A randomized experiment of malaria diagnostic **te**sting and conditional **s**ubsidies to **t**arget **A**CTs in the **r**e**t**ail sector: the TESTsmART trial AIM 1

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Principal Investigator:
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Statement of Compliance

- The study will be carried out in accordance with the principles set forth in The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects.
- All key personnel (all individuals responsible for the design and conduct of this study) have completed Human Subjects Protection Training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines. All personnel involved in the conduct of this trial will complete prior to their involvement Human Subjects Protection Training.

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Principal Investigator, Duke University

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Signed

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List of Abbreviations

ACT	Artemisinin Combination Therapy
AE	Adverse Event
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CRF	Case Report Form
CHW	Community Health Worker
DFID	Department for International Development, UK
DMID	Division of Microbiology and Infectious Diseases, NIAID, NIH, DHHS
DSMB	Data and Safety Monitoring Board
FWA	Federal-Wide Assurance
GCP	Good Clinical Practice
GEE	Generalized Estimating Equation
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ID	Identification
IEC	Independent or Institutional Ethics Committee
IRB	Institutional Review Board
ISM	Independent Safety Monitor
JAMA	Journal of the American Medical Association
MOP	Manual of Procedures
N	Number (typically refers to subjects)
NEJM	New England Journal of Medicine
NIAID	National Institute of Allergy and Infectious Diseases, NIH, DHHS
NIH	National Institutes of Health
OCRA	Office of Clinical Research Affairs, DMID, NIAID, NIH, DHHS
OHRP	Office for Human Research Protections
ORA	Office of Regulatory Affairs, DMID, NIAID, NIH, DHHS
PI	Principal Investigator
RA	Research Assistant
RD	Risk Difference
RDT	Rapid Diagnostic Test
RR	Risk Ratio
SAE	Serious Adverse Event
SMC	Safety Monitoring Committee
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
WHO	World Health Organization

Title: A randomized experiment of malaria diagnostic **te**sting and conditional **s**ubsidies to **t**arget **A**CTs in the **r**e**t**ail sector: the TESTsmART trial AIM 1

Population: We will enroll 840 participants and allocate them to four arms in equal proportions. Participants who are seeking treatment for acute, malaria-like illness will be recruited at medicine retail outlets in western Kenya. Eligible participants are >1 year of age seeking treatment for themselves or present with their parent/guardian at the time of recruitment. Individuals with signs of severe disease will not be eligible

Number of Sites: Webuye West, Webuye East and Kiminini in western Kenya.

Study Duration: 12 months

Subject Duration: 30-45 minutes. Cross-sectional study with no follow-up

Objectives: This objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT**.** We will test two different RDT price levels and two discounted ACT price levels in a factorial design. ACT discounts are conditional on a positive RDT result.

The primary outcome measure is the decision to purchase an RDT before purchasing a drug.

Secondary outcome measures are:

1. Decision to purchase an ACT stratified by testing status
    a. Positive mRDT
    b. Negative mRDT
    c. No malaria test

All outcomes will be measured by interviewing the participant after they make their decision about whether to be tested and which medicines to purchase.

1 KEY ROLES

For questions regarding this protocol, contact *(insert name of DMID Protocol Champion or other appropriate DMID staff) at NIAID/DMID (insert contact information).*

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2 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Artemisinin combination therapies (ACTs) – the WHO-recommended first line therapy for uncomplicated malaria – have played a significant role in reducing global malaria mortality[1], but their overuse is rampant. In 2016 an estimated **216 million cases of malaria occurred worldwide, yet more than 400 million treatment courses of ACT were consumed**[2]. Approximately 75% of global ACT demand is subsidized with international public funds from sources such as The Global Fund, DFID, and USAID[3]. Overconsumption of ACTs is an unnecessary drain on scarce public health resources and threatens the future sustainability of publicly-funded subsidies. In addition, it puts both present and future patients at risk; inappropriate treatment of a non-malaria illness with an antimalarial increases case fatality rates and contributes to population-wide drug pressure that accelerates the spread of drug resistance[4-8].

Global over-consumption of ACTs is driven in large part by its increased distribution over-the-counter in private retail outlets as a result of publicly-funded subsidies directed to the private sector[9]. In 2015, **44% of all donor-funded ACTs consumed world-wide were distributed through the private retail sector** where studies have shown that between **65-91% of ACTs dispensed for malaria are actually purchased by people without malaria**[10-13]. Malaria diagnostic testing is uncommon in the retail sector; fewer than 1 in 10 suspected cases are tested[10]. In the absence of parasitological testing, distinguishing fevers due to malaria from those due to other causes in not possible based on clinical presentation, and most fevers in malaria-endemic areas are assumed to be malaria-associated. As a result, presumptive treatment is prevalent and targeting ACTs to individuals with malaria infection is extremely poor.

Point-of-care malaria rapid diagnostic tests (RDTs), which have excellent sensitivity and specificity and are simple enough to be used by trained laypersons[14], could expand the reach of diagnostics into the retail sector and help improve the rational use of antimalarials.
Several studies have explored the potential role of RDTs in improving case management in the retail sector with mixed and often poor results. In most of these studies retail providers received case management training, followed by supportive supervision visits by researchers. In a few studies, the wholesale RDT price was partially or fully subsidized but retail providers were permitted to set their own price to the consumer and offer testing at their discretion[15,16]. More often, outlets were required to provide testing free of charge or at a low fixed price and instruction to the outlet was quite rigid regarding when an RDT should be performed and an ACT should be dispensed[17-20]. Providers were not explicitly incentivized to conduct RDTs.

All these studies shared two features – 1) ACTs were heavily subsidized for all customers and 2) there was no relationship between the RDT result and the ACT subsidy. This range of implementation strategies resulted in a wide range of testing uptake; between 7 - 100% of suspected malaria cases were tested[21]. Adherence to a negative malaria test was

inconsistent (between 1-40% of those with a negative test purchased an ACT) and often a significant portion of those testing positive, up to 70%, did not take an ACT[21]. Against this highly heterogeneous landscape of RDT implementation in the private retail sector, a few key lessons emerge. First, uptake of ACT is sensitive to the price of the drug[22]; subsidies are necessary to ensure malaria-positive customers purchase an ACT even though higher prices could discourage malaria-negative clients from taking the drug. Second, uptake of RDTs appears to be more sensitive to price than uptake of ACT[22]. Patients are not willing to pay much to confirm a disease they often think they can diagnose themselves[23]. Third, uptake of RDTs may also be sensitive to the price of the ACT, indicating that the relative price of the two commodities is important[24]. Finally, fixed low prices of RDTs or ACTs are not sufficient to ensure adherence to test results[21,24].

