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 2

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National Institute of Allergy and Infectious Diseases (NIAID)

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Statement of Compliance

The study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46; 21 CFR Part 50, 21 CFR Part 56, and 21 CFR Part 312)
- ICH E6; 62 Federal Register 25691 (1997)
- NIH Clinical Terms of Award

All key personnel (all individuals responsible for the design and conduct of this study) have completed Human Subjects Protection Training.

NATIONAL HEALTH RESEARCH ETHICS COMMITTEE, NIGERIA (NHREC)
SCIENTIFIC AND ETHICAL REVIEW COMMITTEE (SERC)
RESEARCH PROPOSAL FORM

Project No._____ (To be given by SERC)

Title:	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 2**		
Person(s) undertaking the project-Study Team			
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Ryan Simmons	MA	Duke Biostatistician	Duke University
Study period: 5 years	**Date of commencement: October 2018**		**Date of completion: September 2023**
Description of study sites: Study sites are the Patent and Proprietary Medicine Vendors (PPMVs) in the private retail sector			

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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.

Site Investigator:*

Signed: _____ Date: _____

Name
Title

Contents

List of Abbreviation

ACT	Artemisinin Combination Therapy
AE	Adverse Event
AM	Antimalarial
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/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
PPMV	Patent and Proprietary Medicine Vendors
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

Protocol Summary

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 2

Population: 48 registered Patent and Proprietary Medicine Vendors (PPMVs) in Lagos State, Nigeria, 8160 participants seeking care from these PPMVs

Number of Sites: 48

Study Duration: 18 months

Subject Duration: 30 minutes

Objectives:

The objective of this study is to test the effect of provider-directed and patient-directed incentives on improving the management of suspected malaria fevers that receive care in the retail sector. Provider-directed incentives include small payments for taking the time to conduct malaria-RDT testing for participants with malaria-like illness. Patient-directed incentives are inexpensive RDT testing coupled with a conditional ACT discount. The ACT discount is only applied if the RDT is positive for malaria. Outcomes will be measured by exit interviews on random days each month at each participating outlet.

Primary:

- The primary outcome will be the proportion of all ACTs that are sold to individuals with a positive malaria diagnostic test. For this outcome, a positive test is anyone who has a malaria-RDT performed at the outlet and receives a positive result or is referred from a health facility or a diagnostic lab with a documented positive test result.

Secondary:

- The major secondary outcome is the proportion of suspected malaria cases that are tested with an RDT at the outlet. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing.
- Other secondary outcomes will measure 1) adherence to the RDT result among all those tested at the outlet, 2) proportion of all suspected malaria cases that are managed appropriately (tested for malaria, and use ACT following a positive test or do not purchase an ACT after a negative test), and 3) ACT use by untested clients.

For questions regarding this protocol, contact *Dr Chuka Ndukauba* at the Clinton Health Access Initiative (CHAI).

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1 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

1.1 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**[1] [2]. Approximately 75% of global ACT demand is subsidized with international public funds from sources such as The Global Fund, DFID, and USAID[2] [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 [4, 5] and contributes to population-wide drug pressure that accelerates the spread of drug resistance [6-8].

Global over-consumption of ACTs is largely driven by its increased over-the-counter distribution 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** [9] where studies have shown that between **65-91% of ACTs dispensed for malaria are actually purchased by people without malaria** [10-13]. Targeting ACTs to only those who receive a confirmatory diagnosis could dramatically reduce inappropriate ACT consumption, in alignment with WHO policy that stipulates that all febrile patients be tested before administering antimalarials.

Although more than half of families in sub-Saharan Africa seek care for febrile illness through the retail sector [14, 15], it has remained largely outside of efforts to improve rational, or diagnosis-directed, use of antimalarials. Private medicine retail outlets are made up of for-profit outlets that specialize in medicines, such as pharmacies and drug stores. These outlets are generally poorly regulated, often operate outside of formal channels, and have weak, sometimes antagonistic relationships with the formal health care sector. The lack of accountability and incentive structure undermines adherence to national case management guidelines and contributes to poor ACT stewardship in the retail sector.

