Official Title:

Malaria Diagnostic Testing and Conditional Subsidies to Target ACTs in the Retail Sector: the TESTsmART Trial Aim 2

NCT:

NCT04428385

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Verbal Informed Consent to Participate in a Research Study

ADULT

(TESTsmART Trial Aim 2)

CONCISE SUMMARY

The Clinton Health Access Initiative (CHAI) in collaboration with the Lagos State Government is conducting a research study at select retail outlets in Lagos to determine if financial incentives help improve the rational use of antimalarials. Specifically, the study is investigating what prices and discounts on malaria rapid diagnostic tests (RDTs) and antimalarials would incentivize someone to take an RDT test before purchasing an antimalarial for treating suspected malaria symptoms. This study will ultimately provide evidence to help policymakers in Nigeria decide if providing discounts on antimalarial conditional on a person taking an RDT first could help ensure people only take an antimalarial medication if they have confirmed malarial infection.

This survey should take up to 20 minutes. In order to be eligible to participate today you must have shopped at this retail outlet. There are no major risks for participating in the study, although there is a small risk of breach of confidentiality should someone overhear this conversation.

You/your child are being asked to take part in this research study because you have purchased medicine from this shop today. Your/your child's participation in this research study is completely voluntary. As I discuss this consent form with you, please ask me to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

THE PURPOSE OF THIS STUDY

This study is being conducted because many people with suspected malaria or malaria-like symptoms in Nigeria buy medicine from pharmacies and shops. Malaria diagnostic testing is usually not available in these outlets and therefore many people purchase antimalarials without having a test for malaria. This could have a negative impact on both a person's health if they take an antimalarial when in fact they are sick with another illness. Over time this will diminish the effectiveness of antimalarials since overuse can help spread resistant parasites. The goal of the study is to test ways to increase the use of malaria diagnostic testing before treatment in pharmacies.

WHAT IS INVOLVED IN THE STUDY?

Participation consists of answering some questions about the illness you or your child are experiencing as well as some information about you (such as age, employment) and your household. We also want to know what medicines you purchased and whether you were tested for malaria.

HOW LONG WILL I BE IN THIS STUDY?

This survey will take about 15-20 minutes to complete. There will be no other follow-up after you finish this survey today.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risk to participating in this study. There is a very small risk of breach of confidentiality if someone overhears this conversation. There will be no paper record containing your information and we will not be collecting any identifying information about you/your child during the survey, so no one will be able to link you to this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you choose to participate in this study, there will be no direct benefit to you/your child. However, the information you provide will help contribute to our understanding of how people take care of themselves or their family members when they are ill. This information may be used to help inform policymakers and guide decisions about the best way to make malaria testing a treatment available in Nigeria.

WHAT ARE THE COSTS TO YOU?

There is no cost to you for participating in this survey.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. You may refuse to answer any question at any time. You may choose to stop participating at any time without penalty. Because we are not collecting any identifying information about you/your child however, if you change your mind after leaving today we cannot withdraw the information you provided from the data collected for this study.

A description of this clinical trial will be available on https://clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you have any questions or would like more information about this study, you can contact Dr Tayo Olaleye at 0807 616 2817 or Tosin Ogunsola at 0706 046 0960.

STATEMENT OF CONSENT

Please say "Yes, I would like to participate in this study today" or "No, I decline to participate in this study today". Please take your time in deciding.

If you would like a written copy of this information, you may take this form with you today.


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