Supplementary Online Material

An innovative public-private partnership to target subsidized antimalarials: a study protocol for a cluster randomized controlled trial to evaluate a community intervention in Western Kenya

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Patient Consent Form (Version: 21st April 2016)

(VERBAL) INFORMED CONSENT FOR MALARIA RAPID DIAGNOSTIC TESTING

Moi University, in collaboration with Duke University, is collecting information to monitor and evaluate community health volunteers (CHVs) performing malaria rapid diagnostic tests (RDTs) as part of the ongoing study titled "Innovative public-private partnership to target subsidized antimalarials in the retail sector - Aim 2." I am a community health worker trained to administer rapid diagnostic tests for malaria. If you agree to participate, I will offer to perform a rapid diagnostic test (RDT) for malaria on you or your child free of charge. The test requires a finger prick to take one or two drops of blood. The blood is placed on the cassette and after 20 minutes the results can be seen. I will record the test result and also ask you about your symptoms and treatment history for your current illness. This rapid diagnostic test for malaria is approved by the Government of Kenya, and is the same that they use in many government health facilities.

The test result can either be positive or negative for malaria; in either case you will be sent back to your referring clinician for appropriate treatment after testing. In the event of a positive RDT result, artemisinin-based combination therapies (ACTs) are free at the participating health facilities, so we will not provide these products to clients. In the event of a negative RDT result, you will receive further treatment from your clinician.

Your participation in this study is completely voluntary and there will be no penalty to you if you choose not to participate. You may choose to discontinue your participation at any time without any penalty.

Risks of participation – There is a small risk of discomfort at the site of the finger prick. There is a very small risk of infection at the site. I have been trained in blood safety. New needles and tests are used for every person so the test is very safe. There is a small risk of breach of confidentiality – your information may become known to others unintentionally. However, we will do everything possible to protect your information.

Benefits of participation – By participating, you will know in the next few minutes whether you (or your child) has malaria. You will be referred back to your clinician to receive appropriate treatment for your test result.

If you agree to be tested for malaria (or for your child to be tested for malaria), please sign below. You may stop the testing at any time if you change your mind about participating.

If you have any questions, you may contact the study team at any time. Contact: Joseph Koech, 0700893319

If you agree to participate, please say now that you agree.

CHILD ASSENT FOR MALARIA RAPID DIAGNOSTIC TESTING

For children 8 years or older and younger than 18 years

We are asking you to be in a research study. Research is a way to test new ideas and helps us learn new things.

Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

In our research study we want to find out if you have malaria today. During this study, the community health workers will take a small blood sample from your finger.

What are the good things that can happen from this research?

We may learn more about your health today. This will help you to know which drug you should take.

What are the bad things that can happen from this research?

The community health workers will also ask you some questions about how you are feeling. You do not have to answer any questions that you don't want to answer. You may feel a little discomfort when we take some blood.

Take the time you need to make your choice. Ask us any questions you have. You can ask questions any time.

If you agree to participate, please say now that you agree.