



A roadmap for optimizing private sector malaria rapid diagnostic testing

*Lessons learned from a multi-country pilot
project in Africa*



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Using this document – key messages

- This Roadmap aims to partially address the current global gap in malaria testing through the expansion of RDT availability and accessibility, and to facilitate the appropriate case management of febrile illness through private sector involvement.
- This Roadmap is written for national malaria control programmes and other key stakeholders working towards the achievement of universal access to malaria diagnostic testing, spanning both public and private health sectors.
- The purpose of this Roadmap is to support the coordination of activities across the health sector (i.e. across public and private health sectors) for the sustainable implementation of quality-assured RDTs for improved malaria case management, and to guide adaptation of national malaria strategic and operational plans and policies.
- This Roadmap provides action steps and links to practical tools for deploying quality-assured RDT services at all levels within the private health care system and among private providers.
- This Roadmap addresses the need for the creation of a sustainable market for quality-assured malaria RDTs (mRDTs).
- This Roadmap can be used alongside the multi-agency operational manual on universal access to malaria diagnostic testing (1). The diagram on the following page shows how this Roadmap is integrated with the content of the universal access manual. This Roadmap is intended to be read comprehensively, although some sections and action steps can stand alone depending on the individual country context.



KEY POINT

WHO recommends *testing every suspected malaria case using quality microscopy or quality antigen-detecting rapid diagnostic tests (RDTs) prior to antimalarial treatment.*



KEY POINT

This Roadmap's goal is to increase the use of quality-assured RDT services by contributing to an increase in both the **access** to and **demand** for **quality-assured RDTs**.

How do I find the content I need?

This Roadmap focuses on needs that are specific to the private sector and differ from those of the public sector. These approaches should be incorporated into existing largely public-sector-focused strategies and implementation plans for malaria diagnostic testing and fever case management. To avoid duplication with existing WHO manuals, the Roadmap should be used as a companion guide to WHO's *Universal access to malaria diagnostic testing: an operational manual (1)*. This diagram helps to identify key content that is different and complementary across the two documents.

1. Programme Planning, Management and Policy

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 - Situational analysis gap identification
 - Roles and responsibilities
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 - Address regulatory issues
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 - Planning for monitoring and evaluation
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Population Services International (PSI) collaborated with the WHO Global Malaria Programme (GMP), Malaria Consortium (MC), Johns Hopkins Bloomberg School of Public Health (JHSPH) and the Foundation for Innovative New Diagnostics (FIND) in a Unitaids-supported project to facilitate and learn about private sector markets for RDTs in Kenya, Madagascar, Nigeria, Tanzania (mainland) and Uganda. The project's main objective was to stimulate the creation of a private sector market for the implementation of malaria rapid diagnostic tests (mRDTs) by increasing both the access to and demand for quality-assured RDTs and by improving private providers' fever case management skills. The evidence and learning generated by the project coupled with other research studies has led to the development of this Roadmap. A first outline of this Roadmap was drafted at a Project Coordination Meeting in Geneva in September 2015 and expanded during a two-day workshop at the End-of-Project meeting in Nairobi, Kenya in March 2016. Principal contributors and reviewers were Population Services International (Nikki Charman, Andrea Cutherell, Stephanie Dolan, Cristina Lussiana, Stephen Poyer,) Population Services Kenya (Anne Musuva and Nancy Njoki) , Population Services International Tanzania (Brenda Mshiu, Cecilia Makafu) Population Services International Madagascar (Rova Ratsimandisa), Malaria Consortium (Elizabeth Streat, Grace Nakanwagi, Kolawole Maxwell, Idowu Akanmu, Aderemi Olawole, Nze Chinwe, Nkabono Nglass, Olusola Oresanya, Geoffrey Namarra, Geoffrey Ssvenuma, Robert Mugerwa, Tonny Kayagulanyi), World Health Organization (Jane Cunningham, Andrea Bosman, Anderson Chinorumba, Ritha Njau, Seye Babatunde, Tolu Arowolo, Augustinte Akubue, Charles Katureebe, Henintsoa Rabarijaona Ep Ratovo, FIND (Sandra Incardona, Christian Nzanzabana, Daniel Kyabayinze), Johns Hopkins Bloomberg School of Public Health (JHSPH) (Steven Harvey, Nina Martin). Writing contributions of consultants Karsten Lunze and Yolande Coombes are also acknowledged.

While this Roadmap offers broad guidance that can be adapted to any country context, specific examples and findings from the Unitaids mRDT project are highlighted in example boxes and case studies.

In addition to PSI, MC, WHO and FIND other organizations involved in the drafting, revision and/or finalization of this Roadmap include the Clinton Health Access Initiative (CHAI), Malaria Control Elimination Path in Africa (MACEPA), JHSPH and ACT Consortium.

The guidance in this Roadmap is aligned with the WHO *Global Technical Strategy for malaria 2016–2030* (2) and the guidance and recommendations provide in the following WHO documents *Guidelines for the treatment of malaria, 3rd edition* (3), *T3: Test. Treat. Track. Scaling up diagnostic testing, treatment and surveillance for malaria* (4) and *Universal access to malaria diagnostic testing: an operational manual* (1).

