Transforming the Private Sector to Support Universal Malaria Diagnostic Coverage

Lessons learned from Kenya, Madagascar and Tanzania

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Contents

2 Introduction

4 Learning from Implementation Experience

4 Quality Assurance

9 Policy

10 Supply Side Stimulation

12 Call to Action

Introduction

WHY IS FEVER CASE MANAGEMENT IN THE PRIVATE SECTOR IMPORTANT?

Despite significant reductions in malaria in endemic countries over the past decade, fever is still often equated with malaria, leading to overuse of artemisinin-based combination therapy (ACT), the frontline treatment for malaria, and to mismanagement of other potentially life-threatening non-febrile illnesses. Considering this challenge, in 2010, the World Health Organization (WHO) recommended that every suspected malaria case be confirmed with parasitological-based testing using either microscopy or malaria Rapid Diagnostic Tests (mRDTs). While this recommendation and the concurrent raise in availability of high-quality, inexpensive mRDTs[1] has led to improvements in diagnostic testing in the public sector, similar gains have not been made in private sector. This leaves a critical gap in testing as the private sector is the first point of contact for health services for roughly 40% of the population in endemic countries. Consequently, this challenge offers an opportunity to leverage the power of the private sector to transform the mRDT market in support of universal access to malaria diagnosis.

40%

of the population in malaria endemic countries access malaria treatment and care in the private sector.

(Source: WHO 2011 World Malaria Report)

1 Approximately 0.30 USD at manufacture level (based on analysis by CHAI in 2014, presented in *Malaria diagnositcs technology and market landscape*, 3rd edition. 2016, UNITAID.)

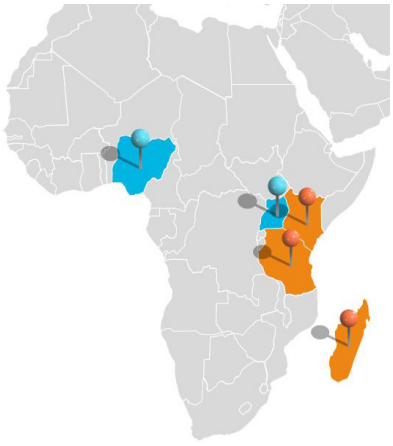
INTERVENTION

In response, PSI and partners[2] conducted a three-year project between 2013 and 2016 to increase the uptake of quality-assured mRDTs in private-sector markets in Kenya, Madagascar, Nigeria, Tanzania, and Uganda. Designed as the largest operations research project in fever case management (FCM) globally, the UNITAID-funded project generated evidence and lessons learned on how to stimulate a private-sector market for mRDTs. Over 44 studies were conducted by three partners, and routine monitoring systems collected data from 3,400 enrolled outlets, ranging from hospital clinics to pharmacies to drug shops.

The project took a market development approach to problem identification and solution generation. As part of the approach, a market landscape was conducted in each country to identify constraints in the market systems. The objective was to determine the most appropriate interventions needed to foster sustainable demand and supply and a supportive enabling environment, which together would create equitable and sustainable mRDT markets for quality FCM.

The market landscape identified three key market constraints: 1) limited commodity and provider quality assurance systems, 2) a non-conducive policy environment, and 3) insufficient supply and demand. Project interventions were designed to address each constraint, and evidence was generated to support learning on whether these interventions did indeed support the uptake of quality-assured mRDTs in the private sector for improved FCM.

UNITAID Private Sector RDT Project Countries



Implemented by PSI

Implemented by Malaria Consortium

This brief identifies ten lessons learned on how to stimulate a private-sector market for malaria diagnostics using evidence and experience from the three intervention countries where PSI lead implementation: Kenya, Madagascar, and Tanzania.[3] It concludes with a call to action to put these lessons into practice in support of universal access to malaria diagnosis.

THREE MARKET CONSTRAINTS IDENTIFIED

Limited Quality Assurance Systems

Lack of quality assurance systems for mRDTs (commodity) and FCM (service) in the private sector, particularly within pharmacies and drug shops, due to limited incentives, capacity and financing to develop and implement them.

