

# Increasing malaria diagnosis in the private sector in Tanzania

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<b>Registration date</b> 07/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/01/2017	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Malaria is a serious infectious disease which is very common in tropical and subtropical countries. It is caused by a microscopic parasite which is spread from person to person by mosquitos. The symptoms of malaria generally consist of fever, headache, aching muscles and lack of energy. Tanzania has seen a reduction in the amount of fevers caused by malaria, which is likely to be due to the scaling up of control measures. While national guidelines require a parasite-based diagnosis before treating a patient, it is thought that more than half of suspected malaria treatment-seeking in Tanzania starts in the private retail sector, where diagnosis by malaria rapid diagnostic test (RDT) or microscopy is illegal. This study is evaluating the operational feasibility of selling RDTs through Accredited Drug Dispensing Outlets (ADDOs), and measuring changes in suspected malaria patient case management that occurred as a result of making RDTs available at two different prices.

### Who can participate?

Certified ADDO dispensers in Kilosa, Kilombero or Mvomero districts (Morogoro Region, Tanzania), and customers wishing to purchase RDTs or antimalarials for themselves (if have suspected malaria) or for others.

### What does the study involve?

Districts are randomly allocated to one of three groups. In the district in the first two groups, all certified ADDO dispesers are offered RDT stocking and performance training, followed by the opportunity to stock and sell RDTs in their ADDO for the duration of the study. Those in the first group are partially subsidized and the recommended retail price is set and 500 TSH. Those in the second group are not subsidized and the recommended retail price is set and 1100 TSH. Those in the third group are not offered any RDT training or stock to sell. Throughout the study, dispensers in each district are surveys regarding RDT stocking, pricing and safety practices. At the start of the study and after 13 months, suspected malaria customers who bought an RDT have a blood test to find out if they have a malaria infection. Customers are also asked to complete a questionnaire during a face-to-face interview at the end of the study about their experiences.

What are the possible benefits and risks of participating?

The risk to ADDO dispensers was the patient demand for RDT stocked in the shop. The greatest burden for participants in this study was the time required to participate in the surveys. Patients and dispensers were always be given the option of not participating or discontinuing their participation at any point in the process. Emphasis was given to the voluntary nature of participation in the consent form and during the study.

Where is the study run from?

The study is run from the Clinton Health Access Initiative-Tanzania and takes place in Accredited Drug Dispensing Outlets (ADDOs) Kilosa, Kilombero, and Mvomero (Tanzania)

When is the study starting and how long is it expected to run for?

March 2013 to May 2014

Who is funding the study?

Department for International Development (UK)

Who is the main contact?

Ms Abigail Ward

## Contact information

**Type(s)**

Scientific

**Contact name**

Ms Abigail Ward

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## Additional identifiers

**Protocol serial number**

N/A

## Study information

**Scientific Title**

Expanding access to parasite-based malaria diagnosis through retail drug shops in Tanzania: evidence from a randomized trial and implications for treatment

## **Study objectives**

Null hypotheses:

1. Availability of rapid diagnostic tests (RDTs) in Accredited Drug Dispensing Outlets (ADDOs) will not differ between shops that are trained to stock and use RDTs and those that cannot stock RDTs
2. Trained ADDO dispensers will not be able to appropriately and consistently use RDTs
3. Trained ADDO dispensers will not be able to appropriately and consistently store RDTs
4. Malaria testing behaviour in ADDOs will not differ between shops that are trained to stock and use RDTs and those that cannot stock RDTs
5. Antimalarial purchasing behaviors in ADDOs will not differ between shops that are trained to stock and use RDTs and those that cannot stock RDTs

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Tanzania National Institute for Medical Research (NIMR) and the Permanent Secretary of the Ministry of Health and Social Welfare of Tanzania, 28/02/2013, ref: NIMR/HQ/R.8A/VOL. IX/1476

## **Study design**

Unblinded cluster randomized controlled intervention trial

## **Primary study design**

Interventional

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Malaria

## **Interventions**

Districts are assigned to one of three study arms via a random number generator.