Acronyms/abbreviations

ACT	Artemisinin-based combination therapy
AMFm	Affordable Medicines Facility-malaria
BCC	Behaviour change communication
CHAI	Clinton Health Access Initiative
CHV	Community health volunteer
DHIS2	District Health Information System 2
DQA	Data quality assurance
FCM	Fever case management
FIFO	First-in, first-out
FEFO	First-expired, first-out
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Global Malaria Programme
HMIS	Health management information system
iCCM	Integrated Community Case Management
IMCI	Integrated Management of Childhood Illness
IVD	In vitro device
LMIC	Low- and middle-income countries
MC	Malaria Consortium
mRDT	Malaria rapid diagnostic test/testing
MoH	Ministry of Health
MoU	Memorandum of Understanding
NMCP	National Malaria Control Programme
NMEP	National Malaria Elimination Programme
POCT	Point-of-care testing
PPMV	Patient and Proprietary Medicine Vendor
PSI	Population Services International
QA	Quality assurance
QoC	Quality of care
RDT	Rapid diagnostic test/testing
RRP	Recommended retail price
SOP	Standard operating procedure
ToT	Training of trainers
TWG	Technical Working Group
TOR	Terms of Reference
VCA	Value chain analysis
WHO	World Health Organization

Glossary

Accreditation: Procedure by which an authoritative body formally recognizes that a body or person is competent to carry out specific tasks.

Certification: Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

Competence: Knowledge, skills, abilities and attitudes at a level of expertise sufficient to perform in an appropriate work setting; this should be a measurable standard.

Country stewardship: The oversight by national actors and government to catalyse ownership and leadership of the structural arrangements, processes and outcomes necessary for fever case management in the private sector. Usually, it is the national malaria control programme that establishes country stewardship. Effective stewardship needs effective leadership.

Demand creation: Activities undertaken with the specific goal of increasing uptake of products, services or behaviours.

Detailer: A manufacturer's representative who calls on customers to supply information on products and visits stores to monitor sales and replenish stocks.

Distributor: An agent who supplies goods to stores and other businesses that sell to consumers.

External quality assessment: Set of activities conducted by an external agency or person to objectively check and monitor the performance and/or the quality management system. This can include external assessment visits, proficiency testing and cross-checking of test results.

Importer: A person or organization that brings goods or services into a country from abroad for sale.

Labeling: Display of information about a product on its container, packaging or the product itself.

Lot (of malaria rapid diagnostic tests): A lot (or batch) is defined as a production run in which particular batches of monoclonal antibodies and nitrocellulose are used. Each lot is usually identified by a lot or batch number assigned by the manufacturer. Lots can be of variable sizes. For malaria RDTs, they are typically between 1000 and 1 000 000 tests.

Lot testing: Quality control testing of a product lot (batch) after manufacturing and before distribution.

Malaria case: Occurrence of malaria infection in a person in whom the presence of malaria parasites in the blood has been confirmed by a diagnostic test.

Malaria test: For the purposes of this manual, this consists of an mRDT or microscopic examination of a blood slide (thick or thin smear) for malaria parasites; PCR is not included, as this manual focuses on tests used for the management of patients.

Market-based approaches: The process to better understand health markets and consumer needs in order to improve market system performance with a vision towards universal health coverage (i.e. a system that ensures that all people have access to quality health care without causing undue financial hardship).

Market facilitation / facilitator: Action or agent that is external to a market system but seeks to bring about change within a market system in order to achieve the intended benefit to the public.

Market functions: The market functions of a health market system are made up of three sets: the core functions, the supporting functions and the rules. The core functions of supply and demand can be understood through the 4Ps (product, price, place and promotion) and are carried out by direct market players in the supply chain of a product or service. The supporting functions and rules create the enabling environment for the core functions; these functions are performed by indirect market players and are necessary for a healthy market system. Key supporting functions include information, guidance, coordination, financing, quality assurance, labour and production capacity. Key rules include regulations, policies, taxes and tariffs, and social norms.

Market leakage: A situation in which products exit the public sector and influence uptake/sales in the private for-profit sector.

Market player: Organizations or individuals who are active in a market system, including those directly involved in the buying and selling of products and services and those indirectly involved in supporting the core functions, such as regulators, developers of standards, and providers of services, guidance, information, etc. This therefore may include organizations in the private and public sectors as well as nonprofit organizations, representative organizations, academic bodies and civil society groups.

Market size/volume: Market size is a measure of the total volume of service or product delivered.

Market system: The multi-player, multi-function arrangement consisting of three main sets of functions (core, rules and supporting) undertaken by different market players throughout a supply chain (private sector, government, representative organizations, civil society, etc.) through which the core functions of exchange take place, enabled by supporting functions and governed by rules. A construct through which both conventionally defined markets and basic services can be understood as they develop, adapt and grow.

Pharmaceutical detailing: a marketing technique used by companies to educate physicians or pharmacists about a vendor's products in hopes that they will use the company's products more often.

Point-of-care: Places at which medical care is delivered to patients; these include all health facilities (from referral hospitals to the smallest peripheral health facilities), as well as community-based providers and outlets.

Post-market surveillance: Collection of processes and activities used to monitor the safety and effectiveness of medical devices once they are on the market.

Private sector: The private sector is the part of a country's economic system that is run by individuals and companies, rather than by the government. Most private sector organizations are run with the intention of making a profit. Private health care provided by private providers (see next entry) other than the government.

Private points of care: Places or providers operating separately and with no financial support from the public sector (Ministry of Health [MoH]/Government). These range from large hospitals to mid-level health clinics to pharmacies and drug shops, and community-based providers. They are often labelled 'formal' or 'informal', with the former implying certification or accreditation and registration by the government.

Quality assurance: A set of planned and systematic activities focused on providing confidence that quality requirements will be fulfilled. For the purpose of this manual, this addresses all factors that affect malaria diagnostic performance, including test performance by health staff, internal audits, external quality assessment, quality of RDT devices, storage and transport of RDTs, use of test results by clinicians, workload, workplace conditions, training and staff support, and community perception.

Quality control: Refers to those measures that must be included in each assay to verify that the test is working properly.