Non-Conducive Policy Environment

Regulations forbid malaria testing in many private-sector channels, particularly within pharmacies and drug shops, due to a lack of evidence on the safety and effectiveness of mRDTs in this setting.

Insufficient Supply and Demand

Supply chains don't ensure access to quality-controlled mRDTs, particularly within pharmacies and drug shops, due to insufficient demand from providers and consumers.

2 Project partners were Malaria Consortium (MC), World Health Organization (WHO), Foundation for Innovative New Diagnostics (FIND), and the Johns Hopkins Bloomberg School of Public Health (JHSPH).

3 Evidence presented in this document was generated by PSI through the UNITAID private sector mRDT project. PSI led implementation in Kenya, Madagascar and Tanzania. Malaria Consortium led implementation in Nigeria and Uganda.

Learning from Implementation Experience

QUALITY ASSURANCE

How can the market ensure ongoing support for quality control of mRDTs and quality assurance of fever case management in the private sector, particularly within pharmacies and drug shops?

Establishing a management system that enables quality-assured fever case management with quality-controlled mRDTs is critical to scaling-up use of mRDTs in the private sector. Evidence of commodity and service quality is necessary to support policy change and can signal an increase in consumer demand to supply chain actors. To address this need, PSI implemented a comprehensive quality assurance (QA) system, including tools (such as case management algorithms and job aids) tailored to new cadres of private providers, condensed classroom-based trainings aligned with national curricula, an innovative supportive supervision system with scheduled visits based on the needs of the provider, and point-of-use tools for post-market surveillance of mRDTs.

The UNITAID project piloted the early stages of the Health Network Quality Improvement System (HNQIS) which is now being rolled out by PSI globally. It is an offline tablet-based application for supervisors to plan visits based on provider quality and client volume, assess providers based on national quality standards, improve performance through tailored feedback, and monitor the quality of facilities over time.

Lesson #1. Private providers can offer high-quality fever case management services with sufficient training and when supported by QA systems.

100%

of providers in Madagascar and Tanzania read the mRDT results correctly

Private providers of all cadres can safely administer mRDTs and correctly interpret results. Routine supervision data recorded consistently high mRDT procedure scores in all three countries and found that 96% of providers in Kenya and 100% of providers in Madagascar and Tanzania read the results correctly.[4] Mystery client and exit interview surveys found adherence to mRDT negative results to be consistently high throughout the project *(Figure 1)*. To achieve this high level of quality care, private-sector approaches and tools should build upon and adapt existing QA systems to avoid QA fatigue and to ensure alignment between the public and private sectors. Training materials and algorithms for pharmacies and drug shops often do not exist and may need to be adapted for this cadre, as was conducted under this project *(Figure 2)*. National training curriculums may need to be adjusted to reduce the length of classroom requirements, given that private providers may be unwilling to leave their clinics and forgo income for an extended period of time. Innovative approaches such as e-learning, on-the-job mentorship, and targeted supervision offer possibilities in this area.

4 Routine monitoring data from supervision visits in Q3, 2015.

Figure 1. Adherence to mRDT negative results

Percentage of clients testing negative for malaria managed per the government recommended treatment algorithm

