



## CASE STUDY

### Increasing availability of malaria rapid diagnostic tests in Tanzania's private sector

MALARIA RAPID DIAGNOSTIC TESTS (RDTs) ARE AN EFFECTIVE TOOL FOR CONFIRMING TRUE MALARIA CASES IN RESOURCE-LIMITED SETTINGS, YET ARE OFTEN UNAVAILABLE IN THE PRIVATE SECTOR WHERE MANY SEEK TREATMENT. CHAI WORKED WITH GLOBAL MANUFACTURERS AND IMPORTERS IN TANZANIA'S PRIVATE SECTOR TO REDUCE THE PRICE OF RDTs. TO DATE, 2.1 MILLION TESTS HAVE BEEN SOLD AND THE CUMULATIVE COST SAVINGS OF THIS WORK IS ESTIMATED AT US\$1.9 MILLION.

#### OVERVIEW

For decades, the standard practice in many African countries has been to treat most fevers as malaria. However, presumptive treatment of malaria in medium to low transmission settings leads to overtreatment, mistreatment of non-malarial febrile illnesses, and obscuration of true malaria patterns. Current malaria control guidelines from the World Health Organization (WHO) recommend parasitological confirmation for all patients suspected of having malaria before treatment is started. Malaria rapid diagnostic tests (RDTs) are an effective tool to diagnose malaria in resource-limited settings and are now used in public sector health facilities in 89 out of 99 malaria endemic countries.<sup>1</sup> However, in the private sector, where many seek malaria treatment in endemic countries,<sup>1</sup> availability of RDTs remains low.<sup>2</sup> High prices, low awareness, and regulatory restrictions are primary barriers to availability in the private sector.

In 2012, with support from the Department for International Development (DFID), CHAI began work to increase access to RDTs in the sizable formal private sector of Tanzania, a medium endemic country. CHAI worked with the National Malaria Control Programme (NMCP), private healthcare providers, and RDT manufacturers and importers to lower prices while increasing awareness and demand. CHAI also rolled out a pilot study to determine if RDTs could be safely and correctly performed in Accredited Drug Dispensing Outlets (ADDOs), which are small, privately operated drug shops that act as a first point of care for many patients. The use of RDTs in ADDOs represents a tremendous opportunity to improve fever management and the rational use of artemisinin-based combination therapies (ACTs), the first-line treatment for uncomplicated malaria. Previously these drug shops were permitted to sell antimalarial drugs but could only treat presumptively as they were not legally allowed to provide malaria testing.

#### THEORY OF CHANGE

Reducing the price of RDTs and increasing their use will help replace presumptive malaria treatment with an effective parasitological confirmation-based treatment system, thereby improving patient outcomes, enabling cost effective management of malaria, and creating a more accurate understanding of the true disease burden.

#### IMPACT

Negotiations with RDT manufacturers resulted in an average price of \$0.27 per test, a 50-75% reduction from the previous prices of \$0.60 to \$0.70. To date, the project has generated an estimated US\$1.9 million in savings.

#### KEY PARTNERS

- DFID
- Johns Hopkins University
- Population Services International

This work led to a major regulatory policy change in early 2015: the Diagnostics, Therapeutics, and Vaccines Technical Working Group agreed to allow ADDOs to perform RDTs.

#### APPROACH

CHAI found that many pharmaceutical importers, the main suppliers of antimalarial drugs in the private sector, were not familiar with RDTs. The few importers that had purchased RDTs were paying two to three times the lowest prices observed in the public sector market. To address this, CHAI took a multifaceted approach to lower prices and improve access in the private sector. On the supply side, CHAI engaged the leading RDT manufacturers with a proposal to grow the private sector market. The proposal included the following components:

- **Generate demand.** CHAI works with importers, partners, and the NMCP to generate demand by

training sales representatives and private healthcare providers and rolling out marketing campaigns;

- **Secure pricing agreements.** Manufacturers provide favorable pricing to a set of approved private market buyers, equivalent to the lowest prices observed in the public sector market, or 50 percent to 75 percent lower than current private sector prices of US\$0.60 to US\$0.70. As added incentive, CHAI guaranteed that the manufacturer offering the lowest price would receive exclusive supply rights to the wholesalers in the ADDO pilot region in Tanzania; and
- **Certify products through branding.** Participating manufacturers include a logo on the RDT packaging to certify the product's high quality and low cost and for use in promotional and training activities.

After receiving commitments from five leading RDT manufacturers, CHAI approached pharmaceutical importers with a proposal: in return for access to the preferred prices, importers would commit to a low yet sustainable markup to ensure cost savings would be passed on. Eight importers agreed to these terms.

