypertension management: focus on blood pressure telemonitoring. *Current hypertension reports.* 2015;17(4):21.
49. Parati G, Omboni S. Role of home blood pressure telemonitoring in hypertension management: an update. *Blood pressure monitoring.* 2010;15(6):285-295.
50. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. *Bmj.* 2011;343:d3805.
51. Tamaki S, Nakamura Y, Teramura M, et al. The factors contributing to whether or not hypertensive patients bring their home blood pressure record to the outpatient clinic. *Internal Medicine.* 2008;47(18):1561-1565.
52. Shea S, Weinstock RS, Teresi JA, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. *Journal of the American Medical Informatics Association.* 2009;16(4):446-456.

53. Gaalema DE, Savage PD, Rengo JL, Cutler AY, Higgins ST, Ades PA. Financial incentives to promote cardiac rehabilitation participation and adherence among Medicaid patients. *Preventive medicine.* 2016;92:47-50.
54. Alison Phillips L, Leventhal H, Leventhal EA. Assessing theoretical predictors of long-term medication adherence: Patients' treatment-related beliefs, experiential feedback and habit development. *Psychology & Health.* 2013;28(10):1135-1151.
55. Krueger KP, Berger BA, Felkey B. Medication adherence and persistence: a comprehensive review. *Advances in therapy.* 2005;22(4):313-356.
56. Osterberg L, Blaschke T. Adherence to medication. *New England Journal of Medicine.* 2005;353(5):487-497.
57. Gollwitzer PM, Sheeran P. Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Advances in experimental social psychology.* 2006;38:69-119.
58. Fujita K, Roberts JC. Promoting prospective self-control through abstraction. *Journal of Experimental Social Psychology.* 2010;46(6):1049-1054.
59. Koo M, Fishbach A. Dynamics of self-regulation: How (un) accomplished goal actions affect motivation. *Journal of personality and social psychology.* 2008;94(2):183.
60. DiMatteo MR. Social support and patient adherence to medical treatment: a meta-analysis. *Health psychology.* 2004;23(2):207.
61. DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. *Archives of internal medicine.* 2000;160(14):2101-2107.
62. SAFARICOM M-TIBA. Available at: http://m-tiba.co.ke/. (Accessed: 7th March 2017).
63. PharmAccess Foundation | mHealth. Available at: https://www.pharmaccess.org/activity/mhealth/. (Accessed: 7th March 2017).
64. Connor RJ. Testing Differences in Proportions for the Paired-Sample Design *Biometrics.* 1987;43(1):207-211.
65. Van Olmen, J., Kegels, G., Korachais, C., de Man, J., Van Acker, K., Kalobu, J.C., van Pelt, M., Ku, G.M., Hen, H., Kanda, D. and Malombo, B., 2017. The effect of text message support on diabetes self-management in developing countries–A randomised trial. *Journal of clinical & translational endocrinology*, *7*, pp.33-41

Appendix 2: Data collection Tools

Quantitative Tool

Evaluating a service model for management of hypertension and diabetes among low and middle- income patients enrolled on M-TIBA in Nairobi, Kenya

	Automatically Preloaded Responses in Survey CTO		
	▪ Phone number: ▪ ID-number: ▪ Clinic: ▪ Does the patient have hypertension, diabetes, or both? ▪ Is the patient new or existing?		
1.1	Sex of the respondent **Jinsia la mhojiwa**	1. Male 2. Female	
1.2	What is your date of birth? **Tarehe ya kuzaliwa**	(DD/MM/YY)	
1.3	How old are you? (Years) **Uko na umri wa miaka ngapi**		
1.4	What is your highest level of education? **Kiwango chako cha juu zaidi ya elimu ni nini?**	1.No formal schooling	
		2. Primary incomplete.	
		3. Primary complete	
		4.Secondary incomplete	
		5.Secondary complete	
		6.College/University incomplete	
		7.College/University complete	
Introduction			
Hello, my name is……and I am working with the African Population and Health Research Center (APHRC). We are conducting a research study on ways to reduce the burden of hypertension and diabetes on the health care system and improve monitoring of blood pressure and diabetes by patients. We aim to do this by developing a mobile application that will enable patients manage their hypertension or diabetes status from home remotely. **Habari, jina langu ni …… na ninafanya kazi na African Population and Health Research Center (APHRC). Tunafanya utafiti juu ya njia za kupunguza mzigo wa shinikizo la damu na ugonjwa wa kisukari kwenye mfumo wa utunzaji wa afya na kuboresha ufuatiliaji wa shinikizo la damu na ugonjwa wa sukari kwa wagonjwa. Tunakusudia kufanya hivyo kwa kuunda programu ya rununu ambayo itawawezesha wagonjwa kutunza viwango vyao vya shinikizo la damu au hali ya ugonjwa wa sukari kutoka nyumbani kwa mbali.**			
		1.Married or living together	

1.5	What is your marital status? **Nini hali yako ya ndoa?**	2.Divorced / separated	
		3.Widowed	
		4.Never-married /never lived together	
		5.Others	
		(SPECIFY)……	
1.6	What is your occupation? **Kazi yako ni nini?**	1.Formal employment 2. Informal employment 2.Casual worker 3.Trader 4.Unemployed 6.Other_____ (SPECIFY)	

2.0	**Actions in response to COVID-19** **Vitendo katikakukabiliana na COVID-19**	
2.1	Have you heard of COVID-19 or Coronavirus **Je, umesikia kuhusu COVID-19 ama Coronavirus**	1.Yes; 2.No; 3.Don't Know
2.2	Have you been in close contact with someone confirmed to be infected with COVID19 **Je, umekua karibu na mtu aliyethibitishwa kuambukizwa na COVID19?**	1. Yes 2. No 3. Don't know
2.3	If yes, where did you get in contact with this person **Ikiwa ndio, je, ulikuwa na huyu mtu wapi?**	1-Healthcare setting 2-At home 3-Workplace 4-Public transport setting 5-Other (Specify) _____
2.4	Have you noticed any of the following over the last 14 days (select all that apply) **Je, umeona dalili zozote zifuatazo katika siku 14 zilizopita?**	1-High temperature- ≥ 38C or subjective fever? 2- Persistent dry cough? 3-Sore throat or pain when swallowing) 4-Breathlessness or a difficulty breathing that you've noticed recently? 5-Pain in your body, especially your muscles hurting more than usual? 6-Recent changes in your ability to taste or smell things? 7- Unusual nausea or vomiting? 8- Diarrhea?

		9-Feeling more tired/sleepy/unable to concentrate/physical weakness than usual? If none of the above skip to 10.7
2.5	Date of symptom onset: **Tarehe ya dalili ya kuanza kuonekana**	___/_____/_____ DD/MM/YYYY
2.6	Have you been tested for COVID- 19? **Je, umepata kipimo cha COVID19?**	1- Yes; 2- No
2.7	Outcome of the test **Matokeo**	1- Positive; 2- Negative; 3- Don't know
2.8	Have you or members of your household changed anything you do as a result of hearing about COVID-19 or Coronavirus? **Je, wewe au familia yako mmebadilisha chochote mlichokua mkifanya kutokana na COVID19?**	1.Yes; 2.No; 3.Don't Know
2.9	What things have you or your household changed as a result of hearing about COVID-19 or Coronavirus? (mark all that apply) **Je, ni nini haswa ambayo wewe au familia yako mnafanya au kubadili kutokana na COVID19?**	1. Washed hands more often; 2. Avoiding crowded areas; 3. Avoided social events; 4. Avoided taking taxis; 5. Avoided going out; 7. Avoided going to work 8. Avoided travelling long distances; 9. Using face masks; 10. Wearing gloves 11. Using hand sanitizer; 12 Others (Specify other)
2.10	How much do you feel you know about the COVID-19 pandemic? **Je, unahisi una ufahamu gani kuhusu janga la COVID19**	1.Less than I should know; 2. A little but not enough; Enough; 3. A little more than most people. 4. I am up to date on the latest research
Household Impact of COVID-19 **Athari ya COVID19 katika jamii**		
2.11	Over the past seven days, have you wanted to access healthcare but have been unable to do so? **Je, ulihitaji kupata huduma za afya katika muda wa siku saba zilizopita lakini hukuweza?**	1. Yes. 2. No; 3. Don't Know
2.12	Over the past seven days, has your family been able to get all food and other household necessities they need?	1. Yes; 2. No; 3. Don't Know