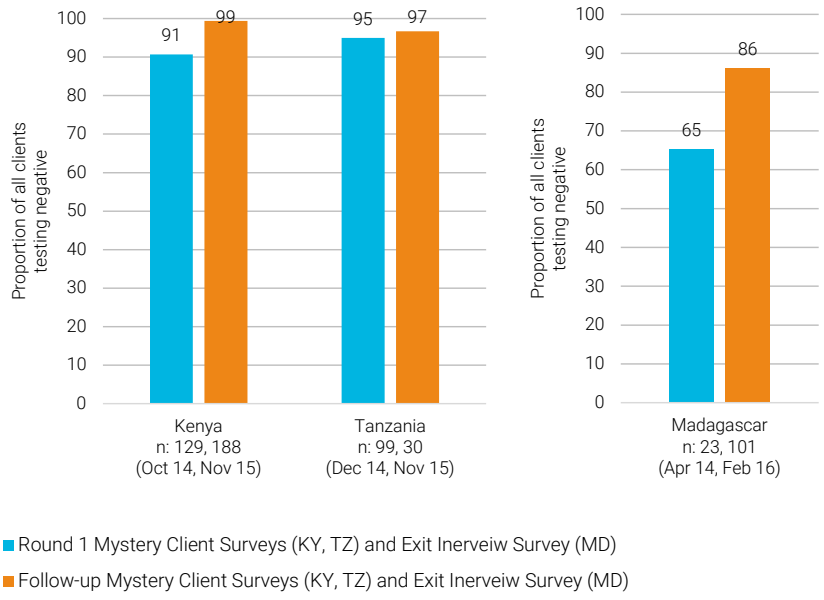
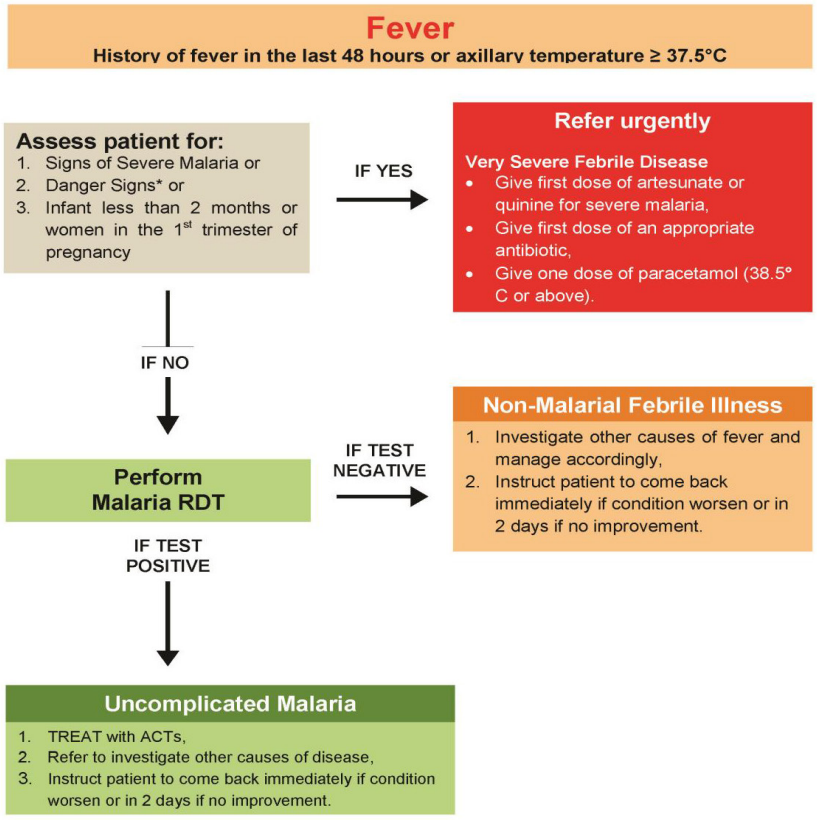