Point-of-care malaria rapid diagnostic tests (RDTs), which have excellent sensitivity and specificity and are simple enough to be used by trained persons with limited formal training [16], could expand the reach of diagnostics into the retail sector and help improve the rational use of antimalarials. However, in the context of subsidized ACTs and a for-profit business model, it may not be in the economic interest of clients to test when the treatment is less expensive than

[1] This includes both 311 million courses of subsidized, WHO-prequalified ACTs as well as an estimated figure of more than 100 million courses of other brands not subsidized or tracked by the WHO. Quality-assured or pre-qualified ACTs are pre-approved ACT brands that meet WHO quality standards. Only quality-assured ACTs are subsidized.
[2] USAID – United States Agency for International Development; DFID – Department for International Development, UK

the RDT. Clients may prefer to forgo the RDT in favor of the treatment if they strongly suspect they have malaria, particularly if testing may increase their out-of-pocket costs. Similarly, use of a test may also mean loss of a sale for the retailer if the test is negative, particularly if there is an expectation that the provider will refer all clients who test negative for further evaluation at a formal health facility, as has been suggested by policy-makers. Therefore, in the presence of highly subsidized ACTs, incentives for testing are not aligned with provider or client interests in the private retail sector. **As a result, the private retail sector remains the largest contributor to inappropriate use of ACTs.**

Currently, recipients of Global Fund grants may use funds to subsidize RDTs in the private sector, including in private retail outlets. However, outside of a few countries (i.e., Cambodia, Ghana, Myanmar), the use of RDTs in the retail sector is uncommon as is evidenced by the very low testing rates (<10%) in the private sector in sub-Saharan Africa [2, 17]. 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 [18, 19]. More often, outlets were required to provide testing free of charge or at a low fixed price. Instructions to the outlets regarding when an RDT should be performed and an ACT should be dispensed were quite rigid [20] [21-23]. Providers were not explicitly incentivized to conduct RDTs. All of 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 [24]. 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 [24].

In order to align both the provider and customer incentives towards testing and targeting, the provider must be willing to perform the test and sell the appropriate medicine and, at the same time, the customer must be motivated to purchase the test and adhere to the results. We hypothesize that offering ACT subsidies for the client (conditional on a positive test), and incentives to the provider to offer malaria testing, will each, on their own, have a very modest impact on uptake of testing and targeting of ACTs in the retail sector. We further hypothesize that when combined, they will have a synergistic effect on RDT testing and ACT targeting. However, it is important to estimate the effect of each intervention separately and in combination in order to provide cogent evidence to support joint implementation. We will test the combination of subsidies for ACTs and RDTs (selected from Aim 1) paired with a provider-directed testing incentive in a four-arm cluster-randomized controlled trial to evaluate their impact on the proportion of ACTs sold to individuals with parasitologically-confirmed malaria among those seeking care in the retail sector.

1.2 Scientific Rationale

The study will be conducted in Lagos, a state in southwest Nigeria with a total population of ~21-23m at risk for malaria (National Malaria Indicator Survey, 2015). Much like in other parts of Nigeria, the retail sector is an important resource for people seeking treatment for fever management. Approximately 67% of fever cases in Nigeria first seek care in the retail sector (National Malaria Indicator Survey, 2015). Given the large proportion of ACTs and other antimalarials distributed through the retail sector, efforts to improve targeting of ACTs must include the retail sector.

Nigeria's national strategic plan aims to provide universal access to prompt parasitological diagnosis before treatment and has endorsed the use of malaria RDTs in the public and private health sector (National Malaria Strategic Plan 2014-2020). However, very high rates of self-treatment in the retail sector undermine the explicit policy that all malaria cases should be confirmed by parasitological diagnosis. Private medicine retailers in Nigeria, consisting of private pharmacies and chemists, can conduct RDTs with adequate training and stakeholder management. For this project, we will partner with the Lagos State Ministry of Health, Pharmaceutical Council of Nigeria (PCN) and the National Association of Patent and Proprietary Medicines (NAPPMED) in exploring new ways to engage Patent Proprietary Medicines Vendors (PPMVs) in malaria case management.

Table 1: Study country characteristics

	Nigeria
First line drug	AL[1]
Year adopted universal testing policy	2011
Estimated malaria cases [2]	53.7 million
Total population	~198M
Percent of cases confirmed [2]	22%
Percent of fevers that seek care in retail sector (MIS 2015)	67%
Current price of ACT in retail sector (adult dose)	$3.33[2]
Expected price in 2018	$2.69[2]
Use of RDTs in retail sector?	Yes
Current retail cost of RDT	$0.28
Study area	Urban
Prevalence of malaria in study area (2017 Lagos MIS)	7.1%

[1]Artemether Lumefantrine
[2]Recent CHAI field assessment in 2019

While simulations of clients' decisions around testing and ACT purchasing based on prices of these commodities exist [25], they do not consider the motivations of providers in the retail sector to offer malaria diagnostic testing. The proposed project is a real-world implementation study that will provide insights into whether an innovative and scalable approach can help overcome the practical challenges of working through the retail sector while improving the targeting of ACTs to individuals with confirmed malaria infection.