To increase the awareness and use of RDTs, CHAI partnered with key stakeholders to implement the following demand-side activities:

- **Design and launch marketing campaigns** that featured billboards and radio advertisements. This work was done in close partnership with John Hopkins University Center for Communication Programs; and
- **Organize trainings for formal private sector providers that focus on performing RDTs.** CHAI collaborated extensively with importers and the NMCP on these trainings.

In the informal private sector, CHAI helped launch a pilot project that rolled out RDTs to ADDOs in two districts in Tanzania. Although dispensers in ADDOs were not allowed to perform RDTs, special permission was provided by the Ministry of Health (MOH) to allow ADDO owners to both stock and perform RDTs for this pilot. The purpose of this project was to inform the NMCP on the feasibility and effectiveness of lower-level providers performing RDTs.

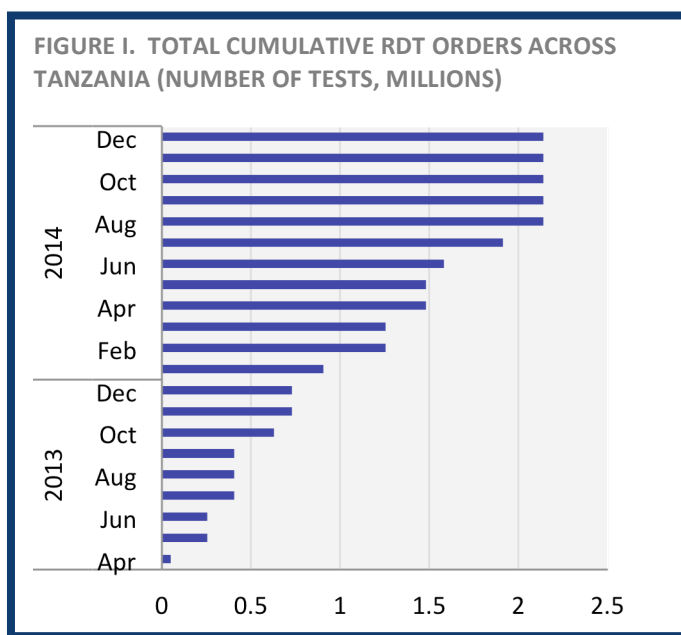
The project also aimed to understand whether or not an RDT subsidy would be required to increase uptake. To test this, RDTs were subsidized beyond the CHAI-negotiated price for patients in only one district of the pilot. All ADDOs in the pilot were permitted to procure RDTs from selected wholesalers at CHAI's preferred

pricing, and trainings and supervision activities were rolled out by experienced national malaria trainers.

## IMPACT

Through negotiations with RDT manufacturers, CHAI helped lower the average purchase price per test for importers to US\$0.27 (a reduction from US\$0.60 to US\$0.70), achieving the objective to match the low prices observed in the public sector market.

Since implementation began in April 2013, 2.1 million RDTs have been sold to participating importers in Tanzania (Figure I). Based on discussions with importers and manufacturers, this represents a vast increase from prior to CHAI's intervention, when little to no RDTs were



sold in the formal private sector.

Price reductions, coupled with increased volumes from demand generation activities, resulted in an estimated US\$1.9 million in cost savings to date.<sup>i</sup>

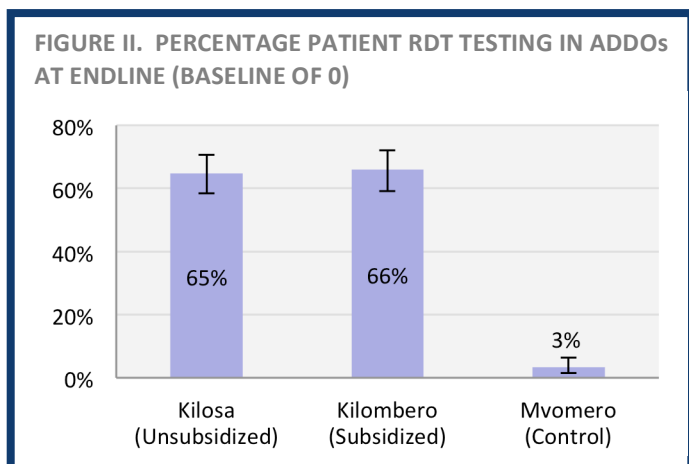
With regard to availability and use of RDTs in ADDOs,<sup>ii</sup> the results of the Tanzania pilot study show that approximately 88 percent of ADDOs in the subsidized arm and 78 percent in the unsubsidized arm stocked and performed RDTs, with 94 percent of providers meeting the criteria for correct performance. Patients who tested positive for malaria were more likely to purchase the recommended ACT than those who did not test at all (75

<sup>i</sup> Savings come from averted RDT subsidies, reduction in the irrational use of ACTs, and averted subsidies that would have paid for those unnecessary ACTs.