	Je, familia yako imeweza kupata vyakula vyote au mahitaji yenu yote pale nyumbani katika siku saba zilizopita?	
2.13	Over the past seven days, have COVID-19 laws/regulations/rules affected the ability of you or your household to earn money? **Katika siku saba zilizopita, je! Sharia/kanuni za COVID19 zimeathiri uwezo wako au familia yako kupata pesa?**	1. Yes; 2. No; 3. Don't Know
2.14	Which of the following statement is true regarding the ability of you or your household to earn money over the past seven days? **Je! Ni ipi kati ya taarifa ifuatayo ni kweli kuhusu uwezo wako au familia yako kupata pesa kwa siku saba zilizopita?** Select all that apply	1. Someone in the household has lost a job; 2.Someone in the household is on unpaid leave. 3. Others (Specify)
2.15	What are you planning to do to as a result of this financial hardship? **Je, unapanga kufanya nini kutokana na hali hii ngumu ya kifedha?** Select all that apply	1.Not pay bills that are due; 2.Take out a loan; 3.Skip meals; 4. Others
2.16	Over the past seven days, have you had access to soap and water at home for hand hygiene? **Je, katika siku saba zilizopita, umeweza kupata sabuni na maji nyumbani kwa usafi wa mkono?**	1.Always; 2. Sometimes 3.Never
2.17	Over the past seven days, how often have you been bothered by having little interest or pleasure in doing things? **Katika siku saba zilizopita, ni mara ngapi umesumbuliwa na kupendezwa kidogo au ukosefu waraha katika kile unachofanya**	1.Not at all; 2.Several days; 3.More than half the days; 4.Nearly every day
2.18	Over the past seven days, how often have you been bothered by feeling down, depressed or hopeless? **Je! Katika siku saba zilizopita, ni mara ngapi umesumbuliwa na kuhisi kuwa chini, kuwa na huzuni au kupoteza tumaini?**	1.Not at all; 2.Several days; 3. More than half the days; 4.Nearly every day
2.19	Over the past seven days, how often have you been bothered by feeling nervous, anxious or on edge?	1.Not at all; 2. Several days;

	Je! Katika siku saba zilizopita, ni mara ngapi umesumbuliwa na kuwa na wasiwasi au ukali?	3.More than half the days; 5.Nearly every day
2.20	Over the past seven days, how often have you been bothered by not be able to stop or control worrying. **Katika siku saba zilizopita, mara ngapi umekuwa ukisumbuliwa na kutoweza kuacha au kudhibiti wasiwasi?**	1.Not at all; 2.Several days; 3. More than half the days; 4.Nearly every day
2.21	Which of the following affected you in managing your Chronic disease condition for which you have been seeking care (Tick all that apply) **Ni yapi kati ya haya yalikuathiri katika kudhibiti hali yako ya magonjwa sugu ambayo umekua ukitafuta matibabu?**	1- Difficulty in securing appointments with a doctor 2- Hesitation in going out of home due to a health risk of COVID-19 3- Difficulty in buying infection control supplies such as sanitizer, masks 4- Difficulty seeking community and social services 5- Transport cost too high 6- Lack of money to buy medications

3.0 Tobacco & alcohol I will start by asking you some questions on tobacco and alcohol use ***Tumbaku na pombe.*** **Nitaanza na kukuuliza maswali kuhusu utumiaji wa tumbaku na pombe**		
3.1	Do you currently use any tobacco products, such as cigarettes, cigars or pipes? **Je! kwa sasa unatumia bidha zozote za tumbaku kama vile sigara, biri au bomba?**	1.Yes ☐ 2.No ☐
3.2	Have you ever smoked tobacco or used smokeless tobacco? **Je! Umewahi kuvuta sigara au kutumia tumbaku usio na moshi?**	1.Yes ☐ 2.No ☐
3.3	In the last 12 months, how frequently have you had at least one alcoholic drink? **Katika miezi 12 iliyopita, ni mara ngapi umetumia angalau aina moja ya kileo?**	1 Daily ☐ 2. Weekly ☐ 3. Monthly ☐ 4 Occasionally ☐ 5. Never ☐

4.0 Diet

Fruits and Vegetables - The next questions ask about the fruits and vegetables that you usually eat. **Matunda na mboga- maswali yafuatayo yanauliza juu ya matunda na mboga ambazo kawaida wewe hula**		
4.1	In a typical week, how many servings of **fruit** do you usually eat? (No. of servings)	

	Je! Unakula matunda mara ngapi kwa wiki ya kawaida?	
4.2	In a typical week, how many servings of **vegetables** do you usually eat? (No. of servings) **Je! Unakula mboga mara ngapi katika wiki ya kawaida?**	

Dietary salt - With the next question. I would like to learn more about salt in your diet. Dietary salt include ordinary diet table salt, unrefined salt, iodized salt, salty sock cube and powders, salty souse such as fish source **Ifuatayo, ningependa kupata maelezo zaidi kuhusu chumvi katika chakula chako.**

4.3	How often is salt, salty seasoning or salty sauces added in cooking or preparing foods in your household **Ni mara ngapi chumvi hutumika katika mapishi nyumbani kwako?**	1.Always ☐ 2.Often ☐ 3.Sometimes ☐ 4.Rarely ☐ 5.Never ☐ 99.Don't Know ☐
4.4	How often do you add salt, salty seasoning or salty sauces on food on the table? Ni mara ngapi huwa unaongeza chumvi kwa chakula mezani?	1.Always ☐ 2.Often ☐ 3.Sometimes ☐ 4.Rarely ☐ 5.Never ☐ 99.Don't Know ☐
4.5	How often do you eat processed foods high in salt? By processed food high in salt I mean foods that have been altered from their natural state, such as packaged salty snacks, canned salty foods including pickles and preserves, salty food prepared at a fast food restaurant, chees, bacon and processed meat. **Ni mara ngapi wewe hula vyakula vilivyo na kiwango cha juu cha chumvi? Hivi namaanisha vyakula vilivyobadilishwa hali yao ya asili kama vile vyakula vilivyo na vihifadhi, vyakula vinavyotayarishwa mkahawani vilivyo na kiwango cha juu cha chumvi, cheese, bacon na nyama ya kushindikwa?**	1.Always ☐ 2.Often ☐ 3.Sometimes ☐ 4.Rarely ☐ 5.Never ☐ 6.Don't Know ☐

Dietary Sugar - Dietary sugar includes ordinary sugar, refined sugar such as candy, chocolate and fizzy drinks. **Sukari katika chakula haswa hutokana: sukari ya kawaida, candy, chocolate na vinywaji vilivyo na vihifadhi.**

4.5	How often do you **add sugar to your beverages** right before you drink them or as you are drinking them? *(SELECT ONLY ONE)* **Ni mara ngapi wewe huongeza sukari kwenye vinywaji vyako kabla au unapovinywa?**	Always (every drink)	1
		Often (every day, not every drink)	2
		Sometimes (every week)	3
		Rarely (not every week)	4
		Never	5
		Don't know	77

4.6	In a typical week how many 300 ml bottles of soda (like fanta, coca cola, Afya or other sugary drinks) do you drink? **Je, kwa wiki ya kawaida unakunywa chupa ngapi ya 300 ml?**	Number of bottles	
4.7	How often do you eat **processed food high in sugar**? By processed food high in sugar, I mean biscuits, wafers, cakes, candy, sweets and chocolate and alike? **Je! Unakula vyakula vilivyo na kiwango cha juu cha sukari mara ngapi?**	Always (every meal)	1
		Often (every day)	2
		Sometimes (every week)	3
		Rarely	4
		Never	5
		Don't know	77

5.0 Physical activity

5.1	In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate? This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job. **Katika wiki iliyopita, ni siku ngapi umefanya jumla ya dakika 30 au zaidi ya mazoezi ya mwili, ambayo yalitosha kuongeza kiwango chako cha kupumua? Hii inaweza kujumuisha michezo, mazoezi na kutembea kwa kasi au baisikeli kwa burudani au kufika na kutoka mahali, lakini haipaswi kujumuisha kazi ya nyumbani au shughuli za mazoezi ambazo zinaweza kuwa sehemu ya kazi yako**	☐ **days per week**

6.0 Clinic visits

6.1	In the past 6 months, on average, how many times have you sought healthcare for any cardiovascular disease at this primary healthcare facility? **Je, kwa kipindi cha miezi 6 zilizopita, kwa wastani, ni mara ngapi umetafuta matibabu dhidi ya ugonjwa wa moyo na mishipa katika kituo hiki cha afya?**	__|__|
6.2	Were all the medications you needed available at this facility? **Ulipata dawa zote ulizohitaji katika kituo hiki?**	Yes ☐ *(skip next)* No ☐
6.3	Why were you unable to obtain the medicines from your primary during the most recent related visit? **Mbona hukupata dawa hizo mara ya mwisho ulipotembelea kituoni?**	1.Too expensive ☐ 2.Medicine(s) not in stock ☐ 3.Referred elsewhere by the medical professional ☐ 4.Other (Specify:____) ☐ 99.Don't know/Refused ☐