1.3 Potential Risks and Benefits

1.3.1 Potential Risks

The intervention proposed is an incentive to providers to perform malaria diagnostic testing and the offer of a conditionally subsidized ACT for the client in case of a positive test. The provider incentive is relatively small, so it is not likely to distort the providers' behavior to the extent where they would perform unnecessary malaria tests in order to obtain the incentive. The subsidized ACT is offered only to patients with a positive test (and only in some arms) but, the client is free to choose whether or not to use the subsidy. 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, and whether to buy an ACT. There is a small risk of breach of confidentiality of this information.

The RDTs to be used in this study will be procured from reputable local suppliers of quality assured mRDTs. Conducted properly, finger-sticks pose no greater than minimal risk to clients, 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 WHO-recommended 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. Previous work in Uganda, Nigeria and elsewhere [18, 20, 22, 24] has demonstrated that clients are willing to be tested with RDTs at pharmacies and the WHO has expressed strong support for this approach [26]. The study will ensure availability of proper sharps disposal equipment and services to participating outlets. All clients who choose to be tested will be advised on what to do if they experience any adverse events as a result of the finger prick.

No venous blood will be drawn.

1.3.2 Known Potential Benefits

There is significant health benefit to the client in 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.

The providers benefit from learning how to perform malaria testing. In some arms, the providers get a direct monetary incentive for performing malaria diagnostic tests.

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

2 OBJECTIVES

The objective of this study is to test the effect of provider-direct and patient-directed incentives on improving the management of suspected malaria fevers that seek care in the retail sector. The ultimate goal of a conditional subsidy scheme is to limit both inappropriate use of ACTs by those without a test or with a negative test, as well as to reduce the programmatic cost of ACT subsidies by offering them conditionally on a positive test at the point of sale.

3 STUDY DESIGN

This will be a four-arm cluster-randomized trial based on an underlying 2x2 factorial design. A random sample of 48 PPMVs (clusters) will be selected from a complete sampling frame of all eligible outlets and subsequently randomly assigned in a 1:1:1:1 ratio to each of the 4 arms (see Table 2).

All clusters (Arm 1-4) will have access to RDTs at the wholesale price that enables the outlet to charge the desired retail price. The study will pre-specify the retail price so that it is consistent across all the arms and pharmacies and will work with in-country wholesalers to provide RDTs at the appropriate price to all participating outlets. In addition, all outlets will be trained on a mobile reporting app and asked to use it to record RDT and ACT sales and to facilitate payment of financial incentives. The four treatment arms are as follows:

(1) Control (Arm 1): No price subsidy or incentive. RDTs are made available at wholesale price to the retail outlet.

(2) Provider-directed intervention (Arm 2): Retail outlet in this arm receives a small incentive to perform an RDT for suspected malaria cases

(3) Client-directed conditional ACT subsidy (Arm 3): Clients visiting outlets in this arm will receive an ACT discount *if* they purchase a malaria test and have a positive test result.

(4) Combined interventions (Arm 4): Retail outlets in this arm receive an incentive to test for malaria and clients visiting these outlets receive an ACT discount conditional on a malaria positive test (i.e. this arm is a combination of the provider-directed and client-directed interventions that are offered in Arm 2 and Arm 3).

Our four-arm study design will allow us to measure the effect of joint incentives to the provider and consumer, relative to no incentives and relative to either incentive alone.

Data will be collected by two independent mechanisms – provider reporting and exit interviews. First, we will examine routine reporting data submitted via mobile phones using the mobile app. All shopkeepers within each enrolled outlet will be trained to use the mobile app which reports on volume of clients, number of ACTs or other antimalarials sold, number of RDT sold. Data reported through the app will primarily be used to track RDT and ACT sales in real-time and will be regularly reviewed to track proportion of positive tests, volume of RDTs used, and visualization of a random sample of uploaded RDT photos. This routine monitoring will detect potential problems (i.e. providers who have unusually high or low test positivity rate, problems with RDT interpretation). Problems detected will trigger support supervision and/or additional on-the-job training to ensure compliance and quality of diagnosis.

Data for our main study outcomes will be collected by exit interviews with customers in order to avoid bias that may arise by relying on provider-reported data. In previous retail-sector studies, results from exit interviews and provider reports differed significantly, with exit interview results considered more reliable [22, 27]. Trained data collectors will approach customers who have transacted at the outlet and ask them if they are willing to participate in an exit interview. Customers will be eligible if they sought treatment for a febrile illness or malaria-like symptoms for themselves or their child, provided the child is present. Exit interviews will be conducted on randomly selected days each month and data collectors will be randomly assigned to outlets in order to minimize behavior change prompted by the presence of the interviewer. The number of days of data collection at each outlet will depend on the sales volume with a target of 10 participants per outlet per month. Customers will be asked to report whether they had a test, the results of the test, and what medicine they purchased.