<sup>ii</sup> Impact on RDT availability, usage, and price will be reported using household and facility survey data provided by ACTWatch2, a study conducted by PSI. The results of the data will be available in mid-2015.

percent vs. 35 percent), and 97 percent of patients who tested negative for malaria adhered to their test result by not purchasing an unnecessary ACT.

A comparable proportion of patients tested in the subsidized vs. unsubsidized district,<sup>iii</sup> demonstrating patient willingness to pay for the RDT without the need for a subsidy (Figure II).



The successful results have been used to make policy changes that will allow informal private sector providers to stock and perform RDTs nationwide.

### LIMITATIONS AND LESSONS LEARNED

CHAI's push to test whether informal private sector providers can successfully perform confirmatory diagnosis has met some resistance. Opponents often believe that only trained laboratory technicians have the requisite training and experience to perform RDTs. To gain the necessary buy in and proceed with the pilot projects, CHAI and partners have worked closely with all stakeholders to address their concerns and demonstrate proof of concept. Support from a diverse range of stakeholders has been important for the necessary policy changes.

In 2014, CHAI replicated this model in Kenya's private sector. While preliminary success has been observed, results are not yet comparable to those seen in Tanzania due to implementation delays from laboratory board concerns, and delayed funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) to train private sector providers. In recent months, the laboratory board agreed to extend a waiver to allow formal private sector providers to use RDTs and trainings have begun.

<sup>iii</sup> Unsubsidized retail price for patient: US\$0.66; subsidized retail price for patient: US\$0.33.

### FUTURE OUTLOOK

CHAI will continue to actively monitor the rollout of RDTs in the formal private sectors in Tanzania and Kenya for one more year, following which CHAI expects the market to sustain itself. Manufacturers have indicated that they will not raise prices after CHAI's exit, given the healthy and competitive market conditions. To maintain the use of RDTs without CHAI support, healthcare provider trainings will be owned by the NMCPs going forward; over 2500 formal providers will be trained by Q2 2015 across Tanzania and Kenya.

The recent policy change allowing ADDOs to perform RDTs has the potential to reduce resource wastage and help patients that test negative find alternative and appropriate treatment, contributing to improved health outcomes. To scale-up RDTs in the ADDOs in Tanzania, CHAI will help the NMCP to seek funding from the GFATM and other donors. Based on this policy change along with a strong training and ongoing supervision program, CHAI believes that nationwide access to confirmatory diagnosis is sustainable, in part because this project demonstrates that subsidization of such a market appears unnecessary.

There is great potential to continue replicating this model in other countries and improve access to quality diagnostics. Given the success of the project in Tanzania, Uganda and Zanzibar have expressed interest in using a similar approach to scale-up mRDTs in the private sector. It may also be possible to adapt CHAI's model for use in other regions such as Southern Africa and South East Asia. CHAI's ability to work closely with manufacturers, importers, NMCPs, and other partners will allow the supply and demand interventions to be tailored to the need of each country.

<sup>1</sup> World Health Organization. World Malaria Report 2014. *World Health Organization Website*. [http://www.who.int/malaria/publications/world\\_malaria\\_report\\_2014/en/](http://www.who.int/malaria/publications/world_malaria_report_2014/en/). December 2014.

<sup>2</sup> ACT Watch. Outlet Survey Data. *ACT Watch Website*. [http://www.actwatch.info/databases/outlet\\_survey\\_data](http://www.actwatch.info/databases/outlet_survey_data).

#### About the Clinton Health Access Initiative, Inc.

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to strengthening integrated health systems and expanding access to care and treatment in the developing world. CHAI's solution-oriented approach focuses on improving market dynamics for medicines and diagnostics; lowering prices for treatment; accelerating access to lifesaving technologies; and helping governments build the capacity required for high-quality care and treatment programs. Though CHAI remains committed to its initial focus on HIV/AIDS; CHAI also has expanded its scope to work in the following program areas: HIV/AIDS and Tuberculosis (TB), Improving the Efficiency and Effectiveness of Healthcare Systems, Malaria, Human Resources for Health, Vaccines, and Maternal, Child, and Newborn Health. For more information, please visit:

[www.clintonhealthaccess.org](http://www.clintonhealthaccess.org)

#### Contact Information

For more information on CHAI's malaria work, [please contact us](#).