Quality management system: System to direct and control an organization with regard to quality.

Quality monitoring: All activities involved in ensuring that the diagnostic tests continue to conform to established specifications during storage, distribution and use; part of quality assurance.

Sensitivity: For diagnostic tests, the proportion of patients with the disease who have a positive result using the test being evaluated, as determined from the results of the reference or 'gold standard' test; ranges from 0% (poor performance) to 100% (optimal performance).

Specificity: For diagnostic tests, the proportion of patients without the disease who have a negative result using the test being evaluated, as determined from the results of the reference or 'gold standard' test; ranges from 0% (poor performance) to 100% (optimal performance).

Situational analysis: This is a critical first step in the programme planning process. A situational analysis builds a comprehensive understanding of the context in which an entity is operating for a particular health area in a country by gathering comprehensive information on the health need, gaining insight into the target audience, and understanding category dynamics and performance. This is critical to designing the most relevant and effective solutions.

Stakeholder mapping: Part of the situational analysis, this is the process of identifying all key players that have a stake in the current and potential market for the health area. These players have an important role in the market in terms of supply and demand, support and rules functions.

Testing site: For the purpose of this document, this is any place in which malaria tests (RDTs or microscopy) are performed in the context of the clinical management of patients.

Test performer: For the purpose of this document, this consists of a health worker, laboratory technician or trained lay provider who performs and interprets an mRDT or prepares, stains and examines a blood slide by microscopy.

Universal access: For malaria diagnostic tests, all sick people who fulfil the definition of a suspected malaria case have access to a reliable malaria test administered by a trained health worker or lay provider at a health facility or community health centre. This does not include asymptomatic people in the context of strategies for eliminating malaria.

Supply chain: The string of market players directly involved in adding value to a product or service as it goes from production to use, usually including manufactures, importers, wholesalers, distributors, providers and consumers.

Wholesaler: A person or company that sells goods in large quantities at low prices, typically to retailers.

Introduction – Why is there a need to expand malaria rapid diagnostic testing services to the private sector?

The global malaria burden has decreased, but remains substantial. Malaria is endemic in 90 countries and over 219 million malaria cases occur each year, leading to 435 000 deaths worldwide (5). Clinically malaria is indistinguishable from the early stages of many other diseases. Therefore, for decades, presumptive treatment was the standard of practice in the highest burden settings, largely due to lack of quality point-of-care testing (POCT).

The availability of accurate and affordable rapid diagnostic tests (RDTs) coupled with effective treatment has revolutionized malaria case management. In response to the emergence of evidence of high-performing and affordable malaria RDTs (mRDTs), coupled with the high cost of artemisinin-based combination therapies (ACTs) and risk of their overuse, WHO changed its guidelines in 2010 to recommend prompt (within 24 hrs) parasitological confirmation of every suspected malaria case by quality RDT or microscopy prior to treatment (3). Reporting testing and results from patients with fever is also an important component of WHO's 3Ts initiative to test, treat and track each malaria case (4), and a central feature of the *Global Technical Strategy for malaria 2016–2030* (2).

RDTs can help to reduce the global malaria testing gap. The availability of high-quality, affordable, inexpensive mRDTs in the public sector of many low- and middle-income countries (LMICs) has expanded diagnostic testing prior to treatment (4). Malaria diagnostic testing rates amongst children in sub-Saharan Africa presenting to public sector facilities has increased to 74% (5); however, universal testing of all cases, especially in the private sector, has not yet been achieved.

Data suggest that the gap in universal testing is due in part to the limited access to RDT services in the private sector, where globally 40% of patients seek care (6) and where febrile illness is often still treated presumptively as malaria. This leads to the overuse of ACTs and to the substandard management of non-malaria febrile illnesses (7).

Private sector points of care include a diverse group of providers, both formal (certified or formally trained doctors, nurses, pharmacists, laboratory professionals and trained community health workers) and informal (independent and largely unregulated drug shops/sellers, village doctors, and faith healers, not-for profit or for-profit (8) (see Fig. 1).

Establishing RDT services in the private sector is challenging. First, RDTs are rarely available in the private sector, which is often the primary point of care for febrile illness. This may be due in part to laws or regulations that prohibit diagnostic testing by the providers selling the bulk of antimalarials. Second, RDTs used in the private sector vary considerably in terms of price and quality. They are often of poor quality or sold at a higher price than the recommended malaria treatment regimen, which discourages their sale and use¹. Third, weak in vitro device (IVD) regulation and post-market surveillance coupled with complex distribution channels in many malaria-endemic countries means that standards of practice may not be respected and poor

¹ In a review of the availability and price of RDTs in ten countries in 2011, private sector availability ranged from 1% to 46%, and median prices ranged from US\$ 1 to US\$ 3. In one setting, 19% of pharmacies stocked RDTs from manufacturers who had not, up to that point, submitted their products for lot testing through the WHO/FIND testing scheme (9, 10).

RDT performance is often not identified or corrected. The private sector is disproportionately affected in this regard.

Many people in LMICs seek care primarily in the private sector, especially from informal drug sellers (5).

Public sector guidelines and policies are not always inclusive of the private sector. Although many private health providers are trained, some potential private sector retailers are sales people without any formal health-related training. Most existing national malaria guidelines and policies support the implementation of malaria testing using mRDTs and related training, but do not support and/or authorize private sector testing by non-health professionals in drug shops or other outlets.