Figure 2. FCM Algorithm for Drug Shops and Pharmacies in Kenya

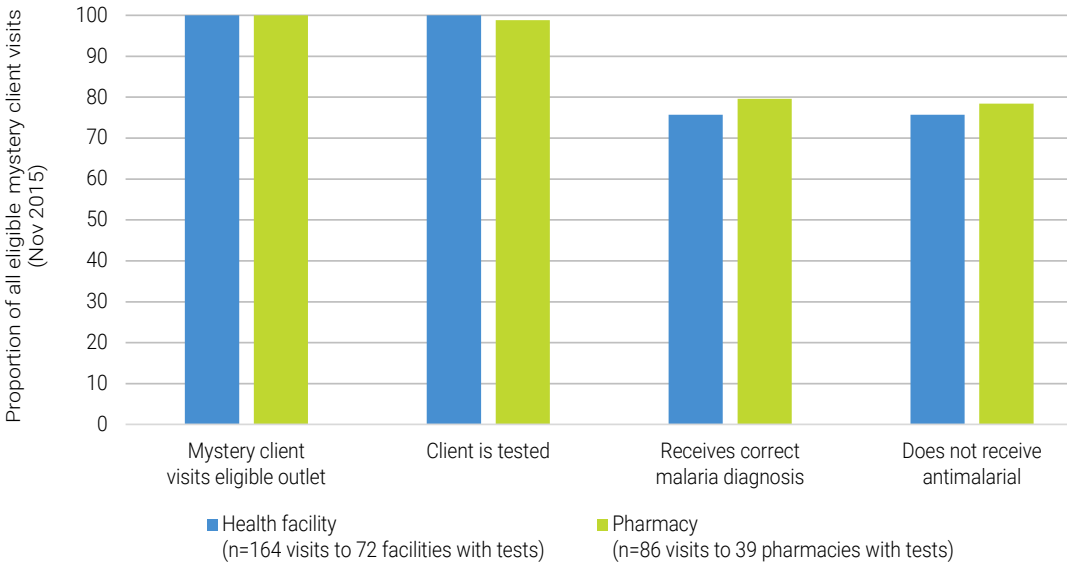


Lesson #2. The quality of fever case management is comparable across pharmacies and facilities

With sufficient training and supervision, pharmacies and drug shops can offer high-quality FCM services. Evidence from mystery client studies in Kenya show comparable levels of quality in project-supported pharmacies and private health facilities *(Figure 3)*. Findings have been shared at international fora[5], and have formed the backbone of advocacy efforts with the regulatory bodies in Kenya to approve use of mRDTs in pharmacy settings nationally.

Figure 3. FCM in Health Facilities and Pharmacies

Percentage of all known test-negative mystery client visits correctly managed at key steps on the FCM algorithm



Source: Mystery Client Survey, Kenya, 2015

Lesson #3. Shifting toward mRDT use from microscopy can reduce misdiagnosis

As part of the project's monitoring and evaluation plan, volunteers known to be negative for malaria by mRDT were employed to assess providers' FCM performance. In Kenya and Tanzania, these mystery clients were consistently more likely to be told they were positive for malaria when tested by microscopy compared with mRDT *(Table 1)*. This finding suggests that introducing mRDTs provides significant advantages in settings where high-quality microscopy is not available as well as where no diagnostics are currently available, such as in drug shops and pharmacies. This also underscores the importance of addressing poor-quality microscopy more thoroughly in training.

Table 1. Mystery client results from Kenya and Tanzania (2014 and 2015)

Type of test	Country, Survey Year, and sample size	Proportion of known malaria negative volunteers reported positive for malaria
RDT	Kenya 2014 (N=64)	20.3%
	Kenya 2015 (N=91)	13.2%
	Tanzania 2014 (N=82)	2.4%
	Tanzania 2015 (N=90)	10.0%
Microscopy	Kenya 2014 (N=81)	56.8%
	Kenya 2015 (N=69)	39.1%
	Tanzania 2014 (N=57)	24.6%
	Tanzania 2015 (N=107)	60.8%

5 At the European Congress on Tropical Medicine and International Health (ECTMIH) in Basel in 2015 and at American Society of Tropical Medicine and Hygiene (ASTMH) in Philadelphia in 2015

