

**Potlako+, an intervention to improve  
timely cancer diagnosis and care**

**Verbal Informed Consent Script  
June 5, 2019**

**NCT04141449**

Protocol Title: Potlako+, an intervention to improve timely cancer diagnosis and care
Principal Investigators: Scott Dryden-Peterson, MD MSc and Neo Tapela, MD MPH
Description of Study Population: Patients with possible cancer
Version Date: 5 June 2019

## **Potlako+ verbal consent script**

Good [morning/afternoon/evening], my name is [state your name]. I am part of the Potlako+ study at the Botswana Harvard AIDS Institute. I believe you received some information from your health provider about it during your recent visit. Do you have time a few minutes to discuss the study?

- If yes, continue below.
- If no, but the potential subject is interested in participating, determine a better time to call back to discuss the study.
- If no and asks not be contacted again, thank them for their time

We are inviting you to take part in a research study because your health provider thought that you could have cancer and needed further care. We are trying to understand if providing education and support to patients can allow cancer to be diagnosed and treated earlier.

Participation in the study involves agreeing to be provided with the education and support messages through telephone calls as described in this form

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. You may discuss your decision with your family, your friends and/or your health provider. You can ask all the questions you want before you decide.

### **Any questions at this time? [pause]**

Most patients will be part of the study for about one year. The study involves 20 communities and their clinics in Botswana. In all communities, the study trained health providers about when to consider cancer and how to make a diagnosis. We will call patients with possible cancer to provide counselling and ask about their symptoms. We will call again at 6 and 12 months later ask questions about medical care you received.

In half of communities, we will provide additional support to patients through a program we call Potlako. Communities are picked at random, like the flip of a coin, to receive the Potlako program. If your community has been picked for Potlako, we will assist you and your health provider with determining the best way to know if you have cancer, scheduling health visits, providing counselling and education, and helping find solutions to challenges you face. We will call you after each of your health visits, when your test results are available, and when we think that a call could help speed your care. If your community was not picked for Potlako you will receive the support calls now and at 6 and 12 months.

### **Any questions at this time? [pause]**

We do not think that the study could be bad for most patients. However, sometimes our calls will come at inconvenient times or our questions could make you uncomfortable. You can tell us to call you at different time and can decline to answer any question. We will protect your private information carefully.

We cannot promise any benefits to you or others from your taking part in this research. However, we think that the counselling and support will help most patients understand their illness and learn faster what they can do about it.

**Any questions at this time? [pause]**

If we are unable to reach you, we will try phone numbers of friends and family that you provide. If we still cannot reach you, we will talk with community leaders to help find you. We will keep your health information private and only ask about ways to find you.

Participation in research is completely voluntary. You can decide to participate or not to participate. Instead of being in this research study, you can continue to receive typical care for your symptoms without our regular calls and support of your health providers. About 1500 people will take part in this research.

You will receive 50 pula for study phone calls at the start of the study, 6 months later, and after 12 months for a total of 150 pula. Money will be given as airtime. You will not be compensated for other calls like those to schedule appointments or provide you with information.

**Do you have any questions? [pause]**

**Do you agree to participate in this study?**

☐

Yes: Document oral consent below and continue with enrollment interview.

☐

No: Thank them for their time.

Name of Subject:

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**Person Obtaining Consent**

I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

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Name and Title (Print)

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Signature of Person Obtaining Consent

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Date