

Increasing malaria diagnosis in the private sector in Tanzania

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| Submission date 20/05/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 07/07/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 05/01/2017 | Condition category 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

ORCID ID

<http://orcid.org/0000-0002-4434-4759>

Contact details

Clinton Health Access Initiative

383 Dorchester Avenue

Suite 400

Boston

United States of America

02127

+1 (0)406 600 5775

award@clintonhealthaccess.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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.

Secondary outcome measures

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

Overall study start date

14/12/2012

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

Age group

All

Lower age limit

18 Years

Sex

Both

Target number of participants

Intervention participation: all certified ADDO dispensers in Kilosa and Kilombero Districts, Morogoro Region, Tanzania (estimated to be approximately 300) Outlet surveys: 273 shops (91 per arm) at each survey; Exit interviews: 1200 (400 per arm) at each survey

Key exclusion criteria

ADDO 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

Sponsor details

383 Dorchester Avenue

Suite 400

Boston

United States of America

02127

+1 617 774 0110

info@clintonhealthaccess.org

Sponsor type

Other

Website

<http://www.clintonhealthaccess.org>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

31/07/2016

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 03/01/2017 | | Yes | No |