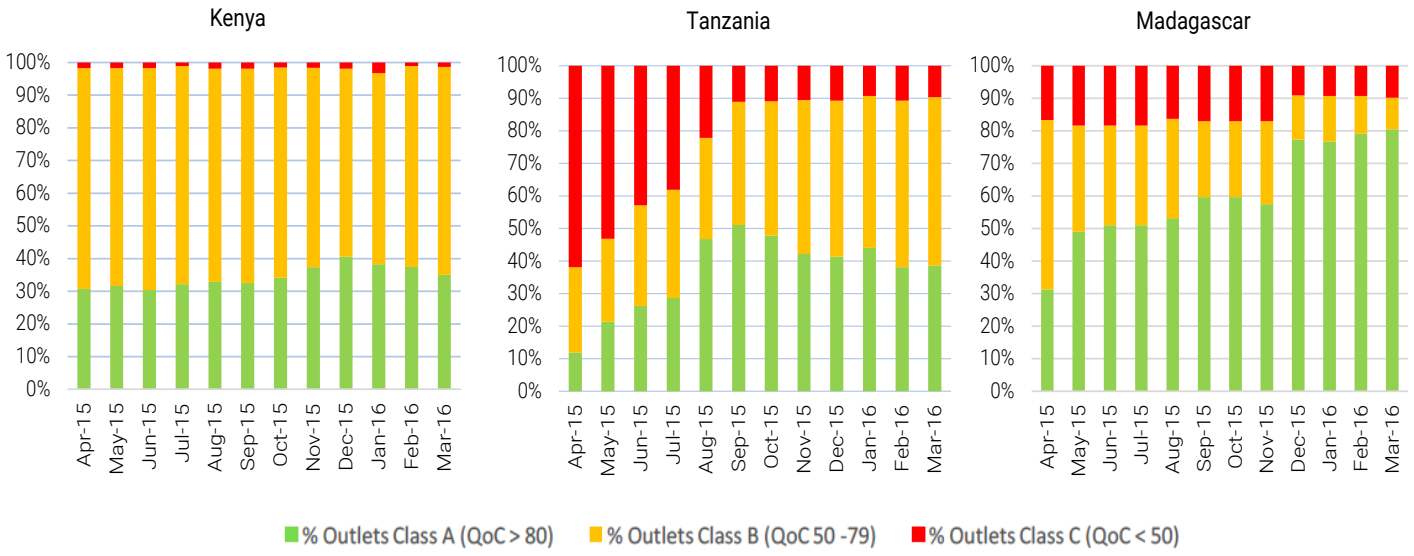
Lesson #4. Establishing QA systems to improve quality of care among providers can and does work in the private sector.

It is possible to monitor private providers' quality of care and utilize routine data for performance improvement. The project trialed an innovative supervision system that prioritizes low-performing high-volume outlets to increase the cost effectiveness of supervision across a network of providers (*Figure 4*). This approach is particularly important and relevant for the private sector, where drugs shops and pharmacies can number in the tens of thousands. PSI's championing of DHIS2 as the national health management information systems (HMIS) for the project, facilitated data sharing with Ministry of Health (MOH) colleagues through interactive dashboards. Despite these significant accomplishments, the project faced challenges with completeness of provider reporting and more work is needed to understand and innovate on incentives for reporting.

Key lessons learned around establishing QA systems for private-sector case management include:

- A technology preparedness assessment is important to determine whether the technological infrastructure is sufficient to support the planned system. The assessment should consider the availability and track-record of local service providers, availability and reliability of internet connectivity, among other considerations.
- Information needs and data definitions must be carefully established at the outset, and existing structures should be adapted to align with the tools used and information collected in the public health sector.
- Regular provider training on routine data reporting is key, as there is often a high turnover of providers at facility level. This can be done as part of the routine support supervision visit.
- When planning for data collection, tablets and phones that can run applications offline without an active Internet/3G connection are strongly preferred, given the poor reach of Internet/3G signals in many remote areas of malaria endemic countries.

Figure 4. Improvements in Quality of Care (QOC) over time
Routine supervision data from enrolled project outlets, April 2015- March 2016



The quality of care score is a compound indicator calculated from a provider's score in the following areas: assessment of danger signs, RDT procedure, classification of patients' illness, provision of treatment as per guideline, and counseling of patient.

Lesson #5. Point-of-use guidance tools are required to recognize and respond to mRDT performance challenges.

Project partner FIND, in collaboration with other partners, developed tools for acting on field problems with mRDTs, which can and should be adopted to recognize and respond to mRDT performance challenges. The troubleshooting guide (available in English, French, and Swahili) provides examples of possible problems and recommendations for on-site resolution and/or reporting if problems are considered critical or frequent *(Figure 5)*. The mRDT problems protocol is an algorithm which defines the chain of actions, and who is responsible for taking them when problems are encountered in the field. These tools can be adapted to any country, and should be integrated into national quality-control schemes to ensure any anomalies with mRDTs are identified and addressed in both public and private sectors.

Figure 5. FIND's Troubleshooting Guide for mRDTs

Lesson #6. Single pack mRDTs are often preferred by private retail outlets but have only recently been quality assured by the WHO.