6.4	How far away do you live from your primary health facility? **Je, unaishi umbali wa kiasi gani na kituo chako cha afya?**	1. Less than 3km away ☐ 2. 3-5Km away ☐ 3. More than 5km away ☐
6.5	Can you please mention the most common form of transport you often use to go to your primary facility **Wewe hutumia mbinu gani mara nyingi kufika kituoni humu?**	1. Walking ☐ 2. Public means ☐ 3. Taxi ☐ 4. Own car ☐ 5. Other (Specify)_____ ☐
6.6	How long does it take for you to get to your primary facility? **Inakuchukua takriban muda wa kiasi gani kufika kituoni chako cha afya?**	Estimated Hours: |__|__| Estimated minutes|__|__|
6.7	During the past 12 months, was there ever a time that you felt you needed medical help (examination or treatment) but you did not receive it?" **Kwa miezi 12 zilizopita, je, kuna wakati ulihisi kuwa unahitaji matibabu lakini hukupata?**	1.Yes 2.No (Skip to 6.9)
6.8	Which of the following would you describes why you did not access healthcare when you should have accessed? (circle all those that apply) **Ni nini haswa katika orodha hii ungesema kilikuwa chanzo cha kukosa matibabu wakati ulipaswa kupata matibabu hayo?**	1. Fear of the risk of contracting Covid 19 in the facility. 2. Curfew and other Covid 19 ban on travel 3. lacked transport (or money for transport) 4. .Because I was too sick to walk 5.. I was told there were no drugs 6. Treated badly by the health workers on last visit 7.I visited a traditional healer 8.I used traditional herbs 9..I bought drugs from a pharmacy Other reasons (specify)
6.9	On your last clinic visit, how long did you wait between arriving at the facility and receiving medical attention? **Ulisubiri muda wa kiasi gani tangu ulipofika kituoni na kupata matibabu?**	__Hours ___Minutes

7.0 Occupational costs

7.1	How many days did you miss work in the last 4 weeks as a result of your diabetic or hypertensive condition? (Only count the missed work days in the last 4 weeks**) (Only asked if employed on a payed work)** **Je, ni siku ngapi ulikosa kwenda kazini kwa kipindi cha wiki nne zilizopita kutokana na hali yako ya kisukari au shinikizo la damu**	☐☐☐ Days
7.2	How many days at work were you bothered by physical or psychological problems? (Only count the <u>days at work</u> in the last 4 weeks) **Je, ni siku ngapi kazini ulisumbuliwa na shida ya kisaikolojia au kimwili?**	☐☐ days

7.3	On the days that you were bothered by physical or psychological problems, how much work could you do on average? 0 – 10 **Je, kwa hizi siku ulikuwa na tatizo ya kimwili au kisaikolojia, uliweza kufanya kazi kiasi gani kwa wastani?** *Look at the figures below. 10 means that you were able to do as much work as you normally do. 0 means that you were unable to do any work on these days. Circle the figure that fits best.*	
7.4	How many days were you forced to do less unpaid work because of physical or psychological problems? Only count the days in the last 4 weeks. **Je, ni siku ngapi ulilazimika kufanya kazi kidogo isiyo na malipo kwa sababu ya matatizo yako ya kimwili au kisaikolojia? Hesabu siku kaika wiki 4 zilizopita.**	☐☐ days
7.5	Imagine that somebody, for example your partner, family member or friend helped you on these days, and he or she did all the work that you were unable to do for you. How many hours on average did that person spend doing this on these days? **Fikiria kwamba mtu, kwa mfano mchumba wako, mtu yeyote katika familia au rafiki alikusaidia katika siku hizi, na akazifanya kazi zote hungewezafanya mwenyewe. Alichukua masaa mangapi kwa wastani kufanya kazi hizi?**	On average …….. hours on these days

8.0 Satisfaction with care & Adherence

8.1	How satisfied are you with the care you have received for your hypertension and/or diabetes at the clinic over the past 3 months? **Je, unaridhishwaje na huduma ulizopokea kuhusiana na hali yako ya shinikizo la damu au kisukari kwa kipindi cha miezi 3 zilizopita?**	1. Very satisfied ☐ 2. Satisfied ☐ 3. Neither satisfied nor unsatisfied ☐ 4. Unsatisfied ☐ 5. Very unsatisfied ☐
8.2	How satisfied were you with the self-monitoring service Afya Pap? **Je, uliridhishwaje na huduma ya kujipima ya Afya Pap?**	1. Very satisfied ☐ 2. Satisfied ☐ 3. Neither satisfied nor unsatisfied ☐ 4. Unsatisfied ☐ 5. Very unsatisfied ☐
8.3.	Are you currently to take medication for your hypertension or diabetes? **Je, kwa sasa, unahitajika kutumia dawa zako za shinikizo la damu au kisukari?**	Yes ☐ No (skip next question) ☐
8.4	How many days during the last week did you take your hypertension medications? (0-7) **Je, ni kwa siku ngapi katika wiki uliopita ulitumia dawa zako za shinikizo la damu?**	|__| day(s)
8.5	How many days during the last week did you take your diabetes medications? (0-7) **Je, ni kwa siku ngapi katika wiki uliopita ulitumia dawa zako za kisukari?**	|__| day(s)
8.6	In the past month, how often did you measure your blood pressure values?	|__|__|

	Katika mwezi uliopita, ni mara ngapi ulichukua vipimo vya shinikizo la damu	
8.7	In the past month, how many times have you failed to relay your blood pressure measurements through your phone **Je, kwa mwezi uliopita, ni mara ngapi hukutuma vipimo vya shinikizo la damu kupitia simu yako?**	|__| time(s)
8.8	What challenges have you faced in relaying your blood pressure measurements? List **Je, umepata matatizo yoyote katika kutuma vipimo hivi vya shinikizo la damu? orodhesha**	……
8.9	In the past month, how often did you measure your blood sugar values? **Katika mwezi uliopita, ni mara ngapi ulichukua vipimo vya kisukari?**	|__| day(s)
8.10	In the past month, how many times have you failed to relay your blood sugar measurements through your phone **Je, kwa mwezi uliopita, ni mara ngapi hukutuma vipimo vya kisukari kupitia simu yako?**	|__| time(s)
8.11	What challenges have you faced in relaying your blood sugar measurements? List **Je, umepata matatizo yoyote katika kutuma vipimo hivi vya kisukari? Orodhesha**	……

9.0	**Underlying conditions**			
9.1	Have you ever been told by a doctor or a qualified health service provider that you have any of the following conditions **Je, umewahi kuambiwa na daktari au mhudumu wa afya kuwa una magonjwa yafuatayo?**			
9.2	Asthma	1.Yes	2.No	3.Dont know
9.3	Cardiac disease			
9.4	Chronic liver disease			
9.5	Chronic neurological/neuromuscular disease			
9.6	COPD/Chronic pulmonary disease			
9.7	Other (Chronic illness) Please specify	_____		
9.8	**Treatment Burden** We are interested in finding out about the effort you have to make to look after your health and how this impacts on your day-to-day life. Please tell us know how much difficulty you have with the following: (Please tick the box that most applies to you) **Mzigo wa tiba** **Tungependa kujua juu ya juhudi unazopaswa kufanya kutunza afya na jinsi hii inaathiri maisha yako yakila siku. Tafadhali tuambie tujue ni shida ngapi unapata na yafuatayo.**			
		5.Ext	**4.Ver**	**3.Qu ite**	**2.A little Diff**	**1. Not**