Exit interview and provider reporting data will be compared to assess agreement between the sources. Specifically, we will compare the following indicators aggregated by outlet: the proportion tested, the proportion of tests positive and, the proportion of individuals using ACTs by test status (untested, positive or negative).

The primary outcome will be the proportion of all ACTs that are sold to individuals with a positive malaria diagnostic test. The ultimate goal of a conditional subsidy scheme is to limit both inappropriate use of ACTs by those without a test or with a negative test as well as to reduce the programmatic cost of ACT subsidies by offering them conditionally on a positive test at the point of sale. For this outcome, a positive test is anyone who is tested at the outlet and receives a positive result or is referred from a health facility or diagnostic lab with a documented positive test result. Although all ACTs purchased after a test, whether tested at the outlet, health facility or diagnostic lab, are included in the outcome measure, only ACTs purchased following *a test at the outlet* are eligible for the conditional subsidy. Our major secondary outcome is proportion of suspected malaria cases that are tested. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing. Other secondary outcomes will measure 1) adherence to the RDT result among all those tested, 2) proportion of all suspected malaria cases that are managed appropriately (tested for malaria, and use ACT following a positive test and do not purchase an ACT after a negative test), and 3) ACT use by test status (untested, negative, positive).

4 Study Population

4.1 Selection of the Study Population

All clients attending a participating outlet on the day selected for exit interviews will be eligible to be screened for inclusion into the interview sample.

4.2 Inclusion/Exclusion Criteria

INCLUSION CRITERIA:

- Participants with fever, or history of fever in the last 48 hours, 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
- Patients <18 years without a parent or legal guardian present

5 STUDY PROCEDURES/EVALUATIONS

5.1 Study Procedures

PPMV owners will be trained to provide malaria RDTs routinely to clients with malaria-like illness who wish to purchase a test. RDTs will be available in all participating PPMVs at the same price. Those who do not wish to purchase an RDT are free to conduct their transaction as planned.

The intervention consists of different subsidy schemes (client-facing conditional ACT subsidy or provider facing subsidy for RDT). The intervention is applied at the level of the PPMVs (cluster) and the effect of the intervention will be measured for a sample of clients served at each cluster (PPMV).

On random days of the month, clients leaving the PPMV will be asked to participate in a brief survey. Those who meet the inclusion/exclusion criteria will provide verbal consent before responding to questions about their current illness and their decisions regarding testing and medicines purchased. The survey will be conducted in one session and last approximately 30 minutes.

5.2 Laboratory Evaluations

None

6 STATISTICAL CONSIDERATIONS

6.1 Study Outcome Measures

The primary outcome measure is the proportion of selected ACTs[3] that are sold to individuals with a positive malaria diagnostic test defined as anyone who is tested at the outlet and receives a positive test result *or* is referred from a health facility or diagnostic lab with a documented positive test result**.**

$$\frac{\#\ people\ who\ tested\ positive\ and\ purchased\ ACT}{\#\ people\ who\ purchased\ ACT}$$

Among secondary outcomes, behavior will be measured for individuals who were tested at the outlet. Untested clients are those who chose not to be tested and did not come with a test result from another facility. The major secondary outcome is the proportion of suspected malaria cases that are tested. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing. Note that "untested people" here refers specifically to individuals that present at the shop without a referral but decline to be tested.

$$\frac{\#\ people\ who\ were\ tested\ with\ an\ RDT}{\#\ people\ who\ were\ tested\ with\ an\ RDT + \#\ untested\ people\ who\ purchased\ an\ antimalarial}$$

Other secondary outcomes will measure 1) adherence to the RDT result among all those tested at the outlet, 2) proportion of all suspected malaria cases that are managed appropriately (tested for malaria, and use ACT following a positive test or do not purchase an ACT after a negative test), and 3) ACT use by untested clients.

- Secondary outcome 2: Adherence to the RDT result among all those tested in the shop

$$\frac{\#\ people\ who\ tested\ positive\ and\ purchased\ ACT + \#\ people\ tested\ negative\ and\ did\ not\ purchase\ any\ AM}{\#\ people\ who\ were\ tested\ with\ an\ RDT}$$

For those who are negative, if they buy any antimalarial (AM), including monotherapies and older therapies, they are not adhering to test result.