In studies of RDT implementation in retail outlets, uptake of testing is sensitive to the relationship between the price of the test and the price of the ACT. As the price of the RDT relative to that of the ACT increases, testing rates drop precipitously. If the price ratio is high, customers will forgo the RDT and simply purchase an ACT, given its lower relative price. Qualitative studies in Uganda confirm that clients with limited resources prefer to spend money on drugs and prioritize testing only when presumptive treatment with the drug has failed[25]. If the price of the ACT is higher than the RDT, then the investment in the RDT becomes a useful tool for discriminating between (more expensive) treatment options. When the price of the RDT is reduced to about a third of the cost of the ACT, uptake increases considerably. Our own work has shown that reducing the cost of the RDT from 40 Ksh (~$0.50, the unsubsidized price) to 0 Ksh (fully subsidized) increases uptake by 25 percentage points[26]. However, there is limited evidence to guide joint implementation of these commodities and to identify relative subsidy levels to maximize impact and minimize wastage. Since high malaria testing rates are a necessary pre-condition for ensuring that ACTs are targeted appropriately, we focus on identifying **the combination of RDT and ACT subsidies that maximizes the percent of clients receiving an RDT,** given a set amount of public funds earmarked to provide subsidized malaria commodities**.** We hypothesize that ACT subsidies that are conditional on the client receiving a malaria positive test can increase the uptake of malaria testing in the retail sector, while minimizing wastage of public funds. Furthermore, we hypothesize that while the uptake of testing will be sensitive to both the prices of the RDT and the ACT, a 50% subsidy on the RDT price will result in greater uptake of testing than increasing the subsidy on an ACT (conditional on a positive malaria test result) from 67% to 100%.

2.2 Scientific Rationale

We have chosen to conduct this study in Kenya for two main reasons. First, RDTs are not currently used in the retail sector in Kenya. Therefore, individuals presenting to an outlet for their illness would not have a prior expectation about receiving a test or have made a prior decision about whether they would like to receive a test. They will not have preconceived ideas about how much they should pay for an RDT. We would like to understand decision-making in the presence of a new tool (RDT) in a ‘naïve’ system.

Second, Kenya has maintained stable retail ACT prices for nearly five years. Although these prices are subsidized they are still likely to be a significant expense for households in the area. This offers two advantages – first, individuals know how much they expect to pay for an ACT before coming to the outlet and second, the ACT discounts we will offer (conditional on a positive test) are expected to be attractive to the customer (ie non-negligible).

Researchers have previously developed a theoretical framework of the decision-making behavior of individuals purchasing subsidized RDTs and anti-malarials. They performed a simulation of the model, with a range of estimated values for each of the parameters to predict the optimal subsidy levels for both ACT and RDTs. However, the predictions of the model depend crucially on individual beliefs that remain unknown: about the likelihood their illness is malaria, whether malaria diagnostic test results are correct, and about the effectiveness of the available anti-malarial treatments. This study provides a platform to empirically measure the decision-making behavior of clients under different subsidy programs, thus testing the validity of the model which could then be extrapolated to other contexts.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

The intervention proposed is a subsidy for diagnostic testing and the use of a conditionally subsidized ACTs in case of a positive test. The subsidy for testing will vary across clients but they can choose whether or not to use a test once they are enrolled and receive a subsidy offer. The subsidized ACT is offered only to patients with a positive test but, once again, the client is free to choose whether or not to use it. Participating in this study involves allowing us to record information about clients' malaria testing and treatment decisions. This includes the clients' decisions about whether to get tested for malaria using the RDT at the subsidized price, and whether to buy an ACT either at the subsidized price (if they test positive for malaria) or at the regular price (if they do not get tested or if they test negative). There is a small risk of breach of confidentiality of this information.

The RDTs to be used in this study are the same brand and test as those used by the Government of Kenya in public health facilities and in their community-based case management for malaria. Conducted properly, finger-sticks pose no greater than minimal risk to participants, including children. While unlikely, there is a small potential for excess bleeding or infection associated with finger pricks conducted in the course of administering an RDT. However, there is no alternative to a blood sample for diagnosing malaria and these risks are equivalent to the risk of seeking the same test from a facility or a community health worker. A finger prick blood sample is the least invasive and safest method to diagnose malaria. Several studies have demonstrated that RDTs can be safely and effectively used following training, even by those with limited formal training and no medical training. Study research assistants will be responsible for conducting RDTs and have been extensively trained in RDTs and dried blood spot collection. They have more than seven years of experience and have tested more than 1,000 people each. They are required to maintain updated CITI certificates and GCP training.

Study staff will be required to carry an identification certifying them as trained in RDT use. Study participants will be advised to contact the study coordinator, or to visit the closest health facility, in the case of any adverse events which may occur after the visit. All participants will be advised to go to a health facility if symptoms persist.

No venous blood will be drawn.

2.3.2 Known Potential Benefits

There is significant benefit to the client to knowing their malaria infection status prior to purchasing a drug. There is also a benefit to the client to be able to purchase an effective drug at a reduced, fixed price when they have a confirmed malaria infection, which may also reduce the likelihood that they would purchase an inappropriate or outdated therapy.

More broadly, there are important future benefits to rigorous testing of subsidy schemes that promote testing before treatment. This work will contribute to evidence-based policy making, improved access to malaria diagnosis and ultimately reduced potential for spread of antimalarial resistance.

3 OBJECTIVES

This objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT. We will test two different RDT price levels and two discounted ACT price levels in a factorial design. ACT discounts are conditional on a positive RDT result.

4 STUDY DESIGN

The study will be carried out in a random sample of 10 retail outlets that carry ACTs in the study area in western Kenya. The study population will be any individual presenting to the outlet with a malaria-like illness on randomly selected days. Children are eligible to be enrolled provided they are physically present and are accompanied by a parent or legal guardian. A research assistant will offer eligible participants a scratch card with a secret subsidy offer that will be revealed after the participant is enrolled. Using the scratch card, the participants will be randomized, in a 1:1:1:1 ratio, to one of four study arms shown in **Table 1**.