9.8.1	Taking lots of medications **Kutumia dawa nyingi**	5	4	3	2	1
9.8.2	Remembering how and when to take medication **Kukumbuka jinsi na wakati wa kutumia dawa**	5	4	3	2	1
9.8.3	Paying for prescriptions, over the counter medication or equipment **Kulipia maagizo, kununua katika duka la dawa au vifaa**	5	4	3	2	1
9.8.4	Collecting prescription medication **Kuenda kuchukua dawa zilizoagizwa**	5	4	3	2	1
9.8.5	Monitoring your medical conditions (e.g. checking your blood pressure or blood sugar, monitoring your symptoms etc.) **Kutunza hali yako (k,v kuchukua vipimo vya shinikizo ladamu au kisukari, kuangalia dalili zako n.k)**	5	4	3	2	1
9.8.6	Arranging appointments with health professionals **Kupanga kuonekana na wataalamu wa afya**	5	4	3	2	1
9.8.7	Seeing lots of different health professionals **Kuona wataalamu wengi wa afya**	5	4	3	2	1
9.8.8	Attending appointments with health professionals (e.g. getting time off work, arranging transport etc.) **Kuhudhuria mikutano na wataalamu wa afya (k.v kuchukua saa yako ya kazi, kutafuta nauli, n.k)**	5	4	3	2	1
9.8.9	Getting health care in the evenings and at weekends **Kupata huduma za afya jioni na wikendi**	5	4	3	2	1
9.8.10	Getting help from community services (e.g. physiotherapy, district nurses etc.) **Kupata usaidizi kutoka kwa huduma za kijamii**	5	4	3	2	1
9.8.11	Obtaining clear and up-to date information about your condition **Kupata habari wazi na mwafaka kuhusu hali yako**	5	4	3	2	1
9.8.12	Obtaining clear and up-to date information about your condition **Kupata habari wazi na mwafaka kuhusu hali yako**	5	4	3	2	1
9.8.13	Having to rely on help from family and friends **Kulazimika kupata usaidizi kutoka kwa jamaa na marafiki**	5	4	3	2	1

10.0 Measurements

ANTHROPOMETRIC MEASUREMENTS - *Next, I am going to request you to take your BP or BG measurements and share t readings me through an SMS text* ***Ifuatayo nitakuomba uchukue vipimo vyako vya BP au BG na unitumie vipimo hivi kupitia SMS***		
1o.1	**For women:** Are you pregnant? 0000000000000	1.yes 2.No IF YES SKIP TO 11.8
11.6	Blood pressure measurement 1	……/…….. mmHg
11.7	Blood pressure measurement 2	……/…….. mmHg
11.8	Eaten anything in the last 8 hours?	Yes ☐ No ☐

11.9	Blood glucose	…… mmol/L

Qualitative Tool

INTERVIEW GUIDE FOR PARTTICIPANTS
Home based model compared to usual care
1. Please describe, your experience with usual care that you receive before you start or started participating in the home based measuring of blood pressure or blood sugar 2. Please tell me, your views about using the home based care model in measuring blood pressure 3. What would you say are the major differences between the two types of care in monitoring (home versus clinic monitoring)? 4. Please tell me, have you seen/observed any changes in your health/life since you started measuring your BP or blood sugar from home? Please tell me more ● Any positive changes ● Any negative changes ● Any unexpected changes
Barriers and facilitators in the home based measurements
1. What are the main facilitators in enabling you measure your blood pressure/blood sugar from home? *Probes* ● What would you say was the easy part in measuring your blood pressure/blood sugar at home? ● What in your view made it easy for you to measure your blood pressure /blood sugar at home? 2. Please describe any barriers and challenges you faced in using the mobile application model? *Probes* ● What would you say made it difficult for you to measure your blood pressure/blood sugar at home? ● How can this barriers and challenges be addressed? 3. What would you say needs to be changed to improve the use of the home care care model?
Medication Adherence
1. Please tell me your experience of using medication for blood pressure and Diabetes 2. Probe: a. Times and duration for taking the medication b. The ease of accessing the medication c. Side effects arising from the medications 3. Please tell me if you have seen any change in your medication adherence after joining the study a. Positive changes b. Negative changes c. Unexpected changes 4. Please tell me how the home based measuring for Blood pressure and Blood sugar, has contributed to you adhering to medication a. Time for taking medication b. Duration of taking medication c. Change in confidence in medicine uptake

ɔring by healthcare providers

1. What is your opinion about the remote monitoring by healthcare providers?
   - Follow up by healthcare provider on the BP/blood sugar measuring through calls
   - The frequency of checkups as a result of home based measuring of blood pressure/sugar
   - The messages you receive to remind you about measuring your blood pressure/sugar.

Satisfaction with model for home based measurement

1. What would you say has been the most interesting thing about home based measuring blood pressure or blood sugar?
2. In your opinion, would you recommend the model to other patients?
3. What in your opinion would be the issues that would keep other patients or hospitals from using this care model?
4. Any questions?

INTERVIEW GUIDE FOR PATIENTS (Swahili version)

Home based model compared to usual care

1) Tafadhali nieleze, uzoefu wako kwa kutumia namna ya uuguzi kutoka kwa hospital ambayo umekuwa ama ulikuwa ukipata kabla ya kujiunga na mradi huu.
2) Tafadhali nieleze maoni yako kuhusu mfano huu wa kupima shinikizo la damu na ugonjwa wa kisukari, ukiwa nyumbani
3) Je, kunatofauti zozote ambazo umeona katika njia hizi mbili za kukuwezesha kupima shinikizo la damu na au ugonjwa wa kisukari yako
   - Tafadhali nieleze, umeona ama kupitia mabadiliko yeyote katika maisha yako tangu uanze kujipima shinikizo la damu na au ugonjwa wa kisukari ukiwa nyumbani? Tafadhali nieleze zaidi.
   - *Probes*:
   - Any positive changes
   - Any negative changes
   - Any unexpected changes

Barriers and facilitators in the home based hypertension measuring

1. Je, ni mambo gani unaweza sema yamekuwezesha wewe kupima shinikizo la damu ukiwa na au ugonjwa wa kisukari nyumbani?

Probes

- Je, unaweza sema ni nini kilikuwa cha raisi kwa wewe kuweza kupima shinikizo la damu ukiwa na au ugonjwa wa kisukari nyumbani?
- Ni nini kwa maoni yako ilirahisisha kwa wewe kuweza kupima shinikizo la damu nyumbani na au ugonjwa wa kisukari?

2. Tafadhali nieleze ni changamoto gani ulipitia kwa wewe kutumia mano huu wa kujipima shinikizo la damu na au ugonjwa wa kisukari nyumbani?

   Probes

   - Ni nini unaweza sema kilileta changamoto kwa wewe kuweza kujipima ukiwa nyumbani?
   - Je, hizi changamoto zinaweza kutatuliwa ki vipi?
   - Ni nini kinastahili kubadilishwa ilikuimarisha upimaji wa shinikizo la damu ukiwa nyumbani?

Medication Adherence

1. Tafadhali nieleze uzoefu wako wakutumia dawa ya shinikizo la damu na ama ugonjwa wa kisukari
2. Probe:
    a. Wakati na muda wa kuchukua dawa
    b. Urahisi wa kupata dawa
    c. Madhara ambayo umepata kutokana na dawa
3. Je, umeona utafauti wowote kwa wewe kuchukua dawa baada ya kuanza kushiriki katika utafiti huu
    a. Positive changes
    b. Negative changes
    c. Unexpected changes
4. Tafadhali nieleze jinsi kupima shinikizo la damu limechangia kwa wewe kufwatilia maelezo kuhusu kuchukua/kunywa dawa

Probe:

a. Wakati wa kuchua dawa
b. Muda wa kuchua dawa
c. Kubadilika kwa kujiamini (confidence) kwako kwa kuchukua dawa

Monitoring by healthcare providers

1. Una maoni gani kuhusu kufwatiliwa kwa umbali na wauguzi wakiwa hospitalini?
    - Na je una maoni gani kuhusu kufwatiliwa na wauguzi kwa hao kukupigia simu kukueleza kuhusu vipimo vyako?
    - Mara ambazo utahitajika kuenda hospitali kwa ajili ya upimaji wa shinikizo la damu na au ugonjwa wa kisukari ukiwa nyumbani
    - Mawaidha ama ujumbe unayopata kukukumbusha kuhusu kujipima shinikizo la damu na au ugonjwa wa kisukari.

Satisfaction with model for home based measuring of hypertension

1. Je unaweza sema ni nini kimekufurahisha kwa mfano huu wa kujipima shinikizo la damu na au ugonjwa wa kisukari ukiwa nyumbani?
2. Kwa maoni yako, unaweza kuwaelezea wagonjwa wengine wa shinikizo la damu na au ugonjwa wa kisukari kuhusu uzuri wa mfano huu?
3. Kwa maoni yako, ni nini kinaweza zuia wagonjwa wengine kutumia mfano huu wa kujipima?
4. Je, una swali?