- Secondary outcome 3: Proportion of all suspected malaria cases that are managed appropriately in the shop

$$\frac{\#\ people\ who\ tested\ positive\ and\ purchased\ ACT + \#\ people\ tested\ negative\ and\ did\ not\ purchase\ any\ AM}{\#\ people\ who\ were\ tested\ with\ an\ RDT + \#\ untested\ people\ who\ purchased\ an\ antimalarial}$$

"Untested people" here refers specifically to individuals that present at the shop without a referral but decline to be tested

- Secondary outcome 4: ACT use among untested clients

[3] The selected ACTs represent the most commonly used ACTs used in the PPMVs as determined in a CHAI conducted 2019 retail CPM audit of available ACTs in the private retail sector in Lagos, Nigeria.

$$\frac{\#\ people\ who\ were\ not\ tested\ in\ the\ shop\ and\ purchased\ an\ ACT}{\#\ people\ who\ were\ not\ tested\ in\ the\ shop,\ did\ not\ have\ documentation\ of\ test\ and\ purchased\ any\ AM}$$

For the primary outcome, we include in both numerator and denominator those individuals who were referred from a health facility or diagnostic lab with a documented positive test result. That is, for the primary outcome we are interested in evaluating the degree to which the interventions impacted the purchasing behavior of all suspected malaria cases seeking treatment. Our secondary outcomes do *not* include these individuals (i.e. the outcomes are calculated on the subset of individuals that present at the shop for testing without a referral). That is, for the secondary outcomes we are specifically interested in evaluating the degree to which the interventions impacted purchasing behavior among individuals who present at the shop for testing.

6.2 Sample Size Considerations

Our primary comparison of interest is the effect on targeting of ACTs, offering a combination of outlet incentives for testing (provider-directed intervention), and ACT subsidies for malaria test-positive clients (client-directed intervention) relative to a control arm where outlets are able to offer malaria testing but neither the provider nor the client receives any extrinsic incentive to test (Arm 4 versus Arm 1). In order to evaluate whether the client-directed intervention and the provider-directed intervention do, in fact, have a synergistic effect on the outcome, we also have two secondary comparisons of interest: (1) the combined provider- and client-directed interventions relative to the provider-directed intervention alone (Arm 4 versus Arm 2) and (2) the combined provider- and client- directed interventions relative to the client-directed intervention alone (Arm 4 versus Arm 3).

We calculated power based on a cluster randomized two-sample two-tailed t-test for the comparison of two proportions using standard formulae [28]. We calculated power for differences in our primary outcome for each of the three comparisons of interest noted above. To ensure that our overall two-tailed Type I error (alpha) is 5%, we fixed the alpha level at 1.667% (i.e. 5%/3) for each of the 3 comparisons of interest, using the conservative Bonferroni correction [29]. We estimated the intra-class correlation coefficients (ICCs) for the primary outcome to be 0.006 in Nigeria.

Table 2: Assumptions in Nigeria for sample size calculation for Aim 2

	Expected Percentage of ACTs taken by Clients Testing Positive for Malaria	Power (# of exit interviews per arm)
		Nigeria (2040)
Arm 1: Control Arm (RDT only, no incentives)	15%	>99%
Arm 2: Provider-Directed Intervention (Shopkeeper incentives for malaria testing)	17%	>99%
Arm 3: Client-Directed Intervention (ACT subsidy to client conditional on positive test)	26%	89%
Arm 4: Combined Provider- and Client-Directed Interventions	40%	Ref. Group

Our primary outcome—the proportion of ACTs that are taken by malaria test-positive clients—is a combination of the proportion of individuals who get tested for malaria and the proportion of tested individuals who treat according to the test result. We anticipate that 15% of ACTs will be purchased by clients with a positive test in the control arm (with 85% of ACTs purchased by those without a test or with a negative test). Moreover, we hypothesize that both the provider-directed intervention, and the client directed intervention on their own will only increase testing marginally (on the order of ~5 percentage points), but that among those who do test, the client-directed intervention alone will substantially increase the proportion of malaria-positive individuals who take an ACT [30]. As a result, we expect that the provider-directed intervention (Arm 2) will have only a small effect on ACT targeting, that the client-directed intervention (Arm 3) will have a somewhat larger effect, but that the largest effect will come from combining the two interventions (Arm 4) (i.e., we assume a statistical interaction). With a sample of 170 exit interviews per outlet (48 outlets in Nigeria), we will have >90% power to detect a minimum difference between Arms 1 and 4 in the primary outcome of 25 percentage points. We will also have >89% power to detect a minimum difference of 16 percentage points for the main secondary comparison of interest (testing uptake).