The research assistant will conduct RDTs for participants who choose to purchase an RDT. They will explain the results of the RDT to the participant, indicating whether the individual has malaria or not based on the test result. If the result is positive, the participant is entitled to an additional discount on their ACT purchase according to their scratch card. If the result is negative, the participant may purchase any medicine they choose, including an ACT at market price. Those who opt not to purchase an RDT may continue with their transaction as they choose, including purchasing a full-price ACT.

The participant will be interviewed before they scratch their card to record their symptoms, age, actions taken prior to coming to the outlet, and their experience with RDTs and ACTs in the past. We will also ask what drug they intend to buy when coming to the outlet. After they scratch the card and complete their transaction at the outlet (including purchasing an RDT if they choose), they will be interviewed again briefly to see what drugs they purchased. All scratch-card recipients will be interviewed regardless of whether or not they used their randomized offer. The two interviews combined will take approximately 20-30 minutes.

The primary outcome for this study is the customer's decision to purchase an RDT (yes/no). Using the 2x2 factorial design we will separately evaluate the effect of RDT price (2 levels: 50% vs. 0% subsidy) and of conditional ACT subsidies (2 levels: 100% vs. 67% subsidy) on the primary outcome of testing uptake. A factorial design is optimal when we are interested in the independent effects of two interventions, in this case, the two types of subsidies. A 67% discount for an ACT gives the following price to the consumer for each age-specific dose based on current market price: 6 tablets – $0.10; 12 tablets - $0.15; 18 tablets - $0.20; 24 tablets - $0.40.

ACT Price to client if he/she tests positive for malaria (Price for RDT negative or untested client = $1.20)	RDT Price to client I. $0.20 USD (50% subsidy)	RDT Price to client II. $0.40 USD (No Subsidy)	Overall Proportion Tested*
I. $0 USD (100% subsidy)	85%	70%	77.5%
II. $0.10-0.40 USD (67% subsidy)	75%	60%	67.5%
Overall Proportion Tested*	80%	65%	

* Assuming the same sample size in each of the 4 study arms
** At current market prices, this subsidy level gives the following prices to the consumer: 6 tablets@$0.10; 12 tablets@$0.15; 18 tablets@$0.20; 24 tablets@$0.40.

Secondary outcomes include adherence to the RDT test result (defined as using an ACT if positive and using another drug if negative) and purchase of regular price ACT without a test. Due to the short time frame of recruitment (i.e. before entering outlet) to data collection (i.e. after leaving outlet), we do not anticipate missing outcome data.

5 Study Population

5.1 Selection of the Study Population

The study population will be any individual coming to a participating medicine retail outlet to purchase medicine for an acute, malaria like illness. Ten randomly selected retail medicine outlets in the study area will be selected for recruitment, which will happen on random days of the month to avoid individuals seeking to be recruited.

840 participants will be recruited and randomly assigned in equal numbers to each of four arms using secret scratch cards. Children are eligible to participate if they are present with a parent or guardian. Inclusion of children ensures that we get a comprehensive picture of malaria infection and treatment decisions across all age groups. Children are at higher risk of malaria infection and disease which increases their importance to the study. They will also benefit from the opportunity to receive diagnostic testing immediately at the retail outlet, and they, along with their parent or guardian, can use the test results in deciding what drugs to purchase or other treatment actions to take. We will attempt to recruit all eligible participants who attend the outlet on a recruitment day. This will ensure that our sample is representative of the population seeking care in retail outlets in terms of age, gender and ethnicity. We do not have targets for recruitment based on gender, age or ethnicity.

5.2 Inclusion/Exclusion Criteria

INCLUSION CRITERIA:

- Participants with fever, or history of fever, or suspects they may have malaria
- Individual with malaria-like illness must be present at recruitment
- Older than one year of age

EXCLUSION CRITERIA:

- Any individual with signs of severe illness requiring immediate referral
- Individuals who have taken an antimalarial in the last seven days, including for the current illness
- Individuals who already have a prescription from a facility or medical provider, regardless of whether they have documentation of a test
- Pregnant women will be enrolled and offered an mRDT, but will be advised to seek treatment through a health care provider.

6 STUDY PROCEDURES/EVALUATIONS

6.1 Study Procedures

Potential participants will be approached when they visit a participating medicine retail outlet. The research assistant will ask whether they are seeking medication for themselves or an individual present at the time of screening and whether they (or the minor child) have had fever or malaria-like symptoms in the last 24 hours. If so, then the RA will ask whether they would like to have more information about the study. Following informed consent, the RA will ask questions about the current illness, any medications taken before coming to the outlet, symptoms, and their familiarity with malaria diagnostic tests. After taking the basic history, they will be offered a scratch card. The cards mask the arm assignment. The participant selects their card and then scratches the panel to reveal their assignment. Once their price levels have been explained, they will be asked to choose whether they wish to have a malaria diagnostic test at the price indicated on the card. If they wish to be tested, the RA will perform the mRDT and explain the results to the participant. The mRDT is a simple immunochromatographic test which requires a drop of blood (approximately 5 microliters) and the results are visible in 15 minutes. In the case of a positive test, the RA will instruct the participant to take the positive test and the scratch card to the shopkeeper in exchange for a discounted ACT. The price of the ACT for participants with a positive test will be determined by their arm assignment. Individuals with a negative test or who choose not to have a test can purchase an ACT at the normal retail price. After the participant has made a selection and purchased medicine for their illness, the RA will record the final treatment decisions.

The encounter should take no more than 45 minutes including consenting, enrollment and mRDT. All responses will be recorded directly onto electronic forms running on android tablets. Electronic forms are pre-programmed with data quality checks to prohibit missing data or values out of range and pre-coded responses to ensure consistency and quality of data collection.

6.2 Laboratory Evaluations

6.2.1 Laboratory Evaluations/Assays

A single drop of blood will be collected from a finger prick. All research assistants are extensively trained in blood safety and specimen collection and have performed hundreds of RDTs. Finger prick blood samples will be collected using aseptic technique under strict protocols for participant and staff safety (see Section 2.3.1).

6.2.2 Specimen Collection, Preparation, Handling and Shipping

6.2.2.1 Instructions for Specimen Preparation, Handling, and Storage

Not applicable

6.2.2.2 Specimen Shipment

Not applicable

7 STATISTICAL CONSIDERATIONS

7.1 Study Outcome Measures

The primary outcome measure is the decision to purchase an RDT before purchasing a drug.