Qualitative tool for health care providers

General overview

1. How was the remote monitoring of the hypertensive diabetic patients? Please describe your experiences
    - The advantages/benefits
    - The challenges/barriers
    - Impact on the hospital's routine
    - Impact on the patients' health

Ufuatiliaji wa mbali wa wagonjwa wa shinikizo la damu na Kisukari ulikuwaje? Tafadhali eleza uzoefu wako
• Faida / faida
• changamoto / vikwazo
• Athari juu ya utaratibu wa hospitali

• Athari kwa afya ya wagonjwa

Patient tracker and Afya Pap review

1. Please describe your experience using the patient tracker
    - Compared to regular treatment, did the tracker lead to you spending more or less time per patient?
    - Prioritization of work
    - Categorization of the hypertensive patients
    - Time with patients
2. Please describe how you used the patient tracker in your daily monitoring of the hypertensive and diabetic patients.
    - When to use the tracker
    - Required and available information on the tracker
    - Compatibility with usual care
3. What are your opinions regarding the use of the patient tracker as an App in health facilities?
    - Efficiency
    - Effectiveness
    - Adaptability
    - Reliability
4. Please tell me the key things that you found useful in the patient tracker that aided your physician role, please tell me more
5. What would you say are things that you feel need to be changed in the App for better functioning and complementing of your work, please tell me more

Tafadhali eleza uzoefu wako kwa kutumia tracker ya wagonjwa
• Ukilinganishwa na matibabu ya kawaida, je, tracker ya wagonjwa ulikuwezesha kutumia muda fupi kuhudumia wagonjwa?
• Kipaumbele cha kazi
• Jamii ya wagonjwa wa shinikizo la damu
• Muda na wagonjwa
Tafadhali eleza jinsi ulivyotumia tracker ya wagonjwa katika ufuatiliaji wako wa kila siku wa wagonjwa wa shinikizo la damu na wale wa Kisukari?.
• Wakati wa kutumia tracker
• Unapohitajika kutumia habari zilizopo kwenye tracker
• Utangamano na huduma ya kawaida
3. Una Maoni gani kuhusu matumizi ya tracker ya wagojwa katika vituo vya afya
• Ufanisi
• Ufanisi
• Kubadilishana
• Kuegemea
4. Tafadhali nielezee vitu muhimu ambavyo umepata vyema katika tracker ya mgonjwa amboyo ilisaidia jukumu lako la kuto huduma za afya, tafadhali eleza zaidi?
5. Je,ni mambo gani inapaswa kubadilishwa kwa programu hii ili kuhahakikishia kazi bora na kuimarisha kazi yako, tafadhali nieleze zaidi?

Discussions of the Afya Pap Mobile Application on the Patients smartphone

6. What are your views on the use of the mobile App, Afya Pap for remote monitoring?
    - Can easily be used
    - Interactive
    - Transmits measurements as required and in real time

7. What would you say are the challenges encountered in the use of the App?
    - Not easy to use
    - Not interactive
    - Restrictive, needs a smartphone to operate
    - Internet challenges

Je maoni yako juu ya matumizi ya programu ya simu ya mkono, Afya Pap kwa ajili ya ufuatiliaji mbali?
• Inaweza kutumika kwa urahisi
• Kuingiliana
• Huwasilisha vipimo kama inavyohitajika na wakati halisi

Unaweza kusema nini ni changamoto zilizokumba matumizi ya programu hii
• Si rahisi kutumia
• Sio ushirikiano
• Kikwazo, inahitaji smartphone kuendesha
• changamoto za mtandao

Medication section

2. In your opinion, would you say that the patient tracker has had an influence on the medication process for your patients
    - Ease of follow up
    - Prioritization
    - Treatment regimen for patients
3. Would you say the information in the Patient tracker App is enough to inform decisions on treatment for your patients, if not what would need to be added?
4. Please tell how this works together with the existing patient records
    - Was the use of the App sufficient on its own? ID you have to update the App with the patients medication and vice versa?
    - Were you able to complete the medication section the same way as you would complete the existing patient record? If not, why not?
    - Were there cases when you felt that the patient's medication needed to be changed? If so, what actions did you take?

Kwa maoni yako, je! Unasema kuwa tracker ya mgonjwa imekuwa na ushawishi juu ya mchakato wa dawa kwa wagonjwa wako
• Urahisi wa kufuatilia
• Kipaumbele
• Matibabu ya matibabu kwa wagonjwa
. Je, unasema habari katika App ya Tracke ni kutosha kuwajulisha maamuzi juu ya matibabu kwa wagonjwa wako, kama sio haja ya kuongezwa?
Tafadhali sema jinsi hii inavyofanya kazi pamoja na kumbukumbu zilizopo za mgonjwa
• Je, matumizi ya App yaliyo ya kutosha? Kitambulisho unapaswa kuboresha App na madawa ya wagonjwa na kinyume chake?
• Je, ulikuwa na uwezo wa kukamilisha sehemu ya dawa kwa namna ile ile kama ungependa kukamilisha rekodi ya mgonjwa? Ikiwa sio, kwa nini sio?
• Je! Kulikuwa na matukio wakati ulihisi kuwa dawa ya mgonjwa inahitaji kubadilishwa? Ikiwa ndivyo, unachukua hatua gani?

Follow of Patients

5. Please tell me if there were times you contacted a patient? If so, for what reasons and what actions did you take?

6. Were there times that a patient contacted you? If so, for what reasons and what actions did you take?
7. Did you receive any feedback (positive or negative) from patients about measuring their blood pressure or blood glucose from home and being monitored by healthcare staff from far?

Tafadhali niambie kama kuna nyakati ulizowasiliana na mgonjwa? Ikiwa ndivyo, kwa sababu gani na ulichukua hatua gani?
Je, kulikuwa na nyakati ambazo mgonjwa alikutana nawe? Ikiwa ndivyo, kwa sababu gani na ulichukua hatua gani?
Je, umepokea maoni yoyote (chanya au hasi) kutoka kwa wagonjwa kuhusu kupima shinikizo la damu au kiwango cha sukari kwenya damu kutoka nyumbani na kufuatiliwa na wafanyakazi wa afya kutoka mbali?

Recommendations

8. Would you recommend for integration of remote monitoring into the usual CVD care using these Apps?
9. Do you think there are patients who can and are willing to pay for their own blood pressure machine (approximately 6000 KES)? If so, can you give an estimate of how many hypertensive patients would purchase one?
10. What recommendations do you have for Measure?

Je! Ungependekeza kuunganisha ufuatiliaji wa kijijini ndani ya huduma ya kawaida ya CVD kutumia programu hizi?
Unafikiri kuna wagonjwa ambao wanaweza na wanapenda kulipa kwa ajili ya mashine yao ya shinikizo la damu (takriban 6000 KES)? Ikiwa ndivyo, unaweza kutoa makadirio ya wagonjwa wengi wa shinikizo la damu watununua moja?
Ni mapendekezo gani unayo?

Appendix 3: Consent Forms

Ethics & Scientific Review Committee

Informed Consent Form

[This ICF should only be used for those who have attained the age of majority, 18 years]

Title	**Service model Hypertension and Diabetes Care**
Investigator(s)	▪ Catherine Kyobutungi. Telephone: 020 400 1000 ▪ Gershim Asiki. Telephone: 020 400 1000 ▪ Herrmann Dounfet. Telephone: 020 400 1000 ▪ Caroline Wainaina. Telephone: 020 400 1000 ▪ Peter Otieno. Telephone: 020 400 1000

Project Sponsor(s)	Boehringer Ingelheim
Collaborators	PharmAccess

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the project with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

The African Population and Health Research Center (APHRC) and PharmAccess are conducting an evaluation on ways to reduce the burden of hypertension and diabetes on the health care system and improve monitoring of blood pressure and diabetes by patients. We aim to do this by developing a service model which gives you access to discounts on your costs of care and self-management tools to help you monitor your condition and adjust to a healthy lifestyle.

We are giving you this information because we would like to invite you to participate in our project. If you prefer not to participate, you are free to choose to do so. You will continue to receive health services the way that you normally would, with no negative impact. We want to make sure that you have all the information that you need before you decide. Members of our team are here to help you understand more about the project. If you do not understand any of the words or ideas that you see on this form, please ask us to explain the information to you. You can talk to anyone from our team whom you feel comfortable with about the project.

Why is this Project Important?

The project is important as we aim to provide a service where your care is co-financed and where you receive tools to help you manage your disease which will lead to patients having better access to care, having control of their own health, improve quality of care and potentially reduce cost through reduced clinic visits.

Who Can Participate?

You are being invited to take part in this project because you are under treatment for high blood pressure or diabetes or have been recently diagnosed with hypertension or diabetes. As a patient with hypertension or diabetes, we feel that your feedback will be very valuable to the development of the care service model.

Participation is Your Choice

Your participation in this project is completely voluntary. You will make the choice about whether you will participate or not. If you choose not to take part, you will continue to receive all of the services that you usually get in the health facility and nothing will change.

What Is Involved in this Project?