Evidence has shown that private providers can safely test clients, thereby reducing the inappropriate antimalarial treatment of patients without malaria (11). A study in Uganda showed that RDT sales influenced treatment decisions, in that, RDT-positive clients were 23% more likely to buy ACTs than RDT-negative clients (12). Within private health facilities, compliance with malaria test result was found to be high (80%) and was not influenced by the age of patients or type of malaria test (13). Aggregate data suggest that, although adherence to test results varies (by setting and by the amount of training and supervision), private providers are able to perform RDTs and interpret results. Results from the Unitaid project (see below) showed that aggregate private sector RDT uptake ranged from 25–72% across study settings, and adherence to negative RDT results was 80% or greater in all settings. A recent systematic review has shown that a range of private medicine retailers in different countries can incorporate RDTs into their practice, but with varying degrees of uptake and influence on case management (14).

Comprehensive policy, conducive regulation, quality assurance and supply-side sustainability **are the private sector’s main challenges to RDT implementation.** Increased understanding of how best to support providers and patients to use RDTs for effective case management is required. Systems for a quality-assured supply chain, safe use and disposal of waste, and monitoring of adherence to guidelines need to be efficiently developed or existing systems expanded as needed (14).

The introduction of mRDTs into private sector markets presents an exciting opportunity to leverage the transformative power of market approaches due to the large-scale availability of high-quality, easy-to-use rapid diagnostic products; the current affordability of those products at less than 30 US cents per test²; and the market size potential (acknowledging that all fevers in malaria-endemic countries should be tested). The challenge behind this opportunity is understanding how to build on these conditions to ensure sustained supply of high-quality testing services that are safe and supported by national governments, and invested in by private sector market players from producers to retailers.



KEY POINT

The Roadmap’s strategic goal is to achieve full geographic coverage and adherence of end-user providers to the WHO-recommended malaria management policy of

- (1) testing with quality-assured mRDTs (or microscopy) prior to treatment,
- (2) treating RDT-positive cases with quality ACTs, and
- (3) treating RDT-negative cases according to national guidelines (validated algorithms).

2 The Global Fund to Fight AIDS, Tuberculosis and Malaria’s Price and Quality Reporting system: <https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting/>

Fig. 1. Public and private sector points of care

	Formal (certified or formally trained)*	Informal (independent and largely unregulated)**	Not-for-profit	For-profit
Public sector points of care	✓			
Private sector points of care	✓	✓	✓	✓

*This includes doctors, nurses, pharmacists, laboratory professionals and trained community health workers.

**This includes unaccredited drug shops/sellers, village doctors, faith and traditional healers.

The Unitaid project

In a collective effort to progress towards universal access to malaria diagnosis, Population Services International (PSI) in partnership with the Malaria Consortium (MC), Foundation for Innovative New Diagnostics (FIND), Johns Hopkins Bloomberg School of Public Health (JHSPH) and WHO with funding from Unitaid implemented a three-year project (2013–2016) to stimulate private sector markets for quality-assured mRDTs (15). The *mRDT Private Sector Project* was implemented in Kenya, Madagascar, Nigeria, Tanzania and Uganda. At the time of the project, private providers accounted for between 31% and 66% of fever treatments in these countries (16). In addition, all five countries were supported by Unitaid and other donors through the Affordable Medicines Facility-malaria (AMFm)³, which, starting in 2010, funded the provision of affordable, quality-assured, subsidized ACTs through the public, private not-for-profit and private for-profit sectors. As a result, customers could readily access affordable ACTs through private health outlets such as clinics, pharmacies and drug shops. However, a variety of obstacles prevented private outlets from offering diagnostic testing services for malaria. The three key market constraints identified were: i) limited commodity and provider quality assurance systems, ii) a non-conducive policy environment, and iii) insufficient supply and demand.



The *mRDT Private Sector Project* implemented activities to address these challenges in the five target countries and conducted rigorous research to document evidence to support market catalysis in other countries. This mRDT Roadmap draws significantly on the experience, data and findings of the *mRDT Private Sector Project*, while offering broad guidance that can be adapted to any country or context.

³ The pilot was implemented in seven countries: Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda. The AMFm was launched in 2010 and ran through to 2013. Source: <http://www.unitaid.eu/en/amfm>.