Secondary outcome measures are:

2. Decision to purchase an ACT stratified by testing status
    a. Positive mRDT
    b. Negative mRDT
    c. No malaria test

7.2 Sample Size Considerations

Our sample size calculations are based on the expected changes in testing uptake with each of the price changes for the two commodities (RDT and ACT). We expect that reducing the price of the RDT from $0.40 USD to $0.20 will increase the percentage of clients who choose to get tested by 15 percentage points. We also expect that reducing the ACT price, conditional on a positive test result, from $0.40 to $0.00 will increase the uptake of testing by 10 percentage points (see Table 2).

As is commonly done for 2X2 factorial trials that seek to separately test for main effects of each of the two factors, our study is powered to detect the effects of the price reductions of each commodity (RDT and ACT) independent of the price of the other commodity. That is, for the purposes of our power calculations we assume no statistical interaction between the two commodities because our previous evidence suggests that any interaction effects between the prices in the two commodities are likely to be small and therefore not large enough in terms of public health importance to choose to power on such interactions[2]. That is, while we expect the uptake of testing to be sensitive to the price of both the RDT and the ACT, we do not expect that price *changes* in one commodity will have a different effect on testing uptake depending on the price of the other commodity.

Using a standard approach based on a two-sample Z-test for a comparison of proportions for each of the two main effects at a two-tailed 5% Type 1 error rate (alpha), our sample size should provide 90% power to detect each of our two comparisons of interest (i.e. two main effects). To determine the overall sample size of the study, we calculate the sample size needed for each of the two main comparisons of interest, and choose the larger overall sample required (see Table 2). Specifically, because we estimate that we need a total sample size of 838 participants (i.e. of 418 participants at each of the two conditional ACT price levels) to test for the main effect of the conditional ACT subsidy price levels compared to a total sample size of 374 (i.e. of 187 at each of the two RDT price levels) to test for the main effect of the RDT

price levels, we therefore plan the study by using the more restrictive sample size in order to be able to address both study goals. Given that the trial will be conducted within 10 drug retail outlets, there could be clustering of outcomes due to some participants being enrolled from the same shops. Based on our ongoing work in the region, we expect such clustering to be minimal with an intra-class correlation coefficient of at most 0.008. Even with this level of clustering, we would still have at least 80% power to detect our expected effect sizes. The sample size calculations were performed in Excel.

Since clients generally enter the shop one at a time, we do not expect there to be any spillovers between the treatment arms (i.e. we do not expect that offering a client one combination of subsidies will affect the decision-making of a client assigned to another treatment arm within the same shop). Moreover, since the study will be administered by the research assistant (and not the shopkeeper), this should minimize the concern that individual testing decisions might be influenced by the shopkeeper. The interventions will be randomized at the individual level which reduces the likelihood that clients will visit specific retail outlets in order to get the highest subsidy levels of the two commodities.

Each client who consents to be part of the study will receive a scratch card that will indicate their intervention arm (i.e. the combination of prices at which they will be offered an RDT and ACT, conditional on a positive result on the RDT). We will stratify on retail outlet to ensure that each of the 10 outlets has a similar number of clients who are assigned to the four study arms (approximately 21 per arm, per retail outlet for a total sample of 210 per arm). Scratch cards will be allocated in batches of 100 or 60 (25 of each or 15 of each arm) and shuffled thoroughly. Batches will be assigned to specific outlets based on sales volume (i.e., higher-volume outlets received larger batches of 100 cards, smaller outlets received batches of 60 shuffled cards). Participants will be asked to select a card from the shuffled stack. Cards will be replenished when ten were remaining. Due to the nature of the interventions, it is not possible to blind participants and research assistants to the allocation received. Study statisticians will be blinded during the analysis phase.

Description of Comparison	Expected Increase in Testing Uptake	Total sample size required for 90% power (alpha=0.05)
Effect of reducing conditional ACT price from $0.40 (67% subsidy) to $0.00 (100% subsidy)	10 percentage points (from 67.5% to 77.5%)	838
Effect of reducing RDT price from $0.40 (no subsidy) to $0.20 (50% subsidy)	15 percentage points (from 65% to 80%)	374

Table 2: Expected effect sizes for the main comparisons of interest and sample size required for 90% power to detect those effect sizes (with two-tailed Type 1 error set at 0.05, and using standard methods for two-sample comparison of proportions).

7.3 Participant Enrollment and Follow-Up

We will enroll 840 participants attending a random sample of 10 retail medicine outlets.

We will develop a sampling frame of all eligible retail medicine outlets by visiting all outlets within our study area. Outlets will be included in the sampling frame if they: 1) are within the study area; 2) carry quality assured (WHO-approved) ACTs; 3) are registered with the Kenya Pharmacy and Poisons Board; 4) would be willing to participate including selling ACTs at the subsidized price for study participants with a positive RDT. From this roster of all eligible outlets, 12 will be randomly selected. The first ten will be approached to request their participation. If any refuse or drop out, the two alternate outlets will replace them. We expect dropout to be minimal given that the role of the outlet/attendant is very minimal and the enrollment phase is very short. We expect enrollment to take less than 6 months, with each shop contributing data only a few days per month.

On the randomly selected dates for study implementation at each outlet, a research assistant stationed outside the outlet will approach potential participants as they enter the outlet to ask if they would like to hear about the study and would consider participating. Any individual that is over the age of one year and has malaria-like symptoms will be eligible to participate. Once enrolled, participants' involvement with the study consists of just one short interview before scratching off their card or transacting at the outlet and one short interview as they leave the outlet after completing their transaction. Following the second interview, participation in the study is complete. All participants will be informed of the duration of their participation (approximately 30 minutes) at the time of consent. Therefore, we expect loss to follow-up to be minimal, if any. If a participant is enrolled but withdraws before randomization, they will be replaced. If they withdraw before the exit interview but after randomization, we will at least have information on the primary outcome (tested or not tested with an RDT).