1) You will be enrolled on M-TIBA and will receive access to the Tiba Poa-benefit. When you pay for your care through M-TIBA you will pay 20-30% of the costs of all hypertension and diabetes-related out-patients visits, tests and drugs yourself. The other costs are covered through the program.
2) You will get access to a self-management service on your phone to help you manage your condition at home. PharmAccess and Boehringer Ingelheim are not responsible for this self-management service, but it is run by an organization named Baobab Circle. They are responsible for the information you receive via the self-management service.
3) We will ask you to measure your blood pressure or blood sugar at home or at your local pharmacist.
4) After measuring the BP, or blood sugar, we will request you to submit your blood pressure or blood sugar values through the self-management service on your phone. Every 24 hours, this measurement will go directly to the computer dashboard in the health facility to enable the nurse to monitor your blood pressure.
5) In case of very high or low BP or blood sugar, your healthcare provider will be in touch to advise on the next course of action.
6) You will receive daily messages with tips to have a healthy lifestyle and you will receive reminders on your phone on measuring of the blood pressure or blood sugar.
7) We will support you to acquire a BP-machine and/or glucometer to monitor your disease at home. If affordability is an issue, you will receive the device through the project officer on loan and we will devise a monthly payment scheme which fits your abilities to pay.
8) We will also request you to participate in several surveys over the duration of the project. In the first month, the survey will be taken after two weeks. After these two weeks, the survey will be distributed every month. The survey will be provided during the clinical checkup by the healthcare nurse, or on your phone. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question.
9) You will be expected to use the self-management service and measure your blood pressure and/or blood glucose for an initial duration of four months with possible extension.

10) If changes are made to the project or new information becomes available, you will be informed.

How long will the project Last?

This project will take place for a period of one year from the time of your enrolement.

What are the Risks?

Your doctor remains responsible for your care and is completely free to provide you with any care you need. Participation in this project does not in any way replace your doctor's care. Your doctor will discuss with you when you need to contact the clinic. For example, when you have a very high or very low measurement.

When filling in the surveys, there is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. Please understand that we do not wish for this to happen. You do not have to answer any question or take part in the survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

What are the Benefits?

Through this project part of your costs of care will be covered and you will receive support in maintaining a healthy lifestyle with daily, practical tips. Also, your participation is likely to help us find out more about how people perceive the core features of co-financing care and the behavioral intervention and home-based measuring of the blood pressure or blood sugar.

How will we protect your Personal Information and Confidentiality?

When you participate in this project we will collect the following data:

- Name
- ID number
- Insurance (if any)
- Telephone Number
- Age, level of education
- Social economic status
- Baseline data on physical activity and diet
- Your blood pressure and/or glucose levels
- Transaction data when you visit the clinic and pay via M-TIBA

We will collect and process personal information through various ways:

- M-TIBA, a service on your mobile phone offered by CarePay. When you sign up for M-TIBA you will be requested to accept the M-TIBA General Terms and Conditions for the Tiba Poa Program. Please be informed that these terms and conditions also contain important information about the processing, use and protection of your personal data, and that by accepting these terms & conditions you give explicit consent in relation to the same.
- The self-management service on your phone to help you manage your condition at home, offered by Baobab Circle. Specific terms and conditions and a privacy statement apply to the use of this service, which you are requested accept.
- The surveys, either via your mobile phone or taken at your health facility.
- The measurements of your blood pressure or blood sugar.

We will use your data for the following purposes:

- To give your physician insight in the blood pressure or glucose measurements you do at home.
- To provide you with the services of the project, including but not limited to administration, providing access to benefits and evaluation of the services provided to you.
- To communicate with you and to send you surveys.
- For research and to analyze the data and possibly to share the anonymized and aggregated data and results with various partners and stakeholders.

We will not be sharing information about you to anyone outside of the project team and partners involved. The information that we collect from this project will be kept private. Any information about you will have a number on it instead of your name. Only the project team members will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone outside of our project.

What will happen with the results?

The knowledge that we get from the evaluation of this project will be shared with you and the other patients in the project before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the health facilities to share the findings and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from it. The results will at all times be anonymized and will not make any reference to you personally.

Can I Refuse to Participate or Withdraw from the project?

You do not have to take part in this project if you do not wish to do so. If you choose not to participate, you will continue to receive all of the normal health services that you would usually

be offered and nothing will change. If you wish to stop participating in the project after you begin, you can stop at any time by telling someone on our project team.

Limitations of exclusion and liability

Although PharmAccess (including its officers, employees, subcontractors, agents or partners) will have taken all reasonable precautions to ensure that the information provided to you on the Program is accurate and that you suffer no loss or damage as a result of participation in the Program, you agree that your participation is entirely at your own risk and you assume full responsibility for any risk of loss or damage arising from you participation with the exclusion of any willful and gross negligence by PharmAccess.

Furthermore, you specifically agree that PharmAccess will not be liable for any loss or damage arising from any mistreatment, malpractices or wrongful actions by the clinic in the line of providing the healthcare services.

Who Can I Contact?

If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact Angela Siteyi, on telephone number 737 002 120, or email address a.siteyi@pharmaccess.or.ke

If you have questions about your rights as a project participant, you may contact the Research Officer:

AMREF Kenya
Wilson Airport, Lang'ata Road
Office Tel: +254 20 6994000
Fax: +254 20 606340
P.O Box 30125-00100
Nairobi, Kenya

Do you have any questions at this time?

Please feel free to let us know at any time if you have any questions. Our team is happy to answer them.

PharmAccess FOUNDATION

Part II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked are answered to my satisfaction.

□ I agree to participate in the project and I understand that my participation is voluntary and that I am free to withdraw my participation at any time without giving any reason. The withdrawal of my participation or my refusal to participate will in no way affect my right to medical care or any other right.

□ I agree that the personal information collected during the project, including medical data, will be used by the project partners for the purpose and in the manner as described in this consent form and in the terms and conditions of the related services and tools.

Print Name of Participant	[at least forename and surname]
Signature of Participant	
DD/MM/YYYY	

If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely to both the participation and the collection and use of personal information.

Print Name of Participant	[at least forename and surname]
Thumb/Toe print of Participant	
Signature of Witness	[A literate witness must sign and should be selected by the participant and MUST have no connection to the project team.

DD/MM/YYYY	

Statement by the person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

He/she will receive an M-TIBA benefit giving access to discounts on all hypertension- and diabetes related visits, tests and selected Sanofi medications
He/she will be given a BP machine/glucometer and glucostrips to measure his/her BP and/or blood glucose over the project period.
Health care staff in the project will monitor the blood pressure measurements/blood sugar and advise accordingly
He/she will receive a self-management service providing daily messages on healthy behavior
During the clinic checkup the patient will be required to fill a short survey questionnaire.
The participant's information will be used for the purposes as described and explained and will be kept confidential.

I confirm that the participant was given an opportunity to ask questions about the project, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of person taking the consent	[at least forename and surname]
Signature of person taking the consent	
DD/MM/YYYY	

Ethics & Scientific Review Committee

Informed Consent Form
[This ICF should only be used for those who have attained the age of majority, 18 years]

Title	**Service model Hypertension and Diabetes Care**
Investigator(s)	▪ Catherine Kyobutungi. Telephone: 020 400 1000 ▪ Gershim Asiki. Telephone: 020 400 1000 ▪ Herrmann Dounfet. Telephone: 020 400 1000 ▪ Caroline Wainaina. Telephone: 020 400 1000 ▪ Peter Otieno. Telephone: 020 400 1000
Project Sponsor(s)	Sanofi
Collaborators	PharmAccess

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the project with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

The African Population and Health Research Center (APHRC) and PharmAccess are conducting an evaluation on ways to reduce the burden of hypertension and diabetes on the health care system and improve monitoring of blood pressure and diabetes by patients. We aim to do this by developing a service model which gives you access to discounts on your costs of care and self-management tools to help you monitor your condition and adjust to a healthy lifestyle.

We are giving you this information because we would like to invite you to participate in our project. If you prefer not to participate, you are free to choose to do so. You will continue to receive health services the way that you normally would, with no negative impact. We want to make sure that you have all the information that you need before you decide. Members of our team are here to help you understand more about the project. If you do not understand any of the words or ideas that you see on this form, please ask us to explain the information to you. You can talk to anyone from our team whom you feel comfortable with about the project.

Why is this Project Important?

The project is important as we aim to provide a service where your care is co-financed and where you receive tools to help you manage your disease which will lead to patients having better access to care, having control of their own health, improve quality of care and potentially reduce cost through reduced clinic visits.

Who Can Participate?

You are being invited to take part in this project because you are under treatment for high blood pressure or diabetes or have been recently diagnosed with hypertension or diabetes. As a patient with hypertension or diabetes, we feel that your feedback will be very valuable to the development of the care service model.