1 Programme planning, management and policy

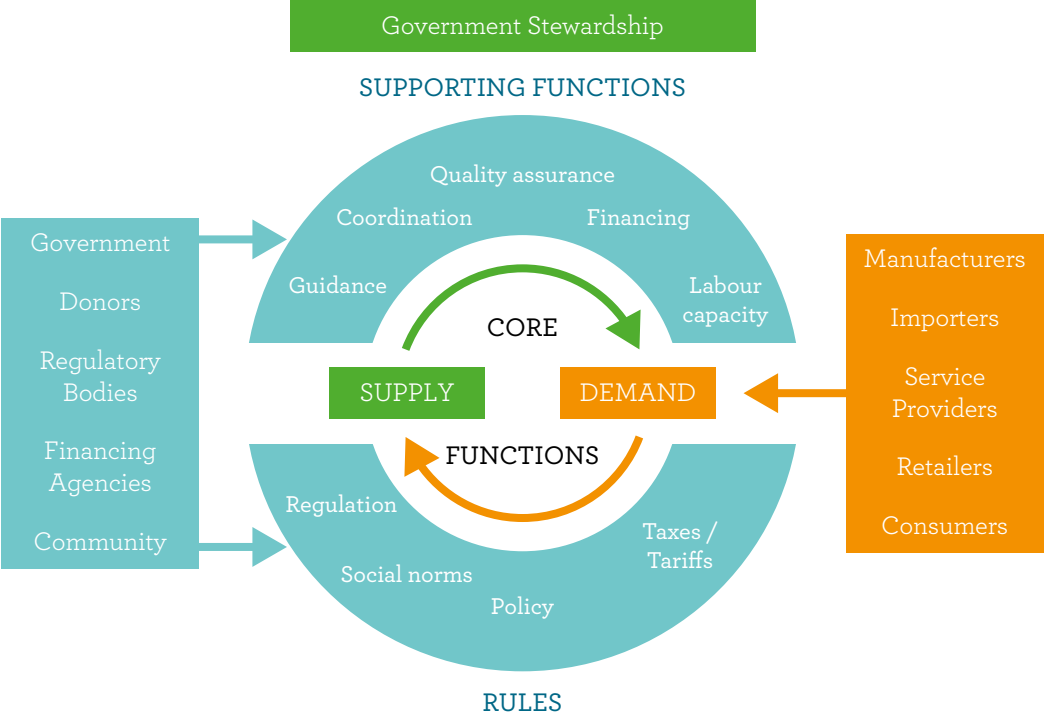
Overview

One of the goals of a national malaria control programme (NMCP) is to provide universal access to accurate malaria diagnostic testing for all patients suspected of having malaria. Many countries will have already established programme planning and management systems for public sector testing as laid out in Chapter 1 of the Universal access manual. This Roadmap does not repeat those steps, but offers guidance on the additional steps in programme planning and management required to meet the needs of the private sector market.

This section takes you from the initial stage of convening stakeholders to a discussion of *how* to include the private sector, to having completed all the necessary steps to be able to assess readiness for implementation and scale-up.

One way to visualize the mRDT health market system, including the role of the private sector market, is presented in Fig. 2. The diagram shows the possible players/stakeholders in blue (public) and orange (private sector supply chain), as they relate to the three key functions of a health system: core functions (i.e. supply and demand), rules (e.g. policy and regulations) and supporting functions (e.g. quality assurance). The government, in the top green box, has the overarching responsibility of stewardship for all health system functions. This figure will be referenced throughout the Roadmap as a framework for understanding how to engage all stakeholders in achieving universal malaria diagnosis through the extension of mRDT services to the private sector.

Fig. 2. Structural elements of a health market system, including the private sector supply chain^a



^a Framework adapted from *The operational guide for making markets works for the poor (M4P) approach*. Springfield Centre. 2015

Key Action Steps in Section 1

Stewarding private sector involvement

1. Write a concept note.....16
2. Seek ministerial approval.....16
3. Carry out stakeholder mapping 17
4. Convene a stakeholders' forum..... 17
5. Set up a national coordinating group ..18
6. Consider developing an MoU.....18

Situational analysis and gap identification

7. Set up a taskforce or Technical Working Group (TWG) to be responsible for the situational analysis and gap identification19
8. Map roles and functions in the supply chain.....19
9. Review country data and conduct stakeholder interviews.....22

10. Assess the total market size to illustrate the value for business and public health impact22

Policies and technical guidelines

11. Confirm that the implementation of mRDT services by various private sector providers is compliant with existing laws, regulations, policies and guidelines23

Planning for private sector scale-up and sustainability

12. Determine readiness to proceed.....25
13. Budget and mobilize resources25
14. Pilot before scale-up 26
15. Assess implementation effectiveness. 26
16. Continuously plan for sustainability ...26

CASE STUDIES

At the end of this section, you will find three case studies illustrating how some of the issues covered in this section were dealt with in countries participating in the Unitaid project.

Madagascar: Regulatory and policy challenge

Nigeria: Adaptation of regulations and policies

Kenya: Securing country commitment and leadership to amend policies and regulations

1.1 STEWARDING PRIVATE SECTOR INVOLVEMENT

The goal of engaging the private sector is to achieve universal diagnostic coverage in the most efficient health system possible. Creating and maintaining private sector markets for quality-assured mRDT services to improve the case management of febrile illnesses may require countries to establish, adapt and/or strengthen laws, regulations, policies and practices. There is also a universal requirement to engage with new stakeholders to support increased access in a sustainable manner. This section outlines several steps needed to align all stakeholders

with an agreed-upon plan for private sector implementation that includes incentives for the private commercial sector and a stewardship role for the public sector.

Initiate the process to commence public sector stewardship of RDT services in the private sector

It is most appropriate for the NMCP to lead and commence country stewardship, especially if a national group on malaria diagnosis already exists (see Universal access manual, section 1). A body that is part of a permanent government institution will help to provide an enduring foundation for initiating and steering interventions in the private sector.

Country stewardship is not a single event; it involves a number of action steps. If the NMCP does not choose to lead this process, another dedicated agency/department needs to take on the responsibility, starting with Action Step 1 (write a concept note). The concept note will provide an overview, rationale and plan for implementing RDT services in the private sector. The concept note can be presented to relevant persons and groups in order to mobilize support and gain approval (Action Step 2). This will engender political support to pursue a coordinated approach and commitment to the implementation process.



ACTION STEP 1

Write a concept note

Develop a concept note or business case document on the implementation of RDT services in the private sector. Relevant information and evidence can be gathered through literature review, consultations and documentation on the current state of RDT implementation in the private sector locally as well as regionally and globally, as relevant.



ACTION STEP 2

Seek ministerial approval

Seek ministerial approval for the private sector engagement concept and endorsement by the national technical or advisory body to the MoH and NMCP on malaria and fever case management.

Map and convene all relevant stakeholders sector-wide

Diverse stakeholders (organizations and individuals) can be involved in malaria or fever case management (FCM) in a country. This diversity increases when including actors in the private sector. Potential stakeholders are all those who can identify *what* should be done and *how* things should be done. Illustrative actors are highlighted in Fig. 2; however, specific entities, agencies and individuals should be identified at country level. For private sector mRDT implementation, key stakeholders that need to be identified and convened include the NMCP, regulatory authorities, professional associations (pharmacists, laboratory technologists, doctors, allied health professionals), manufacturers, wholesalers, importers, distributors, etc. An inclusive, inter-sectorial, private sector-wide stakeholder base is critical to successful implementation, particularly beyond the initial formative years. Persons with technical competence and years

of experience working in the field should conduct extensive consultations and a thorough stakeholder mapping (Action Step 3).