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7.4 Analysis Plan

All outcomes will be binary (e.g. tested – yes/no) and will be analyzed using a modified Poisson regression model[27,28] with log link to estimate risk ratios (RRs) and identity link to estimate risk differences (RDs) in order to provide both relative and absolute measures of intervention effect. Such an approach assumes a Poisson distribution for the binary outcome and then 'fixes' the estimated standard errors to correct for model misspecification. We minimize clustering of outcomes by outlet with highly controlled intervention delivery and careful outcome measurements by research assistants. However, to account for possible clustering due to multiple individuals being randomized within different (randomly-sampled) outlets we will use a generalized estimating equations (GEE) approach with exchangeable working covariance matrix, Kauerman-Carroll correction and robust standard errors (to correct for model misspecification due to specifying a Poisson distribution)[29,30]. The outcome will be regressed on

2 binary indicators, one each for the higher subsidy level of the two subsidies (50% RDT subsidy and 100% ACT subsidy), together with their interaction and a vector of potential confounder variables (e.g., age, gender) to account for possible imbalances between study arms. Although we hypothesize that there will be no evidence of a (statistical) interaction (see Sample Size details above), we will test for this interaction and, if significant, will separately report the effects of each subsidy conditional on levels of the other subsidy. In the absence of an interaction, we will estimate the overall ACT subsidy effect and the overall RDT subsidy effect by taking relative contrasts from the model. All analyses will be based on the intention-to-treat principle whereby all clients will be included in the analysis irrespective of whether they complied with the intervention.

8 SUBJECT CONFIDENTIALITY

Participants will be consented and tested in a private area near the shop or private office inside the shop if available. Enrollment interview data will be collected electronically on password-protected secure tablets and uploaded onto secured machines in the study office. No information that could positively identify an individual in the database, such as phone number, address, date of birth, or names will be collected on the tablet. Anyone older than 80 years of age will be recorded as ‘80’. Individuals in the database will be assigned a unique study ID. Signed consent forms will be locked in a secure cabinet in the office and only the project coordinator will have access to the key.

Despite the aforementioned protections, there is a small risk of breach of client confidentiality if consent forms are viewed by someone external to the study team. However, since no identifying information will be stored with the health data, health information will be protected and cannot be linked to participants. Project staff will keep their human subjects training certificates up to date and will be instructed on the protocol with regards to confidentiality of human subjects data as relevant according to their job duties.

8.1 Future Use of Stored Specimens

Not applicable.

9 INFORMED CONSENT PROCESS

All participants enrolled in Aim 1 will be asked to give written informed consent with their signature or thumbprint before any data is recorded. On the randomly selected dates for study implementation at each outlet, a research assistant stationed outside the outlet will approach potential participants as they enter the outlet to ask if they would like to hear about the study and would consider participating. Any individual that is over the age of one year and has malaria-like symptoms will be eligible to participate. Parents or guardians of children under the age of 18 (the age of consent in Kenya) will be asked to consent for minors. In addition, verbal assent from children over the age of ten years will be required in conjunction with written parental consent. The study procedures will be explained, including the risks and benefits. Potential participants will be informed that their participation is voluntary and there will be no negative consequences should they choose not to participate. Consent will be obtained in as private an area as possible inside or nearby outside the retail outlet. Children will be assented with their guardian present. Participants will be informed that they may withdraw consent at any time during the study. A copy of the consent script will be available for each participant if they desire and will include study contact information. Once enrolled, participants' involvement with the study consists of just one short interview before scratching off their card or transacting at the outlet and one short interview as they leave the outlet after completing their transaction. All participants will be informed of the duration of their participation (approximately 30 minutes) at the time of consent.

9.1 Informed Consent/Assent Process (in Case of a Minor or Others Unable to Consent for Themselves)

Children are eligible to be enrolled provided they are physically present at enrollment and are accompanied by a parent or legal guardian. Minors will be defined as children under eighteen years of age. The assent process for minors will be to obtain consent from the minor's parent or guardian for the participation of the minor and verbal informed assent from minors over ten years old.

All study staff will be trained in human subjects' protections, including how to explain the study appropriately to both children and parents/guardians and the correct procedures for obtaining assent and consent for study participation. Our study staff have many years of experience performing and training others to conduct RDT for both children and adults outside of formal clinic settings as part of other large trials conducted by the PI. During trainings for this study, they will review differences in care and patience required when performing RDTs for children.

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SUPPLEMENTS/APPENDICES

A.1 Informed consent for participation in TESTsmART Aim 1 (English and Kiswahili)

A.2 Questionnaire for participants

A randomized experiment of malaria diagnostic **te**sting and conditional **s**ubsidies to **t**arget **A**CTs in the **r**e**t**ail sector: the TESTsmART trial AIM 1

Informed consent for participants attending medicine retail outlets

Jeremiah Laktabai, Primary Investigator
Diana Menya, Investigator
Wendy Prudhomme O'Meara, Primary Investigator

Duke University and Moi University

Study information and procedures - Moi University, in collaboration with Duke University, is conducting a research study about purchasing of medicines for fevers such as malaria in this area and how malaria diagnostic tests could be used by people buying medicine in a pharmacy or drug store. You have been selected for this research because you (or your child) are visiting a shop to purchase medicines for an illness today. Taking part in this research study is voluntary. You may choose not to take part in the study and it will not affect the normal services you receive at this pharmacy/chemist.

As part of this study we are offering you a voucher that will entitle you to receive a malaria diagnostic test before you purchase your medicine. If the test shows you have malaria, you will be offered an additional discount on the recommended medicine for malaria. The amount of the discount for the test and the medicine is random like a lottery and it will be revealed once you have agreed to participate. There will be a small price for the test, but you are free to decide whether or not you would like to be tested after your secret price is revealed. The test requires a finger stick to take one or two drops of blood. The blood is placed on the cassette and after 15 minutes the results can be seen. The results of the test will tell you whether you have malaria parasites in your blood or not.

We will also ask you a few questions about yourself and your (your child's) illness now and a few questions about which drug you purchased when you leave. These questions should not take more than 30 minutes of your time. We will ask you to answer these questions even if you choose not to have a malaria test. All of your answers will be kept confidential, and we will do everything possible to protect your privacy.

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. Our research assistants have been trained in blood safety and a new needle and test is used for every person so the test is very safe. There is a small risk of breach of confidentiality – your answers may become known to others unintentionally. However, we will do everything possible to protect this information and I will not discuss your answers with anyone else.

Benefits of participation – You may benefit from knowing whether or not you have malaria if you choose to have a malaria diagnostic test. If the test shows you have malaria, you will benefit from a lower price for the medicine you need. If you do not have malaria, the test may help you make a different choice about the right medicine for you. Participation is voluntary and if you choose not to participate, you are free to purchase medicine as you normally would.

You may stop the interview at any time if you change your mind about participating. If you wish to stop, you may proceed and purchase medicine as you normally would.

If you have any questions, you may contact the study at any time. Contact: Joseph Kipkoech - [redacted]

A description of this study will be available at http://www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can view the website at any time. The identification number for this study is NCT03810014.