Participation is Your Choice

Your participation in this project is completely voluntary. You will make the choice about whether you will participate or not. If you choose not to take part, you will continue to receive all of the services that you usually get in the health facility and nothing will change.

What Is Involved in this Project?

11) You will be enrolled on M-TIBA and will receive access to the Ngao Ya Afya benefit. When you pay for your care through M-TIBA you will receive:
    a. An 80% discount on costs of all outpatient visits and tests for hypertension and diabetes
    b. A price discount on Sanofi medications
12) You will get access to a self-management service on your phone to help you manage your condition at home. This part of your benefit is not funded by Sanofi, but by PharmAccess.
13) We will ask you to measure your blood pressure or blood sugar at home or at your local pharmacist.
14) After measuring the BP, or blood sugar we will require you to submit your blood pressure or blood sugar values through the self-management service on your phone. Every 24 hours, this measurement will go directly to the computer dashboard in the health facility to enable the nurse to monitor your blood pressure.
15) In case of very high or low BP or blood sugar, your healthcare provider will be in touch to advise on the next cause of action.

16) You will receive daily messages with tips to have a healthy lifestyle and you will receive reminders on your phone on measuring of the blood pressure or blood sugar.

17) We will support you to acquire a BP-machine and/or glucometer to monitor your disease at home. If affordability is an issue, you will receive the device through the project officer on loan and we will devise a monthly payment scheme which fits your abilities to pay.

18) We will also require you to participate in several surveys over the duration of the project. In the first month, the survey will be taken after two weeks. After these two weeks, the survey will be distributed every month. The survey will be provided during the clinical checkup by the healthcare nurse, or on your phone. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question.

19) You will be expected to use the self-management service and measure your blood pressure and/or blood glucose for an initial duration of four months with possible extension.

20) If changes are made to the project or new information becomes available, you will be informed.

How long will the project Last?

This project will take place for a period of one year. You are being recruited to participate for a minimum of four months, probably to be extended to one year.

What are the Risks?

Your doctor remains responsible for your care and is completely free to provide you with any care you need. Participation in this project does not in any way replace your doctor's care. Your doctor will discuss with you when you need to contact the clinic. For example, when you have a very high or very low measurement.

When filling in the surveys, there is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. Please understand that we do not wish for this to happen. You do not have to answer any question or take part in the survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

What are the Benefits?

Through this project part of your costs of care will be covered and you receive support in maintaining a healthy lifestyle with daily, practical tips. Also, your participation is likely to help us find out more about how people perceive the core features of co-financing care and the behavioral intervention and home-based measuring of the blood pressure or blood sugar.

How will we protect your Personal Information and Confidentiality?

When you participate in this project we will collect and process personal information through various ways:

- M-TIBA, a service on your mobile phone offered by CarePay. When you sign up for M-TIBA you will be requested to accept the General Terms and Conditions for the Ngao Ya Afya Program as well as the General Terms & Conditions for the M-TIBA Service. Please be informed that these terms and conditions contain important information about the processing, use and protection of your personal data, and that by accepting these terms & conditions you give explicit consent in relation to the same.
- The self-management service on your phone to help you manage your condition at home. Specific terms and conditions and a privacy statement apply to the use of this service, which you are requested accept.
- The surveys, either via your mobile phone or taken at your health facility.
- The measurements of your blood pressure or blood sugar.

We will use your data for the following purposes:

- To provide you with the services of the project, including but not limited to administration, providing access to benefits and evaluation of the services provided to you.
- To communicate with you and to send you surveys.
- For research and to analyze the data and possibly to share the anonymized and aggregated data and results with various partners and stakeholders.

We will not be sharing information about you to anyone outside of the project team and partners involved. The information that we collect from this project will be kept private. Any information about you will have a number on it instead of your name. Only the project team members will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone outside of our project.

What will happen with the results?

The knowledge that we get from the evaluation of this project will be shared with you and the other patients in the project before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the health facilities to share the findings and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from it. The results will at all times be anonymized and will not make any reference to you personally.

Can I Refuse to Participate or Withdraw from the project?

You do not have to take part in this project if you do not wish to do so. If you choose not to participate, you will continue to receive all of the normal health services that you would usually be offered and nothing will change. If you wish to stop participating in the project after you begin, you can stop at any time by telling someone on our project team.

Who Can I Contact?

If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact Angela Siteyi, on telephone number 737 002 120, or email address a.siteyi@pharmaccess.or.ke.

If you have questions about your rights as a project participant, you may contact the Research Officer:

AMREF Kenya
Wilson Airport, Lang'ata Road
Office Tel: +254 20 6994000
Fax: +254 20 606340
P.O Box 30125-00100
Nairobi, Kenya

Do you have any questions at this time?

Please feel free to let us know at any time if you have any questions. Our team is happy to answer them.

Part II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked are answered to my satisfaction.

□ **I agree to participate in the project and I understand that my participation is voluntary and that I am free to withdraw my participation at any time without giving any reason. The withdrawal of my participation or my refusal to participate will in no way affect my right to medical care or any other right.**

□ **I agree that the personal information collected during the project, including medical data, will be used by the project partners for the purpose and in the manner as described in this consent form and in the terms and conditions of the related services and tools.**

Print Name of Participant	[at least forename and surname]
Signature of Participant	
DD/MM/YYYY	

If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely to both the participation and the collection and use of personal information.

Print Name of Participant	[at least forename and surname]
Thumb/Toe print of Participant	
Signature of Witness	[A literate witness must sign and should be selected by the participant and MUST have no connection to the project team.
DD/MM/YYYY	

Statement by the person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

He/she will receive an M-TIBA benefit giving access to discounts on all hypertension- and diabetes related visits, tests and selected Sanofi medications
He/she will be given a BP machine/glucometer and glucostrips to measure his/her BP and/or blood glucose over the project period.
Health care staff in the project will monitor the blood pressure measurements/blood sugar and advise accordingly
He/she will receive a self-management service providing daily messages on healthy behavior
During the clinic checkup the patient will be required to fill a short survey questionnaire.
The participant's information will be used for the purposes as described and explained and will be kept confidential.

I confirm that the participant was given an opportunity to ask questions about the project, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of person taking the consent	[at least forename and surname]
Signature of person taking the consent	
DD/MM/YYYY	

Ethics & Scientific Review Committee

Informed Consent Form

[This ICF should only be used for those who have attained the age of majority, 18 years]

Study Title	**Home-based Hypertension Care Study**
Investigator(s)	▪ Dr. Catherine Kyobutungi. Telephone: 020 400 1000 ▪ Dr. Gershim Asiki. Telephone: 020 400 1000 ▪ Caroline Wainaina. Telephone: 020 400 1000 ▪ Peter Otieno. Telephone: 020 400 1000
Study Sponsor(s)	Sanofi
Collaborators	

Hii fomu ina sehemu mbili:

- **Information Sheet (Maelezo kuhusu utafiti huu)**
- **Certificate of Consent (Kwa kuweka sahihi ukiwa utakubali kushiriki)**

Utapewa nakala hii ya fomu hii

Part I: Information Sheet

The African Population and Health Research Center (APHRC) inatekeleza utafiti ya kutafuta njia ya kupunguza uzito wa ugonjwa wa shinikizo la damu na ugonjwa wa kisukari kwa huduma ya afya na kuimarisha upimaji wa shinikizo la damu na ugonjwa wa kisukari kwa wagonjwa. Tunatengeneza chombo cha kudhibiti magonjwa haya kutoka nyumbani

Tunakupa maelezo haya kwa ajili tungependa uhusike katika utafiti huu. Ukiwa hautataka kuhusika, ni sawa, unahaki ya kukataa. Utaendelea kupata huzuma za afya kama kawaida. Tunataka kuhakikisha kuwa unapata maelezo yote unayohitaji ilikukuwezesha kufanya uamuzi. Kikundi cha watafiti kiko hapa kukusaidia kuelewa zaidi kuhusu utafiti huu. Kama hauelewi maelezo haya, tafadhali unaweza kutuulizia, ili tukupe maelezo zaidi. Unaweza kuongelesha mtu yeyote katika kikundi chetu ukiwa utahisi kutokua na amani/starehe kuhusu utafiti huu.

Why is this Project Important?

Hii utafiti ni ya maana kwa ajili tunapangia kutoa njia ya urahisi ya kupima kwa wagonjwa wa shinikizo la damu na ugonjwa wa kisukari na wauguzi kufwatilia kwa umbali wakiwa hospitalini. Hii itawezesha wagonjwa hawa kudhibiti hali yao ya afya, kuboresha huduma ya afya kwa

wagonjwa wa shinikizo la damu na ugonjwa wa kisukari na kujaribu kupunguza gharama kutokana na kupunguka kwa wagonjwa kwenda hospitalini.