Due to the nature of the interventions, it is not possible to blind participants and the implementation team to the allocation received. Data collectors will be blinded throughout collection and study statisticians will be blinded during the analysis phase.

6.3 Participant Enrollment and Follow-Up

Medicine retail outlets will be eligible if they regularly stock and sell regulatory approved ACTs and are licensed medicine outlets. From this roster of all eligible outlets, 56 will be randomly selected (8 additional above the required sample size). Of those retail outlets, 48 outlets will be randomly selected for training and enrollment in the study and will be randomized to one of the 4 study arms in a 1:1:1:1 ratio. The remaining 8 outlets will be alternates in the event that any of the initial outlets drop out of the intervention. The alternate outlets will also be

randomized equally across the 4 study arms (2 alternates per arm per site), but they will not undergo training unless they are needed for replacement.

We will retain these enrolled outlets through effective supportive supervision and communication between providers at participating outlets and study staff. All outlets will receive thorough, in-person training on using the mobile reporting tool, conducting RDTs and overall study procedures. They will also receive extra support during the start of the intervention and burn in period (3 months), including an initial stock of RDTs provided by the study at no cost. At least once per month, the Project Manager, and/or Field Coordinator will visit each outlet in person to answer questions, check RDT stock and testing performance, and identify and address any problems. Providers will also receive phone calls from the Field Coordinator and Project Manager between in-person visits and will themselves be provided with phone numbers and encouraged to call the study staff with any questions or concerns. Additionally, outlets will be reimbursed promptly to ensure participation in the study presents no financial strain.

In our previous work, we have experience on the retention of outlets in research activities and therefore expect attrition of clusters. Should one of the outlets selected choose to leave the study within the first 6 months of the intervention, the outlet will be replaced by one of the alternate outlets assigned to the same arm. If any outlet chooses to leave the study after the first 6 months of the intervention, they will not be replaced because, after joining the intervention at such a late stage, a newly added outlet is not likely to be comparable to that of all other participating outlets. Changes in the clusters (dropped and/or replaced) will be accounted for in the analysis.

Our sample size estimates correspond to a total of 8160 exit interviews with clients. Since not everyone interviewed will have purchased an ACT, our estimates account for the fact that only a subset will enter into our analysis for the primary outcome.

6.4 Analysis Plan

We will analyze client-level outcomes by fitting a modified Poisson regression model [31, 32] with log link to estimate risk ratios (RRs) and identity link to estimate risk differences. Such an approach assumes a Poisson distribution for the binary outcome and then ‘fixes’ the estimated standard errors to correct for model misspecification.

To account for clustering by outlet we will use a generalized estimating equations (GEE) [33, 34] approach with exchangeable working covariance matrix and robust standard errors (to correct for model misspecification due to specifying a Poisson distribution). The outcome will be regressed on three binary indicators for each of the treatment arms 1-3, with treatment arm 4 (the combined interventions) serving as the reference group. The model will also include a vector of potential confounder variables (e.g., age, gender, education, household distance to closest health facility, study quarter) to account for possible imbalances between study arms. 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 in the outlet at which they sought care (e.g. even if they did not use the ACT subsidy if they tested positive in an outlet in Arms 3 and 4 that received the client-directed intervention).

Given that the literature indicates that when there are fewer than 40 clusters in a cRCT, small sample correction methods should be used to ensure that standard error estimates are correctly estimated when using GEE to analyze binary outcomes, and given that the size of the cRCTs in each country are close to this cut-off, we plan to adopt the use of the Kauerman-Carroll correction to avoid any possible problems [35, 36]. We will compare secondary outcomes using the same modeling approach.

7 SUBJECT CONFIDENTIALITY

Participant confidentiality will be maintained during and after the interview in several ways:

- The interview will be conducted in a private place where the interview cannot be overheard.
- Interviewers will be trained in research integrity and ethics, including protecting participant information.
- Informed consent will be conducted verbally, thereby reducing the risk of a breach of client confidentiality by eliminating any paper record of clients' participation in the study with signature.
- Data will be collected on tablets which will be encrypted and password protected.
- Individuals will be assigned a unique study ID. No information that could be used to identify the participant will be recorded such as names, identification numbers, dates of birth or address.
- Anyone older than 80 years of age will be recorded as '80.'
- Data will be transferred from the tablet to a secure, password protected computer once per week.
- Data will be stored on an encrypted, password protected computer and backed up on Duke Box. The data will only be accessible to the Data Manager and the PI. It will be reviewed regularly to ensure quality and completeness.
- Only fully de-identified data will be provided to other study personnel or statisticians. Only fully de-identified data will be shared.