Patient consent and signature
I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

Signature _____Date_____

Study ID_____

For participants 10 years up to 18 years, was assent obtained from the minor?
Y N Not applicable

Signature of person obtaining consent _____ Date_____

A randomized experiment of malaria diagnostic **te**sting and conditional **s**ubsidies to **t**arget **A**CTs in the **re****t**ail sector: the TESTsmART trial AIM 1

IDHINI YA KUSHIRIKI KATIKA UTAFITI YA WANAOHUDHURIA MADUKA YA DAWA

Watafiti
Jeremiah Laktabai, Mtafiti mkuu
Wendy Prudhomme O'Meara, Mtafiti mkuu
Diana Menya, Mtafiti

Duke University na Moi University

HABARI NA UTARATIBU WA UTAFITI HUU

Chuo Kikuu cha Moi, wa kishirikiana na Chuo Kikuu cha Duke, wanafanya utafiti kuhusu ununuzi wa madawa kwa ajili ya malaria katika eneo hili, na jinsi vipimo vya uchunguzi wa malaria au malaria RDT vinaweza kutumika na watu wanaonunua dawa katika maduka ya dawa. Hivi leo, umechaguliwa kwa ajili ya utafiti huu kwa sababu wewe (au mtoto wako) umetembelea duka hii, ili kununua dawa kwa ajili ya ugonjwa. Tungependa kukueleza kwamba, kushiriki katika utafiti huu ni kwa hiari yako. Unaweza kuchagua kutoshiriki katika utafiti hu una uamuzi wako hautaathiri huduma za kawaida unazopata kwenye duka hili la dawa.

Kama sehemu ya utafiti huu, tunakupa chaguo ambayo itakuwezesha kupimwa kama una malaria kabla ya kununua dawa. Matokeo ya uchunguzi ikionyesha kuwa una malaria, basi utapewa dawa ya malaria iliyopendekezwa, kwa bei nafuu. Kiasi cha bei ya kupimwa ili kuchunguza kama una malaria na pia bei ya dawa itakuwa kama bahati nasibu na itafunuliwa kwako mara tu umekubali kushiriki. Kiasi cha bei ya kupimwa malaria itakuwa ya chini, una uhuru wa kupimwa kabla au baada ya bei yako ya siri kufunuliwa. Ili kupima malaria, tutakusanya tone moja au mbili ya damu kutoka kwenye kidole, kisha tuiweke kwenye kanda ya uchunguzi na baada ya dakika 15 hivi matokeo yataweza kuonekana. Matokeo ya uchunguzi wa malaria itakuambia kama una vimelea vya malaria au "malaria parasite" katika damu yako au la.

Pia tutakuuliza maswali machache kuhusu ugonjwa wako au ugonjwa wa mtoto wako na pia maswali machache kuhusu dawa ulizonunua unapoondoka kwenye duka. Maswali haya hayapaswi kuchukua zaidi ya dakika 30 ya muda wako. Tutakuuliza kujibu maswali haya hata kama hukuchagua kupimwa malaria. Majibu yako yote yatahifadhiwa kwa siri, na tutafanya kila kitu iwezekanavyo ili kudumisha usiri wako.

HATARI ZA USHIRIKI

Kuna hatari ndogo ya uchungu kwenye kidole itakayo dungwa ili kukusanya tone moja au mbili za damu. Kuna hatari ndogo sana ya maambukizi kwenye kidole kilichodungwa. Wasaidizi wetu wa utafiti wamefundishwa kuhusu utaratibu na usalama wa damu na kila wakati wanapopima, sindano mpya hutumiwa kwa kila mtu. Hivyo uchunguzi wa malaria ni salama sana. Kuna hatari ndogo ya uvunjaji wa siri kama vile; majibu yako kuweza kujulikana kwa wengine bila ya nia yetu. Hata hivyo, tutafanya kila kitu iwezekanavyo kulinda habari hii na hatutajadili majibu yako na mtu mwingine yeyote.

FAIDA ZA USHIRIKI

Unaweza kufaidika kwa kujua kama una malaria ikiwa utaamua kupima malaria. Ikiwa uchunguzi utaonyesha kuwa una malaria, utafaidika na bei ya chini ya dawa unayohitaji. Ikiwa huna malaria,

uchunguzi huu unaweza kukusaidia kufanya uamuzi tofauti kuhusu dawa sahihi kwako. Kushiriki ni kwa hiari na ukichagua kutoshiriki, uko huru kununua dawa kama kawaida.

Ikiwa una maswali yoyote, unaweza kuwasiliana nasi kupitia Joseph Kipkoech - 0720393547

Maelezo ya utafiti huu yatapatikana kwa tovuti; http://www.clinicaltrials.gov. Tovuti hii haitajumuisha maelezo ambayo yanaweza kukutambua. Kwa zaidi, tovuti hii itajumuisha muhtasari wa matokeo. Unaweza kuona tovuti hiyo wakati wowote. Nambari ya utambuzi ya utafiti huu ni NCT03810014.

IDHINI YA MGONJWA NA SAHIHI
Nimesoma au nimeelezwa kuhusu utafiti huu na msaididizi wa utafititi, pia amejibu maswali yote niliyo nayo wakati huu. Nimeambiwa juu ya uwezekano wa hatari au madhara, pamoja na faida ya utafiti huu. Mimi najitolea kwa hiari yangu kushiriki katika utafiti huu.

Sahihi _____Tarehe _____

Nambari ya utambulishu ya utafiti_____

Je, umepata idhini ya mdomo kwa washiriki wa miaka 10 hadi miaka 18?
Ndio _____ Hapana _____ Haihusiki_____

Sahihi ya anayepokea idhini _____ Tarehe_____

CHILD ASSENT FOR PARTICIPATION AND MALARIA RAPID DIAGNOSTIC TESTING

For children 10 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. Research 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 researchers will ask you and your parent some questions about your health. They will also take a small blood sample.

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

We may learn about whether or not you have malaria today. This will help you to know which drug you should take.

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

You may also 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.

Do you agree to take a malaria test today?

Yes (1)

No (2)

IDHINI YA MDOMO KWA MTOTO ILI KUSHIRIKI NA KUPIMWA NA RDT

Kwa watoto chini ya miaka 10 na wasiozidi miaka 18

Tunakuuliza ruhusa ya kushiriki katika utafiti. Utafiti ni njia ya kudadisi mambo mapya. Utafiti hutusaidia kujifunza mambo mapya.

Kushiriki katika utafiti ni kwa hiari yako. Unaweza kusema ndio au hapana. Kile utakachoamua ni sawa. Bado tutakuhudumia tu vyema.

Katika utafiti wetu, tungependa kujua kama una malaria leo. Ukishiriki, msaidizi wa utafiti atakuuliza pamoja na mzazi wako maswali yanayohusu afya yako. Pia atachukua damu kidogo kutoka kwako.

Kuna faida gani inayoweza kutokana na huu utafiti?

Tutaweza kujua kama una malaria leo au la. Jambo hili litakusaidia kujua ni dawa ipi unayostahili kutumia.

Kuna madhara gani yanoyoweza kutokana na huu utafiti?

Kuna uwezekano wa wewe kuhisi uchungu kidogo tunapochukua sampuli kidogo ya damu. Chukua mda unaohitaji ili kufanya maamuzi. Uliza maswali yoyote unayoweza kuwa nayo. Unaweza kuuliza maswali wakati wowote.

Je, unakubali kupewa kipimo cha malaria leo?

Ndio (1)

Hapana (2)

Appendix A.2

Aim 1: TESTsmART Participant questionnaire

Number	QUESTION	RESPONSE	SKIP
0.1	**Date**	DD/MM/YYY	
0.2	**Participant ID**		
0.3	**Outlet ID**		
0.4	**Interviewer ID**		
0.5	**Arm assignment from scratch card**		

SECTION 1: RESPONDENT INFORMATION

1.1	**Who is the respondent?**	Adult with fever……1 Guardian of the child…….2	→Q1.5
1.2	**What is your relationship with the child?**	Parent……..1 Grandmother/grandfather……2 Brother/Sister…….3 Uncle/Aunt……4 Other_____	
1.3	**Gender of the child**	Female……..1 Male……..0	
1.4	**How old is the child?**	__ ___ . __ years	
1.5	**Gender of the respondent**	Female……..1 Male……..0	
1.6	**How old are you?** *[In the case the child is ill, please collect this information for the parent/guardian of the child]*	_____ _____ years	
1.7	**How many people live in your household?**	☐☐	

	[In the case the child is ill, please collect this information for the parent/guardian of the child]		
1.8	**What is the highest level of schooling you completed?** *[In the case the child is ill, please collect this information for the parent/guardian of the child]*	1. None 2. Primary 3. Secondary 4. College 5. University	
1.9	**What is your primary occupation?** *In the case the child is ill, please collect this information for the parent/guardian of the child]*	**Agriculture** 1. Farming/Livestock keeping **Paid employee** 2. Government or parastatal 3. Private ..... **Self -employed (Not in agriculture)** 4. With employees 5. Without employees (e.g. motorcycle taxi, vendor) 6. Unpaid family helper in a business ..... 6 **Not working** 7. Casual worker/day laborer 8. Househelp 9. Homemaker 10. Student 11. Not available to work 12. Other (Specify) _____	

SECTION 2: CURRENT ILLNESS

Number	QUESTION	RESPONSE	SKIP
2.1	**Which symptoms do you/your child have or had in the last 24 hours?** *[Mark all that apply]*	1. Fever 2. Nausea 3. Headache 4. Body aches 5. Vomiting 6. Shivering 7. Stomach ache	

		8. Other_____ 99. Don't know	
2.2	**How serious is this illness in your opinion?** *[Guardian of the child can guess how the child feels]*	1. Not very serious/minor 2. Moderate 3. Very serious	
2.3	**How many days ago did the symptoms start?**	_____days	99=Don't know
2.4	**Have you taken/given to the child any medication before coming here today?**	1. Yes 2. No 99. Don't know	If 1, go to 2.5 If 2, go to 2.6
2.5	**Which medicines (select all that apply)**	1. CoArtem/Artefan/other AL 2. Quinine 3. SP (ie Fansidar/metakelfin/ Malodar) 4. Amoxyl 5. Other antibiotic 6. Painkiller (ie Panadol/Brufen/Hedex/ Action/Maramoja) 7. Cough medicine or decongestant 8. Other_____ 99. Don't know	If 1, 2 or 3 STOP
2.6	**Have you sought treatment elsewhere before coming here today?**	1. Yes 2. No 99. Don't know	If no or don't know→ skip to 2.8
2.7	**What did you do?**	1. Visit hospital 2. Visit health center 3. Visit private clinic 4. Visit dispensary 5. Visit pharmacy/chemist 6. Buy medicine at general shop 7. Gave medicine available at home 8. Visit traditional healers 9. Visit religious/cultural healers 10. Visit CHW 11. Other_____ 99. Don't know (ie another parent was involved)	NOTE: Confirm whether the participant has a prescription. If YES → STOP

2.8	**Which medicine are you planning to buy for you/ your child?**	9. CoArtem/Artefan/other AL 10. Quinine 11. SP (ie Fansidar/metakelfin/ Malodar) 12. Amoxyl 13. Other antibiotic 14. Painkiller (ie Panadol/Brufen/Hedex/ Action/Maramoja) 15. Whatever the doctor/shopkeeper recommend 16. Whatever I can afford 17. Other_____ 12. Don't know	
2.9	**Approximately how much do you expect to spend?**		9999= Don't know

SECTION 3: EXPECTATIONS

Number	QUESTION	RESPONSE	SKIP
3.1	**As you know, fever can be a symptom of many different illnesses, including malaria. How likely is it that an ADULT person living in your village who currently has fever actually has malaria?**	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. This is the only thing they could have **99.** Don't know	
3.2	**How likely is that the illness that you/your child have today is malaria?**	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. This is the only thing they could have 99. Don't know	

3.3	**Are you aware you can have your blood tested for malaria?**	1. Yes 2. No 99. Don't know	If no, skip to 3.11
3.4	**Have you ever had your blood tested for malaria?**	1. Ye Yes 2. No 99. Don't know	If no skip to 3.6
3.5	**How much did it cost?**		9999=Don't know or don't remember
3.6	**Are you aware of malaria rapid diagnostic tests?**	1. Yes 2. No 99. Don't know	If no, skip to 3.11
3.7	**Have you ever been tested for malaria using a malaria rapid diagnostic test?**	1. Yes 2. No 99. Don't know	If no, skip to 3.9
3.8	**How much did it cost?**		9999=Don't know or don't remember
3.9	**If you believe you HAVE malaria and the test shows that you do not have malaria, how likely do you think the result from the test is correct?**	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. No doubts 99. Don't know	
3.10	**If you believe you DON'T have malaria and the test shows that you have malaria, how likely do you think the result from the test is correct?**	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. No doubts	
3.11	**If you have malaria and use AL, how many days before you feel completely well*?***	_____ days	98= don't know 99=never – Coartem is not very effective