ACTION STEP 3

Carry out stakeholder mapping

Identify both typical and less typical players affecting the private sector market through stakeholder mapping. This step should be conducted by persons who are technically sound and experienced in the local market. Some countries hire national consultants who are familiar with the country context.

In many countries, professional associations, generally seeking to further the interests of their members but also the public interest, have turned out to be key players. Private sector RDT services may require legal and/or policy change in many settings. Professional health cadres (e.g. doctors, pharmacists, laboratory workers) often have considerable influence and power to advocate for policy and regulatory change for the successful implementation of private sector RDT markets.

Incentivize and secure commitment from stakeholders

The next step is to secure commitment to the private sector RDT intervention from different stakeholders. Incentives that align with stakeholders' interests can motivate them to become and remain part of the initiative. For example, the goals of improving testing for FCM are consistent with the missions of many health players. The stakeholders' forum or meetings (Action Step 4) can also provide the opportunity to explore and discuss competing interests among different stakeholders *viz.* provider types, professional groups, regulatory authorities, etc. For example, physicians are at times reluctant for pharmacists to provide RDT services; pharmacy owners may consider drug shops illegal competitors, while the clients may only perceive the difference as a matter of immediate self-preference or personal convenience.



ACTION STEP 4

Convene a stakeholders' forum

Convene all stakeholders in a forum dedicated to strengthening the enabling environment for RDT services in the private sector. Explore the willingness of private actors and policy makers to engage the private sector in order to expand access to quality FCM services with RDTs. Assess the current private sector architecture, public sector interests and private sector interests in expanding access to mRDT services at private sector points of care.

Planning for sustainability and scale-up should also be factored into the selection of a national champion, who will have a prominent role in ensuring sustainability. The choice of the person should be given critical and objective thought, as it will be crucial for the person to be able to command the respect of all and sway opposing opinions towards consensus and mutual commitment.



ACTION STEP 5

Set up a national coordinating group

Set up a national coordinating group for private sector participation in mRDT services. This could be an existing working group, e.g. a national coordination group on malaria diagnosis that modifies its Terms of Reference to include private sector market creation. Alternatively, a dedicated private sector national coordinating group or task force could be created, but would need to feed into the NMCP activities. Ensure the Terms of Reference for the national coordinating group are developed, with roles and responsibilities assigned to each individual.

The national coordinating group will be responsible for overseeing the roll-out of a national programme for implementing FCM that is inclusive of mRDT services among private providers. The composition of the group should reflect all relevant organizations. Following the mapping and convening of stakeholders, the coordinating group will need to agree on how to assign roles and responsibilities to other stakeholders, such as subnational health authorities, regulators, private sector players, and others. *Also refer to the Terms of Reference for the national coordination group on malaria diagnosis outlined in the Universal access manual, section 1.1.*



ACTION STEP 6

Consider developing an MoU

A Memorandum of Understanding (MoU) can serve as a form of written commitment between the MoH and key nongovernmental stakeholders for mRDT implementation in the private sector.

In developing and signing an MoU, stakeholders demonstrate that they agree to and endorse the proposed interventions and affirm their commitment. A signed MoU can be a meaningful output of the stakeholder engagement meetings. For example, in Nigeria, Malaria Consortium developed MOUs with multiple stakeholder groups including the Union of Allied Health Professionals and the Proprietary and Patent Medicine Vendors.

1.2 SITUATIONAL ANALYSIS AND GAP IDENTIFICATION

The stakeholder mapping carried out under Action Step 3 seeks to identify the different stakeholders or players who could be involved in bringing the private sector on board and their potential roles. The situational analysis takes this process further by understanding the roles, incentives and capacities of the players as they relate to the key health market system functions: core (i.e. supply and demand), supporting (e.g. quality assurance) and rules (e.g. policy and regulations). The aim is to identify the key constraints or gaps that prevent the health system from operating at its ideal state. This analysis is complemented by an assessment of the total market size in order to illustrate value for business and public health impact. The national coordinating group should set up a specific taskforce or Technical Working Group (TWG) to carry out the situational analysis and gap identification (Action Step 7).

**ACTION STEP 7****Set up a taskforce or Technical Working Group (TWG) to be responsible for the situational analysis and gap identification**

The national coordinating group should form a taskforce or TWG to undertake the situational analysis and gap identification. It should develop Terms of Reference for the taskforce's work and assign the leadership and roles and responsibilities to members of the taskforce. The group can task consultants with supporting and/or completing the situational analysis. If necessary, Terms of Reference could be developed for a consultant or partner to conduct the analysis.

Understand roles and responsibilities in the private market

As part of the situational analysis, an understanding of the roles of all players affecting the private sector market is needed (Action Step 8). Many actors within the health system (public and private) can and should influence the equitable and sustainable coverage of RDTs for FCM services. Therefore, it is important to understand and address the roles, functions and incentives of these actors. Private sector market players are often involved in the manufacturing, distribution and delivery or provision of products and services within the health system (refer back to Fig. 2).

**ACTION STEP 8****Map roles and functions in the supply chain**

Map out the players in the health system along with their roles and functions. A useful way to do this is to map them along a continuum that follows commodities (RDTs and accessories) and services (testing, training and supervision for testing; distribution, marketing) from their initial production to their use with patients, ensuring that key issues related to core functions (i.e. supply and demand), supporting functions (e.g. quality assurance) and rules (e.g. policies and regulations) are addressed. This continuum is the supply chain for mRDTs.

All players involved in the mRDT supply chain (from production, to importation and distribution, to use through a variety of channels) should be mapped (Action Step 3) and analysed with respect to their capacities and influence on the market (Action Step 8).

PSI uses a [framework to map market players](#) along the spectrum from production to use of mRDTs. Utilizing this tool involves summarizing the quantitative and qualitative information gathered from the situational analysis in order to best map and analyse the current health system for mRDTs. Existing secondary data (e.g. drug registration, import/customs documentation, foreign chamber of commerce reports, and forecasting/allocation and quantification information) can be the source of information for this work, supplemented by key stakeholder interviews where information gaps exist.

To complete the situational analysis, the roles, incentives and capacities of all players identified in the mapping exercise (Action Step 3) should be considered as they relate to the key health market system functions (Fig. 2).

Core functions: A good understanding of supply and demand of commodities and services is needed to achieve full geographic coverage. It is useful to understand the role of the different health system players according to four key areas impacting supply and demand, specifically, product, price, place and promotion.



KEY POINT

Core market functions of supply and demand

1. **Products:** What are the relevant RDT products and services (and the specific brands under which they are marketed) available in the health system?
2. **Price:** What are the RDT price points and trade margins of all relevant products and services in the health system? Are there any subsidies or taxes/customs that impact prices? Do these vary for different commodities (e.g. diagnostic versus therapeutic commodities)?
3. **Place:** What is the number of active players along the supply chain; what are the locations of RDT delivery points and number of providers; and what is the RDT availability along the supply chain?
4. **Promotion:** What is the role of health system players in demand generation; and who demands the product or service at different points along the supply chain (i.e. at manufacture, import, distribution, and provider and consumer level)?

Supporting functions: The effectiveness of the core functions of supply and demand performed by the health system players depends on a range of supporting functions in the health system. Supporting functions can be considered to be levers that facilitate health market system development.



KEY POINT

Supporting functions are defined in terms of elements that need to be in place in order to positively impact a health market system's performance. Effective supporting functions include:

1. Information about the market, including regulations, is available or made available to all health system players directly or indirectly involved with the production or dissemination of RDT kits and accessories, training and supervision, etc.
2. Guidance is provided by national and international agencies and is available to all health system players relevant to the operation and development of RDT markets to include the private sector.
3. Coordination is provided not only across related health system players, but also across other stakeholders operating in the health system, as their actions influence the performance of the health system players. This coordination may be in the form of broad TWGs or vertical integration among market players in a supply chain, etc.
4. Financing includes internal (domestic, national) and external (international) funding sources and mechanisms available to the different market players that enable them to operate, improve and/or grow their supply or purchase capacity for mRDTs.
5. Quality assurance includes the various standards, systems and activities in place to ensure quality manufacturing and delivery of mRDT products and quality testing, reporting and waste disposal.
6. Labour capacity is a supporting function that considers whether the cadres treating malaria have sufficient training and support to offer mRDT products and services, and whether organizations have sufficient labour and production capacity to scale their services.

Rules: In addition to the core market and supporting functions to be summarized in the situational analysis, it is important to recognize that health systems are influenced by rules that govern the functions of the different health system players. A review of policies, taxation and pricing regulations across the entire supply chain is required because, for example, the health system regulatory environment may not be directly captured in the supply chain for the core functions of supply and demand. Regulations may need to be established in order to ensure quality (see next section), but these should not shut down the market by being too strict (see case study on Madagascar at the end of this section).



KEY POINT

Policies are typically issued by national government agencies or related global stakeholders (e.g. WHO).

Regulations govern all aspects of the production-to-use spectrum, ranging from importation to the use of IVDs in the country. A review of existing regulations related to IVDs should cover the IVD registration process, any restrictions on IVD use (by whom and where they can be performed) and post health system surveillance activities.

Taxes and tariffs are important market influences that can differ by commodity. A review of taxation and pricing regulations needs to cover processes from the point of importation along the entire supply chain.

Gap Identification

Once the roles, incentives and capacities of the players involved in the mRDT supply chain have been identified, the situational analysis should be expanded to identify specific gaps or constraints that may prevent the market from functioning in its ideal state (e.g. lack of regulatory guidelines to enable malaria testing where treatment with ACTs can be prescribed). This gap identification should expand upon previous analyses conducted for the scale-up and roll-out of RDTs in the public sector, as outlined in the Universal access manual, section 1.2. It is recommended that all supply chain players involved in RDTs be included. The situational analysis and gap identification should be developed based on a combination of literature review, desk review and stakeholder interviews (Action Step 9)



ACTION STEP 9

Review country data and conduct stakeholder interviews

Conduct a literature and desk review of relevant country data in order to assess the incentives and capacities of each player to perform the health market system functions and stimulate the private sector market for RDTs. Given that literature and data are often incomplete, gaps in knowledge of the market system will be identified in the process of the literature and desk review. These gaps should be used to design interview guides for primary research with key market players and stakeholders. Key market players and stakeholders, such as government representatives, implementing partners, child health funders, and malaria programmes, as well as private sector importers, distributors and salespersons/retailers, can provide important information to help with planning and implementation.



ACTION STEP 10

Assess the total market size to illustrate the value for business and public health impact

Assess the size of the potential private sector market

In order to estimate the total market size for private sector growth, the following must be determined:

1. Where is the national malaria burden located geographically, and what are its trends over time and across seasons?
2. What are patients' current care-seeking patterns for febrile illness in the private sector? (to estimate the proportion of patients attending public vs private sector for febrile illness)
3. From what type(s) of private provider (health facility, pharmacy, retail outlet) do patients with febrile illness seek treatment?
4. Map the potential number of suspected malaria cases seen by each provider.
5. Estimate the total aggregate volume (adding all of the different private providers together) and convert this to a monetary value that reflects the total private health system in terms of potential treatment and services.