Single pack mRDTs are often preferred by private retail outlets as they are only willing to buy small quantities of stock during the initial stages of market stimulation. This is particularly the case for those with poor access to credit. Consequently, the majority of mRDTs procured under the UNITAID project were single packs as opposed to hospital packs, which package mRDTs and accessories into boxes of 25 or 50 test cassettes. Due to the large volumes of single pack mRDTs procured under the project, PSI and partners identified a problem with buffer evaporation from individual buffer vials manufactured by three suppliers (Standard Diagnostics, Premier Medial Corporation, Access Bio).

Single pack mRDTs are often preferred by private retail outlets as they are only willing to buy small quantities during the initial stages of market stimulation

As a result, WHO issued a Global Information Notice For Users highlighting the instability of individual single-use buffer vials in mRDT kits, and began working with global manufactures to quality assure single pack accessories. In March 2016, Standard Diagnostics submitted new data concerning the stability of their single-use buffer vials which found them to be acceptable; their products are now re-listed on the WHO Prequalification list and on the WHO/Goods Manufacturing Practice (GMP) information note on recommended mRDT procurement. Manufacturers should be encouraged to improve their single-use buffer vial design and, when ready, resubmit data to WHO to increase market competition for quality-assured single pack mRDTs. Further, manufacturers should be supported in exploring how they can meet the preferences and demands of the private retail sector through the provision of smaller unit hospital packs containing 5 and 10 cassettes. Evidence of private sector demand is available from a variety of sources, including market information from the *ACTwatch surveys*.[6] In all cases – be it single-packs or small hospital packs – all products should be quality controlled at the manufacturer level. Lot quality testing of accessories, in addition to the mRDTs themselves, should also be considered.

6 Datasets and reports are available on http://www.actwatch.info/.

POLICY

How can a conducive policy environment be shaped to ensure differential diagnosis before treatment wherever febrile clients seek care, particularly at pharmacies and drug-shops?

Despite being the first point of care in many malaria endemic countries, some cadres of private providers are not permitted to diagnose malaria even if they have permission to sell ACTs over the counter. Before the project began, formal private health facilities were allowed to test in Kenya, Madagascar and Tanzania, but registered pharmacies and drug shops in these settings could not. Through targeted advocacy and collaboration, PSI and partners supported the revision of regulations in Madagascar to ensure all private outlets could test. The project also secured a waiver for pharmacies to test in three coastal counties in Kenya following appropriate training. At the time of writing, PSI and partners continue to advocate for national regulatory changes in Kenya and Tanzania to permit all trained private outlets to provider mRDT services. This advocacy is supported by the evidence collected and QA systems initiated through the project.

Lesson #7. Competing provider and regulatory interests must be proactively managed to create a conducive policy environment.

A key learning from the project in all countries has been the need to understand and manage competing interests among different provider types and regulatory authorities. For example, physicians are often reluctant for pharmacists to perform mRDTs, while registered pharmacy owners consider drugs shops illegal competitors. In Madagascar, partner advocacy efforts resulted in approval for trained personnel in both facilities and pharmacies to diagnose using mRDTs. In Kenya, the Kenya Medical Laboratory Technician and Technologists Board offered a waiver for PS Kenya to test in pharmacies during the project pilot, and is considering countrywide testing through pharmacies based on the final results of the project. Working through the Diagnosis, Therapeutic and Vaccine (DTV) Task Force, sustained advocacy efforts by PSI Tanzania, CHAI and other partners has supported the government of Tanzania to consider revising its regulations which would allow trained, non-lab personnel to test within Accredited Drug Dispensing Outlets (ADDOs). This should significantly increase coverage of malaria diagnostics in Tanzania, as ADDOS are the first point of contact for many febrile clients.

Similarly, WHO has completed systematic reviews on the regulatory bodies governing medical devices and their users to better understand where competing interest may lie and how to overcome them. They identified that national regulatory bodies' lack the capacity to fully regulate the in vitro diagnostic product (IVD) industry. Without strengthening the capacity of the regulatory bodies (manpower, equipment, expertise and financial resources) to register IVDs and enforce regulations, malpractices by both registered and unregistered suppliers and providers might continue.