Intervention arm 1:

All certified ADDO dispensers are offered RDT stocking and performance training, and those who successfully complete the two-day training are allowed to stock and sell RDTs in their ADDO for the duration of the study. ADDOs with a certified RDT-trained dispenser are given a storefront sign advertising availability of RDTs within the ADDO. Suspected malaria customers have the option of purchasing RDTs at these shops. The RDTs in this district are partially subsidized and the recommended retail price was set at 500 TSH.

Intervention arm 2:

All certified ADDO dispensers are offered RDT stocking and performance training, and those who successfully complete the two-day training are allowed to stock and sell RDTs in their ADDO for the duration of the study. ADDOs with a certified RDT-trained dispenser are given a storefront sign advertising availability of RDTs within the ADDO. Suspected malaria customers

have the option of purchasing RDTs at these shops. The RDTs in this district are not subsidized and the recommended retail price was 1100 TSH.

Control arm:

No RDT trainings are offered in this district, but the same survey questions are asked at baseline and endline around treatment choices.

Each ADDO dispenser is surveyed regarding RDT and ACT stocking, pricing, and safety practices. Additionally, exit interviews took place outside the selected ADDOs at 13 months. Survey participants who met inclusion/exclusion criteria and signed an informed consent form were asked questions from a pre-tested, structured questionnaire (approximately 30 minutes) during a face-to-face interview. Participants were asked to show their RDT results slip and/or drug purchases if available.

## **Intervention Type**

### **Primary outcome(s)**

Blood-based diagnosis of malaria rate is measured by the percentage of suspected malaria customers that received an RDT in an ADDO at baseline and 13 months.

### **Key secondary outcome(s)**

1. Availability of blood-based diagnostic tests is measured by the percentage of ADDOs with a trained dispenser and RDTs in stock at baseline and 13 months
2. Positive adherence is measured by the percentage of customers who tested positive with an RDT and also purchased an artemisinin-combination therapy (ACT) at baseline and 13 months
3. Negative adherence is measured by the percentage of customers who tested negative with an RDT and also purchased an artemisinin-combination therapy (ACT) at baseline and 13 months
4. Affordability is measured by reported price paid for an RDT at baseline and 13 months
5. RDT performance safety is measured using a 17-point checklist at 1, 4, 8, and 13 months
6. RDT disposal safety is measured by the percentage of shops disposing of waste at a public health facility at 1, 4, 8, and 13 months

### **Completion date**

20/05/2014

## **Eligibility**

### **Key inclusion criteria**

ADDO dispenser inclusion criteria:

1. A certified ADDO dispenser in Kilosa or Kilombero District
2. Attended and passed the two-day RDT training

Survey participants (exit interview):

1. 18 years or older unless accompanied by a parent, guardian, or family member 18 years or older
  2. A patient presenting at the ADDO with fever, suspected malaria, or wishing to purchase an RDT or antimalarial
- OR
3. A customer at an ADDO wishing to purchase an antimalarial for someone else

### **Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

All

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

ADD0 dispenser exclusion criteria

1. An ADDO employee who is not a certified ADDO dispenser in Kilosa or Kilombero District
2. Any ADDO employee in Mvomero District

Survey participants (exit interview):

1. A patient presenting at the ADDO with symptoms of severe illness or reasons other than fever, suspected malaria, or wishing to purchase an RDT or antimalarial
2. A customer at an ADDO wishing to purchase something other than for fever or suspected malaria
3. Children under 18 years old and unaccompanied by a parent, guardian, or family member 18 years or older

**Date of first enrolment**

01/03/2013

**Date of final enrolment**

20/05/2014

## **Locations**

**Countries of recruitment**

Tanzania

**Study participating centre**

Clinton Health Access Initiative-Tanzania

P.O. Box 77277

Dar es Salaam

Tanzania

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## **Sponsor information**

**Organisation**

Clinton Health Access Initiative

**ROR**

<https://ror.org/013mr5k03>

## Funder(s)

**Funder type**

Government

**Funder Name**

Department for International Development

**Alternative Name(s)**

Department for International Development, UK, DFID

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/01/2017		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes