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INFORMED CONSENT FOR PT4A PILOT STUDY

Consent Start time: _____

Principal Investigator: Rajesh Vedanthan, MD, MPH, New York University Langone Health

Emergency Contact: Benson Njuguna, Moi Teaching and Referral Hospital

Protocol Title: Peers and Technology for Adherence, Access, Accountability, and Analytics (PT4A) - A Qualitative Study

Purpose of This Research Study

The purpose of this study is to find ways to improve medication adherence and blood pressure among patients with hypertension in western Kenya. AMPATH and the Ministry of Health has implemented a program of chronic disease management in the rural health facilities in this region and has built a solid foundation of several years and iterations of peer- and health information technology (HIT)-based strategies. AMPATH is planning to evaluate the impact of health information technology (health IT) combined with peer (trained patients with hypertension) delivery on successful medication adherence and control of blood pressure for patients with hypertension. We therefore plan to compare the impact of the combined intervention (that is, health IT and peer delivery) on medication adherence and blood pressure control versus the usual standard clinical care. The results of this study will not only improve hypertension care in Kenya, but will also be applicable to the management of other chronic diseases in Kenya and other developing countries.

You are eligible to take part in this research study because you are greater than 18 years old, enrolled in the AMPATH Chronic Disease Management Program, and you have hypertension.

Duration of Participation and Number of People Expected to Participate

Participation Duration: Up to 3 months

Anticipated Number of Subjects: Up to 30

Description of Procedure

If you agree to participate in this research study, the following information describes what may be involved.

As you know, the AMPATH Chronic Disease Management Program has an established chronic disease management program for hypertension in your community. We would like to evaluate the impact of combining health IT and peer delivery on the quality of hypertension care at three pilot health facilities. The health information technology (HIT) + peer delivery intervention does not change the way in which you receive care for your hypertension. The change in delivery of your medications and support provided by the peer is the intervention. The clinicians will be the same clinicians who staff your local health facility. This will have no impact on the services normally offered to you by your health facility. The fee schedule, which has been agreed upon by AMPATH and the Ministry of Health, will also remain the same.

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During the study, a peer-delivery agent will be assigned to your health facility. This person is a patient with high blood pressure who is employed and trained by the AMPATH program. The peer delivery agent will contact you and provide education and counseling about hypertension and the referral process, and will deliver medication refills to you at a convenient location and time. This peer delivery agent will not be able to offer medical advice or financial support.

At the end of the pilot study, we will invite you to provide feedback on your experience through a focus group discussion. Your feedback will help adapt our integrated HIT and peer delivery program to something that can help people with high blood pressure in your community.

Confidentiality of Study Data
We will not use your name or any other identifying information when we use this information that you are telling to us. The only people who will know that you are a research participant are members of the research team and, if appropriate, your physicians or health care providers. No individual identifying information about you will be disclosed to others, except if required by law. The results of this research project will be summarized for reports and may be summarized for presentation at meetings or in publications. No individual identities will be disclosed in any of these reports or presentations.

All information will be collected on coded forms, which do not include other personal identifying information. Study records will be stored in locked cabinets in a locked room. Only the study personnel will have access to the data. All computerized information will be protected by access codes known only to the PI and certain designated staff members. Data that are contained on a digital audio recording device will be encrypted. All staff members will be trained to keep your information confidential, and they will be informed of the penalty for breach of confidentiality.

Potential Benefits
You may not experience any direct benefit from the study. However, a greater understanding of the facilitators and barriers to using health IT and peer delivery in improving medication adherence and blood pressure for patients with hypertension will help AMPATH improve and optimize the implementation of this program. You, your family, and your community may therefore benefit from this research.

Potential Risks or Discomforts
We will only be collecting personal health information that is a routine part of clinical care. This information will be shared only with your clinicians, in order to provide you the best clinical care possible. Any information shared by you will be safely stored and will be confidential, as described above.

Risks associated with blood pressure testing are minimal and and no more than what you may experience during your usual routine clinical care visit.

Compensation

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Participants will get transport reimbursement at the follow up visit, however, the initial visit, or any costs associated with completing usual clinical care will not be provided. A snack will be provided during the consenting and interview procedures as these will take away time from you.

Voluntary Participation and Right to Discontinuation
It is completely voluntary for you to take part in this study. If you choose to take part, you can refuse to answer any question or ask us to stop at any time with no penalty. This will not affect your ability to receive medical care at the dispensary or health center, or to receive any benefits to which you are otherwise entitled.

Disclosure of Financial Interests
Funding for conducting this research is provided by the National Institutes of Health, USA, Grant Number: 1R56HL150036. There are no financial interests to disclose.

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Is it okay for you to participate in this research study?

PARTICIPANT'S INFORMED CONSENT

I Mr/Mrs/Ms/Dr……..have read/ have had the document read to me, all my questions have been answered and I have understood the information contained in the consent form above. I agree to voluntarily take part in the study. I acknowledge receipt of a copy of the informed consent statement.

PARTICIPANT'S SIGNATURE: _____ Date_____

(Must be dated by the participant if literate)

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NAME OF WITNESS: ……

SIGNATURE OF WITNESS: _____Date: _____
(Impartial witness) (Must be dated by witness)

NAME OF PERSON OBTAINING CONSENT: _____

SIGNATURE OF PERSON OBTAINING CONSENT: _____ Date: _____
Consenting stop time: _____