Figure 6. Drug Shop Policy Forum Madagascar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SUPPLY SIDE STIMULATION

How can private sector supply chains be catalyzed through increased demand to ensure a sustainable supply of quality-controlled mRDTs with the right level of subsidy?

Establishing QA systems and an enabling policy environment removes key market barriers to entry and provides fertile ground to incentivize importers, distributors, and wholesalers to supply mRDTs and compete for market share. Under the project, PSI and partners piloted different approaches to priming and developing the private-sector mRDT market, with the aim of being able to exit and leave behind a self-sustaining supply chain. Key activities included conducting market research, developing pricing strategies, demand generation among consumers and providers, mRDT procurements, and linking providers with sustainable mRDT supply chains.

Lesson #8. Unsubsidized, quality-assured mRDTs can be made available and affordable in the private sector provided there is sufficient demand, and that pricing strategies across mRDTs and ACTs are aligned

Currently, global manufacturers are selling mRDTs for as little as 0.30 USD, making them affordable yet profitable across the supply chain, if sufficient volumes are ensured. In Tanzania and Kenya, PSI procured an initial tranche of mRDTs and sold them to the local supply chain with no subsidy to prime the market. In Tanzania, the project exited direct procurement as sufficient demand was generated for private importers and wholesalers to supply outlets directly. While this exit coincided with an increase in median retail price (*Table 2*), discussions with importers and wholesalers are required to explore the impact ending direct procurement had on price. PS Kenya exited direct procurement midway through the project, and at the time of writing, the enrolled outlets continue to be supplied by local wholesalers. The median retail price met the recommended retail price (RRP) for mRDTs in Kenya by project end, suggesting that in Kenya unsubsidized, quality-assured mRDTs are affordable at retail level. In Madagascar, given market conditions PSI directly procured all mRDTs used by the project and sold them to the supply chain at a subsidized price. However, by project end the median retail price was still higher than the RRP. Further research is required to understand why subsidized mRDTs at the top end of the supply chain did not result in affordable mRDTs to the consumer.

The interplay of ACT and mRDT prices and their influence on consumer and provider behavior has to be understood and addressed in pricing strategies, as highly subsidized ACT markets will require subsidized mRDTs to ensure the cost of diagnosis is less than treatment. Given this, all market players, including those subsidizing ACTs, need to be engaged when stimulating the mRDT market.

Table 2. mRDT Pricing Summary (intervention, recommended retail price, and median retail price)

	Intervention	Recommended Retail Price (RRP)	Median Retail Price at project start: 2014	Median Retail Price at project end: 2015/2016
Kenya	No subsidy; initial direct procurement to prime the market (250,000 mRDTs)	USD 1.10 (pharmacies) USD 0.90 (facilities)	USD 1.14	USD 1.00
Tanzania	No subsidy; initial direct procurement to prime the market (215,000 mRDTs)	USD 0.45	USD 0.58	USD 0.90
Madagascar	Subsidy; direct procurement in two tranches (767,814 mRDTs)	USD 0.84	NA (no baseline due to ethical approval delays)	USD 1.59

Lesson #9. Consumer marketing can raise awareness and build demand for quality assured mRDTs, although the key driver of demand appears to be price.

Over a short period of time, awareness of quality-assured mRDTs increased (*Table 3 & 4*). The key activities implemented which likely affected this were behavior change campaigns and branding of quality-assured products and providers. In Tanzania, demand grew steadily after the introduction of behavior change communications in late 2014. In Madagascar, demand also grew at a constant but slower pace once the marketing campaign was introduced. In Kenya, the introduction of consumer and provider marketing campaigns in the middle of 2014 coincided with a doubling of monthly sales. Logos and branding to help consumers identify quality-assured mRDTs and participating outlets (*Figure 7*) were rolled out in all countries and the end of project interviewees indicated these logos have increased demand for quality-assured products and for outlets carrying the logo in general.

Table 3. Number and % of caregivers surveyed in project areas who can cite a private provider source of mRDTs by target country

	Baseline	Endline
Kenya	13%	22%
Tanzania	9%	19%
Madagascar	11%	54%

Table 4. Number and % of caregivers in project areas that can recall messages about seeking fever diagnosis by target country

	Baseline	Endline
Kenya	16%	34%
Tanzania	4%	22%
Madagascar	38%	59%

Figure 7. Branded outlet selling quality-assured mRDTs in Kenya

Lesson # 10: All partners must monitor and adapt to the changing market landscape

A thorough market landscaping needs to be conducted, and regularly revisited, to support the optimal mix of push and pull activities (e.g. distribution models and trade promotions) to ensure correct volumes of quality-assured mRDTs are moved through the supply chain. In some countries, mass distribution of free mRDTs to both public and/or private sectors takes place, which threatens an mRDT market. Yet even in these contexts, clear and coordinated planning across the National Malaria Control Programs (NMCPs), donors, supply chain actors, and providers can support an effective mRDT market that includes both free distribution targeted to those unable to pay as well as low-cost mRDTs, for those able to pay within a framework of universal health coverage.

Call to Action

These lessons learned suggest three calls to action addressing quality assurance, policy, and supply.

1 In the immediate future, continued funding is required for quality assurance (training of providers, supportive supervision, and maintenance of QA systems) while long term, financially sustainable solutions are sought.

Based on an analysis of the five markets (Kenya, Madagascar, Nigeria, Tanzania, and Uganda) at project end, key stakeholders determined that the quality assurance market function will likely require continued subsidy/support. These QA activities must be conducted under the overall stewardship of the NMCP, and take into consideration best practices such as those highlighted in this brief. This includes emphasizing QA systems and supportive supervision over classroom based trainings, as well as innovative tablet-based supervision systems that enable cost-efficiencies through planning visits based on the client load and quality of outlets while integrating data into DHIS2 and, therefore, national HMIS. Further innovation is required to explore cost recovery options, such as providers paying into QA systems in return for regulatory approval for diagnosis, and/or wholesalers subsidizing initial training of providers to open up the market.

2 In order to achieve universal diagnostic coverage, national country governments should review the growing body of evidence which supports the quality of diagnostic services provided through the private sector, particularly pharmacies and drug shops.

This project added significantly to the growing evidence base on the safety and effectiveness of introducing mRDTs in the private sector. Project results have been published in peer reviewed journals[7] and have fed into the Roll Back Malaria Case Management Working Group Literature Review of mRDT provision in private retail outlets as well as the cost effectiveness modelling being undertaken by the London School of Hygiene and Tropical Medicine (LSHTM). Collectively, these data establish that with proper supervision and support, malaria diagnosis through mRDTs can take place safely and effectively across a variety of channels, including drug shops and pharmacies. Revision of national policies to allow for trained providers to diagnose wherever treatment takes place will greatly support the WHO's call for universal diagnosis, a goal which is reflected in national malaria strategies in nearly all malaria endemic countries.

3 The FCM community of practice (ministries of health, donors, implementing bodies, and private sector players) should coordinate closely in the development of malaria diagnostic plans that take into consideration all channels (public and private) and align of mRDT and ACT pricing.

This can be coordinated through existing diagnostic groups, such as the DTV Task Force in Tanzania, and reflected in national strategies, donor operational plans, and private sector forecasting.

Finally, these lessons learned and calls to action point to one final conclusion: the importance of continued investment in market development for mRDTs to achieve universal malaria diagnosis. Market development takes time and the level of subsidy required will vary depending on the context, the evolution of that market, and the roles and incentives of existing market players. Based on a robust market landscaping, existing market actors can be supported to play their roles more effectively. Over time this will lead to improved targeting of interventions and a greater return on investment for donors, governments and the market.Consequently, investing in mRDT market development can offer a cost-effective solution to improved malaria case management, a priority for the malaria community globally for both malaria control and elimination.

7 Visser T, Bruxvoort K, Maloney K, Leslie T, Barat LM, Allan R, et al. (2017) Introducing malaria rapid diagnostic tests in private medicine retail outlets: A systematic literature review. PLoS ONE 12(3): e0173093. doi:10.1371/journal.pone.0173093

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