3.12	**If you have malaria and use Fansidar, how many days before you feel completely well*?***	_____ days	98= don't know 99=never – Fansidar is not very effective
3.13	**f you have malaria and don't take any drug, how many days before you feel completely well*?***	_____ days	98= don't know 99=never – you must take a drug to treat malaria
3.14	**If you DO NOT have malaria and you take AL, how many days until you will feel completely better?**	_____ days	98= don't know 99=never – CoArtem is not the right drug

SECTION 4: INTENTIONS

Number	QUESTION	RESPONSE	SKIP
4.1	**Did the participant choose to purchase an RDT?**	1. Yes 2. No	If yes skip to 4.3
4.2	**Why not?**	1. Too expensive 2. Already sure I have malaria 3. Already sure I don't have malaria 4. Don't want to get finger pricked 5. Other?	Next skip to section 5
4.3	**RDT results**	1. Negative 2. Positive 3. Invalid	
4.4	**How likely is it that the result of the RDT was correct?** ***Only if tested***	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. Absolutely sure 99. Don't know	

4.5	**Now that you have the test result, how likely is that the illness you/your child has is malaria?** ***Only if tested***	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. Absolutely sure 99. Don't know	

SECTION 5: POST-PURCHASE FOLLOWUP QUESTIONS

ACTIONS

Number	QUESTION	RESPONSE	SKIP
5.1	**Which medicine did you buy? Choose all that apply**	1. CoArtem/Artefan/other AL 2. Quinine 3. SP/Fansidar/metakelfin/Malodar 4. Amoxyl 5. Panadol/Brufen/Hedex/painkiller/Action/Maramoja 6. Don't know/don't remember 7. Did not purchase any medicine **8.** Other……..	If 7, skip to 5.5
5.2	**[Ask the respondent to show you the drug she/he purchased]** **Did the respondent show you the drug he/she purchased?**	1. No 2. Yes (if yes, write brand names) [Write down brand names] _____	
5.3	**How much did you pay in total? (The amount refers to how much <u>money</u> respondent paid for the medicine and RDT. Don't add the amount of the voucher if any was used)**	_____KES Don't know/remember…9999	

5.4	**If possible, please tell me how much you paid for each drug you bought today**	Drug 1 Name_____ Amount_____ Drug 2 Name_____ Amount_____	
5.5	**Did you use the study voucher (RDT-positive only)**	1. Yes 2. No	If yes, skip to 6.1
5.6	**Why not?**	1. Lacked Money/still too expensive 2. Preferred a drug not covered by the voucher 3. The shop attendant counseled me to buy another drug 4. Did not believe illness is malaria 5. Other_____ 99. Don't know	

SECTION 6: POST-PURCHASE BELIEFS

Number	QUESTION	RESPONSE	SKIP
6.1	**How likely is it that the result of the RDT was correct?** ***Only if tested***	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. Absolutely sure 99. Don't know	
6.2	**How likely is that the illness you/your child has is malaria?**	1. Not possible 2. Unlikely but not impossible 3. 50/50 4. Likely 5. Absolutely sure 99. Don't know	

SECTION 7: HOUSEHOLD CHARACTERISTICS

Number	QUESTION	RESPONSE	SKIP

7.1	**What is the main source of drinking water for your household?**	1. Piped water/Public Tap/borehole ..... 1 2. Unprotected well 3. Protected well 4. Protected Spring 5. Unprotected Spring 6. Surface water (river, dam, lake, pond, stream, canal, irrigation channel) 7. Rain water 8. Bottled water 9. Other	
7.2	**Does your household have the following items:**		
a)	**Electricity?**	1. Yes 2. No 99. Don't know	
b)	**A television?**	1. Yes 2. No 99. Don't know	
c)	**A refrigerator?**	1. Yes 2. No 99.Don't know	
d)	**A radio?**	1. Yes 2. No 99. Don't know	
e)	**A mobile phone (at least one member of the household has)?**	1. Yes 2. No 99. Don't know	
f)	**A motorcycle (at least one member of the household has)?**	1. Yes 2. No 99. Don't know	
g)	**A car/truck?**	1. Yes 2. No 99. Don't know	

h)	**A bank account (at least one member of the household has)?**	1. Yes 2. No 99. Don't know	
7.3	**How many of the following livestock does your household have?**	1. None 99. Don't know	
a)	**Cows**		
b)	**Sheep**		
c)	**Goats**		
d)	**Pigs**		
7.4	**What kind of toilet does your household have?**	2. Flush or pour flush toilet 3. VIP / Ventilated improved pit latrine 4. Pit latrine with slab 5. Pit latrine without slab 6. Composting toilet 7. Bucket toilet 8. No facility / bush / field 9. Other (Please specify): _____	

7.5	**What type of fuel does your household <u>mainly</u> use for cooking?**	1. Liquefied petroleum gas 2. Paraffin/Kerosene 3. Charcoal 4. Firewood 5. Dung 6. Biogas 7. Crop residue 8. Other (Specify)_____ _	
7.6	**What is the <u>main</u> material of the floor in your house?**	1. Earthen 2. Cement 3. Floor Tiles 4. Wood planks 5. Polished wood Other (please specify) _____	
7.7	**What is the <u>main</u> material of the walls in your house?**	1. Stone 2. Brick 3. Timber 4. Iron Sheet	

		5. Mud 6. Wood 7. Cement Other (please specify)_____	
7.8	**What is the <u>main</u> material of the roof of your house?**	1. Iron sheets 2. Roof tiles 3. Grass Thatched 4. Wood Other (please specify)_____	
7.9	**How many acres/hectares/feet of land for farming does your household own?**	1.None..... 0 2. Acres_____ 3. Square Feet (xx by xx)_____ 9999. Don't know	

SECTION 8: INTERVIEW SECTION NOTE

Number	QUESTION	RESPONSE
8.1	**What is your evaluation of the accuracy of respondent's answer?**	1. Excellent 2. Good 3. Fair 4. Not so good 5. Very bad
8.2	**What is your evaluation of the seriousness and attentiveness of the respondent?**	1. Excellent 2. Good 3. Fair 4. Not so good 5. Very bad