7.1 Future Use of Stored Specimens

Not applicable.

8 INFORMED CONSENT PROCESS

Informed consent will be obtained prior to collecting any participant information for research purposes. Clients will be approached as they leave the PPMV and asked if they would be willing to participate in a brief interview. If so, the interviewer will conduct screening and consent in a private area away from other clients. The client will be given time to ask questions and will be asked to give verbal consent for the interview, which will be documented by the interviewer. The interviewer will explain the purpose of the study, the risks, benefits, and safeguards in place to protect the participant's information. A printed copy of the consent script will be available for them to read and to keep. Contact information for the Study Coordinator or PI will be provided so the participant can ask questions after the interview.

No individual identifying information will be collected during the interview, therefore withdrawing consent after the interview is closed will not be possible. To mitigate this, the interviewer will confirm consent by asking at the end of the survey if the participant is comfortable with all the answers and agrees for their information to be retained.

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

The study will only enroll minor participants present with a parent or guardian and all questions will be directed to the parent/guardian. Therefore, we do not anticipate interacting with minors or needing assent from the minor.

We will not enroll individuals who are unable to consent for themselves such as those who are mentally impaired or are experiencing impaired consciousness.

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SUPPLEMENTS/APPENDICES

Aim 2: TESTsmART Participant exit interview - Screening Questions

Number	QUESTION	RESPONSE	SKIP
0.01	**Did the person meet all of the inclusion criteria?**	1. Yes 2. No	If yes, skip to 0.03
0.02	**If no, why were they excluded from participating in the study today? (select all that apply)**	1. Person did not have a fever or malaria-like illness 2. Patient with malaria-like symptoms not present 3. Patient younger than 1 year of age 4. Had symptoms of severe malaria and referred for care 5. Took antimalarial in the last seven days for current illness 6. No parent or guardian present	STOP
0.03	**Did the person consent to participate in the study?**	1. Yes 2. No	If No, STOP

GENERAL STUDY INFORMATION

Number	QUESTION	RESPONSE	SKIP
0.1	**Date**	MM/YYYY	
0.2	**Participant ID**		
0.3	**Outlet ID**		
0.4	**Interviewer ID**		
0.5	**Language of interview**	1. English 2. Yoruba 3. Igbo 4. Hausa 5. Other	

SECTION 1: RESPONDENT INFORMATION

Number	QUESTION	RESPONSE	SKIP
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……5	

		Specify:	
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	

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	**How likely is it 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. Absolutely sure 99. Don't know	
2.5	**Have you sought treatment or care elsewhere for this illness?**	1. Yes 2. No 99. Don't know	If no or don't know, go to 3.1

2.6	**What did you do?** *Check all that apply*	1. Buy medicine at general shop 2. Visit pharmacy/chemist 3. Visit government health center/dispensary 4. Visit private clinic 5. Visit hospital 6. Visit private laboratory 7. Gave medicine available at home 8. Visit traditional healers 9. Visit religious/cultural healers 10. Visit community health worker 11. Other_____ 99. Don't know (i.e., another caregiver was involved)	
2.7	**Why did you come to this facility?**	1. Treatment was not available in other facilities 2. RDT tests were not available in other facilities 3. It's the closest chemist shop to me 4. This chemist shop has better prices 5. I was referred here for treatment 99. Don't know (i.e., another caregiver was involved)	
2.8	**Did you have a malaria test from another provider/facility/lab before coming here today?**	1. Microscopy 2. RDT 3. Don't know 4. No test	If 4, go to 3.1
2.9	**Malaria test results from elsewhere**	1. Negative – report observed 2. Positive – report observed 3. Reported negative by respondent 4. Report positive by respondent 5. Doesn't recall result	
2.10	**Do you have a copy of the test result?**	1. No, nothing written 2. Yes	
2.11	**Have you taken/given to the child any medication for this illness since it started?**	1. Yes 2. No 99. Don't know	If 1, go to 2.12 If 2 or 99, go to Section 3
2.12	**If so, which medicines (select all that apply)**	1. AL (Lonart/CoArtem/Artefan) 2. Other ACT (DHAP, DP, Duocotexin, P-alaxin)	If 1, 2 or 3 STOP

