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REMEDI study: Improving malaria diagnosis and treatment in Nigeria

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
18/10/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study to assess the feasibility and acceptability of introducing malaria rapid diagnostic tests in privately-owned drug shops in Nigeria. About 100 drug shops will be surveyed and will be used as recruitment sites to conduct about 1500 customer surveys. Our goal is to assess the overall prevalence of malaria by conducting rapid diagnostic tests on individuals who are seeking malaria treatment at drug shops. We will also look at patients willingness to pay for the test, ways in which adherence to test results can be improved, and patients opinion of drug shop sellers as able to conduct the tests on people. The studys findings will inform the design of national plans for the rollout of rapid diagnostics tests into the private health care sector in Nigeria.

Who can participate?
The REMEDI study aims to recruit about 1500 customers seeking malaria drugs for themselves or an accompanying minor at about 100 participating drug shops that sell at least one type of anti-malaria drug.

What does the study involve?
At participating drug shops, customers will be approached when exiting the shop and asked to participate in the study. Those who are eligible and consent to participate will be randomly allocated to receive a malaria rapid diagnostic test either for free or for a small fee. The participant will then be administered a questionnaire during the time it takes to see a test result, usually about 15 minutes. Based on the test result, customers will be given advice on the appropriate use of their anti-malaria drug, as well as referral information for a nearby facility. A free course of the first-line anti-malaria drug will be given to all customers who test positive to ensure that they have the appropriate drug.
One day after enrolment and testing, customers phone numbers entered into an automated text messaging service will be randomized to either receive no text message, a text message with a general information message, or a text message with a specific information message. All text messages will involve a standard script that reminds the participant of their test result and appropriate drug treatment. The computer system will automatically conduct the randomization procedure.
Four days after enrolment and testing, a surveyor will conduct a phone interview with the

participant to conduct a short survey assessing self-reported drug taking behaviour and other perceptions of the diagnostic test and drug vendors.

What are the possible benefits and risks of participating?
Participants will benefit by knowing whether or not they have malaria and provided with information about what to do with their anti-malarial drugs. For those who test positive, a free course of the first-line recommended drug will be provided.
The main risks associated with the study are a slight pain will be associated with the finger prick to obtain the blood sample for the test kit, and a chance that non-participants who have access to the participants mobile phone device may inadvertently receive the text message and discover the participants malaria status and participation in the study. To minimize these risks, text messages will not use any personally-identifying information.

Where is the study run from?
The study has been set up by the University of California, San Francisco with assistance from the Society of Family Health in Nigeria. 100 drug shops are in Karu Local Government Area in Nasarawa State.

When is the study starting and how long it is expected to run for?
It is anticipated that recruitment will start in October 2013. All participating drug shops will be enrolled in October 2013. Customer participants will be enrolled and followed up on an ongoing basis until about 15 December 2013.

Who is funding the study?
ExxonMobil Foundation. Once funding stops, data and samples collected during the study will be maintained by the University of California, San Francisco.

Who is the main contact?
Dr. Jenny Liu
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A121186

Study information

Scientific Title
The REMEDI study Rapid Examination of Malaria and Evaluation of Diagnostic Information

Acronym
REMEDI

Study objectives
The study will test the following hypotheses:
1. The prevalence of malaria in Nigeria is lower than popularly believed.
The null hypothesis is that the prevalence of malaria is similar to what is popularly believed.
2. Text message reminders of the test result and correct treatment will increase treatment adherence.
The null hypothesis is that text message reminders will have no effect on treatment adherence rates.
3. Individuals who pay for the diagnostic test will show higher treatment adherence compared to those who received the test for free.
The null hypothesis is that payment does not affect adherence rates.
4. Information specific to drug shop vendors in Nigeria delivering new malaria diagnostic tests will increase the acceptability of these sellers to conduct the test among their patrons.
The null hypothesis is that specific information will not have any differential effect on acceptability than general information.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Health Research Ethics Committee of Nigeria (NHREC), Federal Ministry of Health, Abuja, 21 September 2013, ref: NHRED/01/01/2007-21/09/2013
2. Committee on Human Research, University of California, San Francisco, 17 September 2013, IRB# 12-09472, ref# 072086

Study design
Single site double-blind parallel-group study with two behavioral randomizations

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Diagnosis and appropriate treatment of malaria

Interventions
The study will involve 1500 participants who will be followed-up 4 days after initial enrollment and testing to assess self-reported adherence (the recommended malaria treatment regimen is 3 days). There are two randomized components.

1. Randomization #1: Participants will be randomized to be either given the malaria rapid diagnostic test for free or for a small fee.
2. Randomization #2: One day after enrollment into the study, a text message reminder will sent to the mobile phone number provided by the participant. For participants who agreed to be tested with the malaria rapid diagnostic test at the time of enrollment, their phone numbers will be randomized to either receive no message vs. a text message with general information of the rapid diagnostic test availability in Nigeria vs. a text message with specific information of the rapid diagnostic test availability from drug shop vendors.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Malaria rapid diagnostic test result measured at baseline

Secondary outcome measures
Assessed 4 days after enrollment and testing and will include:
1. Self-reported treatment with anti-malarial medication
2. Self-reported treatment with non-antimalarial medications
3. Perceptions of drug shop vendors ability to perform rapid diagnostic tests
4. Perceptions of rapid diagnostic tests in general
5. Cost effectiveness
6. Perceptions of the text message reminders

Overall study start date
21/10/2013

Completion date
15/12/2013

Eligibility

Key inclusion criteria
1. Adult aged over 17 years and having purchased malaria drugs for either him/herself or an accompanying minor at an enrolled study site
2. Customers must be willing to be assigned to any of the study intervention groups
3. Participating drugs shops must sell at least one type of antimalarial drug

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1500

Key exclusion criteria
1. Pregnant women who are seeking malaria treatment for herself are excluded because the recommended treatment for malaria is a different drug regimen than one than the study can provide
2. Any individual seeking treatment for illnesses other than malaria
3. Any adult who is purchasing malaria for a minor and the minor is not present at the time of enrollment
4. Because the study involves a follow-up survey conducted via phone, participants who cannot provide at least one phone number at which they can be reached are excluded
5. Drug shops that do not sell antimalarial drugs are excluded

Date of first enrolment
21/10/2013

Date of final enrolment
15/12/2013

Locations

Countries of recruitment
Nigeria

United States of America

Study participating centre

University of California, San Francisco
San Francisco
United States of America
94105

Sponsor information

Organisation
University of California, San Francisco (USA)

Sponsor details
c/o Mr. Regnier Jurado
Contracts and Grants
3333 California Street, Suite 315
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United States of America
94118

Sponsor type
University/education

Website
http://www.ucsf.edu/

ROR
https://ror.org/043mz5j54

Funder(s)

Funder type
Industry

Funder Name
ExxonMobil Foundation (USA) (PO046342)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015	21/01/2019	Yes	No
Results article	results	01/12/2016	21/01/2019	Yes	No