Who Can Participate?

Unakaribishwa kushiriki katika utafiti huu kwa ajili unatumia madawa ya ugonjwa wa shinikizo la damu na ugonjwa wa kisukari. Kama mgonjwa wa shinikizo la damu, tunahisi kuwa maelezo yako yatakuwa ya maana kwa ujenzi wa chombo hiki cha kudhibiti shinikizo la damu na ugonjwa wa kisukari. Ulichaguliwa kushiriki kwa ajili una miaka inayohitajika na kukubalika na una simu ambayo itahitajika katika utafiti huu.

Participation is Your Choice

Kushiriki kwako katika utafiti huu ni wa hiari. Ni wewe utaamua kushiriki ama la. Ukiamua kutoshiriki, utaendelea kupata huduma za afya kama kawaida.

What Is Involved in this Project?

1. Kupima shinikizo la damu na ugonjwa wa kisukari yako kwa wakati ambao wewe mwenyewe utachagua, ukitumia chombo cha kupima ambayo utapewa kwa muda wa utafiti huu. Utahitajika kuweka sahihi form ya kuonyesha kuwa umepewa hicho chombo cha kupima.
2. Baada ya wewe kupima damu utahitajika kutuma vipimo hivi ukitumia simu yako ambayo itakuwa na chombo cha kuhakikisha vipimo vyako vimefika kwenye hospital, iliwauguzi waweze kuiangalia na kukujulisha kuhusu vipimo ikiwa kutakuwa na vipimo vya juu ama chini.
3. Ikiwa kiwango cha shinikizo la damu na ugonjwa wa kisukari likiwa juu au chini, muuguzi wako atakupigia simu kukupa mawaidha kuhusu ni nini unastahili kufanya
4. Utapata vikumbusho katika simu yako, ilikukukumbusha kuhusu kupima shinikizo la damu na ugonjwa wa kisukari. Kunauwezekano wa wewe kuwa kati ya wale ambao watapata maagizo au ujumbe kuhusu kupima kwa shinikizo la damu na ugonjwa wa kisukari. Uamuzi utalinganisha na kikundi ambacho utachaguliwa kushiriki. Umuhimu ni kutaka kujua umaana wa maagizo haya kwa watu kuweza kutilia umanaani upimaji wa shinikizo la damu na ugonjwa wa kisukari
5. Kuhusika kwa kujibu maswali ambayo utapewa kwa muda kwa utafiti. Kwa mwezi wa kwanza, utapewa maswali ujibu kila wiki mbili. Baada ya hizo wiki mbili, utakuwa ukipewa maswali kila mwezi. Utapata kujibu maswali haya wakati utaenda kumtembelea muuguzi wako. Majibu ambayo utapeana yatachambuliwa na watafiti katika mradi huu. Kama utahisi kutokujibu maswali haya, unaweza kuachana nayo au kuruka na kujibu maswali yafuatayo.
6. Kunauwezekano wa wewe kuwekwa katika kikundi ambapo utapewa maelezo kuhusu kupima shinikizo la damu kwa wakati tofauti. Hii itafanyika baadaye katika utafiti huu.
7. Katika mwanzo wa hii utafiti, Utahitajika kushiriki kwa muda wa mwaka moja . Kutakuwa na uwezekano wa muda kuongezeka.
8. Kukiwa na mabadiliko katika utafiti huu au maelezo mapya kupatikana, tutakueleza.

How long will the Project Last?
Unaaalikwa kushiriki katika utafiti huu kwa wa miezi minne. Hata hivyo, ushiriki wako unawezaendelea hadi mwaka mmoja kulingana na matokeo ya miezi minne ya kwanza ya utafiti huu.

What are the Risks?
Utafiti hii haitachukua nafasi ya uuguzi wa Daktari. Daktari wako atakueleza ni lini unastahili kuenda kwenye kliniki. Kwa mfano kama unavipimo vya shinikizo la damu na ugonjwa wa kisukari vya juu sana au chini sana.

Wakati wakujaza maswali utakayo ulizwa, kunauwezekano wa kuwa na hatari ya kupeana maelezo ambayo ni ya siri, ama unaweza kuwa na shida ya kuelezea maswala ambayo utauliziwa. Hatutarajii haya kufanyika. Siyo lazima ujibu maswali yeyote au kuhusika katika utafiti ukiwa utahisi kuwa maswali haya yanaangazia mambo ya kindani au ya siri.

What are the Benefits?
Hautafaidika moja kwa moja, lakini kuhusika kwako kutatusaidia kuelewa kuhusu vile watu wanavyoona maswala muhimu kuhusu utafiti huu wa kuingilia kati ugonjwa wa shinikizo la damu na ugonjwa wa kisukari.

How will we protect your Information and Confidentiality?

Kunauwezekano kwa utafiti huu kuvutia maswali kutoka kwa watu kwenye hospitali unapoenda, kwa hivyo unaweza kuulizwa maswali kuhusiana na utafiti huu. Hatutatoa maelezo yako nje ya kikundi cha wanautafiti. Maelezo yako na yale tutapata katika utafiti huu, tutaweka kwa siri. Jina lako au nambari yako ya simu haitatumika mahali popote, tutakupa number ambayo itakuwa yako pekee. Ni wanautafiti tu ambao watatambua numbari yako na maelezo hayo yatawekwa kwa siri.

What will happen with the results?
Maswala ambayo tutapata kwenye utafiti huu tutakushirikisha na wagonjwa hao wengine watakao shiriki katika utafiti huu kabla ya kuyafanya wazi kwa watu wote. Tutapanga mikutano ma wanasera wengine, na utaalikwa kwenye mikutano hayo. Baada ya mikutano hayo, tutaandika repoti na kuweka maswala haya kwenye mtandao wa internet ili watu wengine wapate kusoma kwa kutokana na utafiti huu.

Can I Refuse to Participate or Withdraw from the Study?
Ukiamua kutoshiriki, hautalazimishwa, utaendelea kupata huduma za afya kama kawaida. Ukiwa utahisi kutaka kuacha kushiriki, tafadhali kuwa huru kumweleza mtu yeyote kwenye kikundi hiki cha utafiti.

Who Can I Contact?
Ukiwa na maswali yeyote, unaweza kuuliza sasa ama baadaye. Kama utakuwa na maswali baadaye, unaweza wasiliana na Dr. Gershim Asiki, 0204001000, gasiki@aphrc.org. Ukiwa unaswali kuhusu haki yako ya kushiriki katika utafiti, unaweza wasiliana na:

The Research Officer
AMREF Kenya
Wilson Airport, Lang'ata Road
Office Tel: +254 20 6994000
Fax: +254 20 606340
P.O Box 30125-00100
Nairobi, Kenya

Do you have any questions at this time?

Part II: Certificate of Consent

Nimesoma maelezo ama nimesomewa. Nimekuwa na nafasi ya kuulizia maswali na maswali yote ambayo nimeulizwa yamejibiwa. Ni na kubali kushiriki katika utafiti huu.

Print Name of Participant	[at least forename and surname]
Signature of Participant	
DD/MM/YYYY	

If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Participant	[at least forename and surname]
Thumb/Foot print of Participant	
Signature of Witness	[A literate witness must sign and should be selected by the participant and MUST have no connection to the research team.
DD/MM/YYYY	

Statement by the researcher/person taking consent

Nimemsomea maelezo yote mhusika na kwa uwezo wangu nimejaribu kuhakikisha kuwa mhusika ameelewa kuhusu mambo yafwatayo ambayo yatafanyika kwake:

Atapewa chombo cha kupima shinikizo la damu na ugonjwa wa kisukari kwa muda wa utafiti.
Wauguzi katika utafiti watafuatilia upimaji huu wa shinikizo la damu na ugonjwa wa kisukari na kunipa mawaidha ikiwa kiwango cha ugonjwa kitakuwa chini au juu
Wakati anapotembelea kliniki atahitajika kujaza maswali mafupi kuhusu upimaji wa shinikizo la damu na ugonjwa wa kisukari
Maelezo kutoka kwake yatawekwa siri.

Ninathibitisha kuwa mhusika amepewa muda wa kuuliza maswali kuhusu utafiti huu na maswali yote amabayo ameulizia yamejibiwa kwa ukweli. Ninathibitisha kuwa muhusika ajalazimishwa kukubali kushiriki, amapeana ruhusa kwa hiari yake mwenyewe.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent	[at least forename and surname]
Signature of Researcher/person taking the consent	
DD/MM/YYYY	