		3. Monotherapy (Artesunate, Quinine, Chloroquine, SP/Fansidar) 4. Antibiotic (Amoxyl/Septrin, Metronidazole/Flagyl, Ampicillin) 5. Painkiller/fever medicine (Panadol/Brufen/Hedex/ Action/) 6. Cough medicine or decongestant 7. Other_____ 99. Don't know	
2.13	**Did you come to the chemist/shop today with a prescription from another provider/facility/lab?**	1. Yes 2. No	If 2 skip to Section 3.
2.14	**If yes, what was the prescription for?**	1. AL (Lonart/CoArtem/Artefan) 2. Other ACT (DHAP, DP, Duocotexin, P-alaxin) 3. Monotherapy (Artesunate, Quinine, Chloroquine, SP/Fansidar) 4. Antibiotic (Amoxyl/Ceptrin, Metronidazole/Flagyl/Ampicillin) 5. Painkiller/fever medecine (Panadol/Brufen/Hedex/ Action/Maramoja) 6. Cough medicine or decongestant 7. Other_____ 99. Don't know	

Section 3: Test at Shop

Number	QUESTION	RESPONSE	SKIP
3.1	**Did you (or your child) have your blood tested for malaria today at the shop?**	1. Yes 2. No	If yes skip to 3.3
3.2	**Why not? (Mark all that apply)**	1. Too expensive 2. RDT was not offered 3. RDT not in stock 4. No time 5. Already sure illness is malaria 6. Already sure illness is not malaria 7. Don't want to get finger pricked 8. Was tested elsewhere before coming 9. Had a prescription for drug I needed before coming 99. Other	Next skip to section 4

		Specify: _____	
3.3	**RDT results from shop (self-report)**	1. Negative 2. Positive 3. Invalid	
3.4	**How much did you pay for the RDT?**	_____ Naira	

Section 4: Purchase Questions

Number	QUESTION	RESPONSE	SKIP
4.1	**Which medicine(s) did you obtain from the shop today to treat your/your child's illness** **Choose all that apply**	1. AL (Lonart/CoArtem/Artefan) 2. Other ACT (DHAP, DP, Duocotexin, P-alaxin) 3. Other antimalarial (Artesunate injection, Quinine, Chloroquine, SP/Fansidar) 4. Antibiotic (Amoxyl/Ceptrin, Metronidazole/Flagyl, Ampicillin) 5. Painkiller/fever medicine (Panadol/Brufen/Hedex/ Action) 6. Cough medicine or decongestant 7. Other_____ 8. None 99. Don't know	If 2, 3, 4, 5, 6, 7 or 99 Skip to 4.4 If 8, skip to 5.1
4.2	**How much did you pay today for the ACT?** **(The amount refers to how much <u>money</u> respondent paid for the ACT. Don't add the amount of the voucher if any was used-the amount should be between 0-5000, or 9999 for don't know)**	ACT= _____Naira OR Don't know/remember…9999	
4.3	**How much did you spend at the chemist/shop today? (*Total cost to client including RDT, ACT and any other drugs*)**	_____ Naira	
4.4	**Was there any discount for your ACT at the shop today?**	1. Yes 2. No 3. Don't know	

4.5	**I would like to record information about each drug you purchased today. May I see the packaging?**	1. Type _____ 2. Brand Name _____ 3. Price _____ Naira 4. *Did participant show you the drug?* 1. Yes 2. No	Repeat for every drug purchased for illness

Section 5: Household Characteristics

Number	QUESTION	RESPONSE	SKIP
5.1	**What is the main source of drinking water for your household?**	1. Piped water/Public Tap/borehole 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	
5.2	**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	
5.3	**How many of the following livestock does your household have?**	1. None 99. Don't know	
a)	**Cows**		
b)	**Sheep**		
c)	**Goats**		
d)	**Pigs**		
5.4	**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): _____	
5.5	**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)_____ _	
5.6	**Do you/your family own the house you live in?**	1. Own the house 2. Rent the house	
5.7	**What is the <u>main</u> material of the floor in your house?**	3. Earthen 4. Cement 5. Floor Tiles 6. Wood planks	

		7. Polished wood 8. Other (please specify) _____	
5.8	**What is the <u>main</u> material of the walls in your house?**	1. Cement 2. Brick 3. Timber 4. Iron Sheet 5. Mud 6. Wood 7. Stone 8. Other (please specify)_____	
5.9	**What is the <u>main</u> material of the roof of your house?**	1. Iron sheets 2. Roof tiles 3. Asbestos 4. Grass Thatched 5. Wood 6. Other (please specify)_____	
5.10	**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	
5.11	**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. Polytechnic 5. University	
5.12	**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 (specify: .....) Self-employed 4. With employees 5. Without employees (e.g. motorcycle taxi, vendor) 6. Unpaid family helper in a business Other 7. Casual worker/day laborer 8. House help	

		9. Homemaker 10. Student 11. Not available to work 12. Other (Specify) _____	