This information can be summarized in a [use \(i.e. total actual consumers of mRDTs\) over all need \(i.e. all suspected malaria cases\) analysis](#) in order to determine the exact market size for potential growth – i.e. suspected malaria cases that are not diagnosed. This population (non-users) should be analysed through equity lenses and considering risk behaviours in order to better understand who constitutes the potential market growth and how to reach them.

1.3 POLICIES AND TECHNICAL GUIDELINES

Private sector mRDT implementation should be guided by existing laws, regulations, policies and guidelines that are tailored to accommodate a diverse set of care providers and care settings. For example, performing RDTs involves the handling of blood; therefore, operators and their places of work must comply with national blood safety and health care waste management standards. Existing policies may need to be adapted to ensure that important safeguards are put in place outside of hospital laboratory settings. Fever management for patients with negative RDT results remains a major challenge in many settings. As in the public sector, detailed and clear guidance on specific actions to take in RDT-negative cases is needed for private sector RDT providers. The action taken should be commensurate with the level of training the provider has received. For example, a private sector physician will be qualified to conduct further investigations of RDT-negative cases, whereas a pharmacist who has not received training in Integrated Community Case Management (iCCM) or Integrated Management of Childhood Illness (IMCI) will more likely need to refer negative cases to health professionals. Consequently, implementation should link with malaria and child survival departments in the MoH and other relevant ministries so as to facilitate engagement with the private sector and vice versa. Subsequent implementation of policies will require integration of activities as well as corresponding budgets.



ACTION STEP 11

Confirm that the implementation of mRDT services by various private sector providers is compliant with existing laws, regulations, policies and guidelines



KEY POINT

Updating documentation

National policies that may need updating to address the specific needs of the private sector include:

- National malaria strategic plan
- National malaria control policy
- Integrated Management of Childhood Illness (IMCI)
- Integrated Community Case Management (iCCM)
- National clinical laboratory policies and guidelines
- Regulations for: in vitro diagnostics; health professionals and non-health professionals who may carry out testing; health care and non-health facilities and waste management.

These should be verified against the more comprehensive list provided in section 2.1 of the Universal access manual.

The revision of regulations and policies usually entails a formal review process, which must be factored into timelines for implementation. If the key stakeholders responsible for relevant policy development, regulations and guidelines are involved in the national coordinating group, they will be able to elaborate on specific requirements and propose ways to accelerate the review process and/or propose alternative solutions such as temporary waivers.

More detailed information on regulations, policies and technical guidance can be found in the Universal access manual, section 2. The case studies at the end of this section also shed light on some of the potential challenges associated with the introduction of private sector mRDTs and how to address them. The example from Madagascar shows how existing policies had to be adapted to include the private sector and change the specifications for which mRDTs could be used. In Nigeria, policies also had to be adapted to make a specific cadre of private provider eligible to conduct RDTs because this type of provider was the first point of care for most patients seeking treatment for febrile illness. Finally, the case study from Kenya outlines some of the steps needed to influence policy change.

1.4 PLANNING FOR PRIVATE SECTOR SCALE-UP AND SUSTAINABILITY

A convincing business case can be made if the introduction of mRDTs into the private sector will lead to positive results in terms of both public health gains and the profit-making goals of all market players by improving the supply and demand for RDTs. Clear incentives for the private sector and a conducive regulatory environment are necessary to open the market to its full potential, i.e. all suspected malaria cases annually are covered by testing in the public and private sectors.

The final steps in this initial stage of programme planning and management are to convene the stakeholders to determine readiness to proceed, mobilize resources, pilot implementation, assess effectiveness, and plan for sustainability.



ACTION STEP 12

Determine readiness to proceed

In collaboration with key stakeholders, assess the country's readiness to expand access to mRDTs in the private sector. Make a shared decision on how to achieve that readiness and proceed with the intervention: whether to regroup, prepare or proceed with expansion of quality mRDT services in the private sector.

Various scenarios are possible:

1. Conditions are prohibitive to the inclusion of RDT services in some or all of the private sector care settings. **REGROUP**: The taskforce implements at a small scale in the private sector in order to gather evidence with which to develop a more conducive legal, regulatory and policy environment.
2. Major efforts and initiatives are necessary to gain support and create realistic conditions for the inclusion of some or all of the private sector care settings. **PREPARE**: Determine next steps at the end of the workshop to move through the 'prepare' stage, and set timelines and responsible parties to implement, with a date to re-convene and evaluate readiness to move on to the next stage.
3. The situational analysis indicates that the legal and regulatory environment is compatible and stakeholder support can realistically be mobilized to implement the subsequent steps in this Roadmap. **PROCEED**: At the end of the situational analysis workshop, develop a work plan and monitoring and evaluation (M&E) plan to proceed.



ACTION STEP 13

Budget and mobilize resources

All possible sources of funding for the initial steps should be considered, including from domestic, international and private sector sources. Countries between rounds of Global Fund grant funding could justify budget to support tasks related to private sector mRDT implementation. Other in-country partner organizations could be approached for support, particularly if such partners are participating in initiating the agenda to implement private sector mRDTs.

The overall implementation processes are informed by the situational analysis. Previously collected information on the players within the RDT market, including their various roles, will aid in deciding the scale of implementation. Economies of scale for implementation also need to be considered. Therefore, it is necessary to determine the scale of the implementation phase. The number of outlets and provider cadres included in the implementation plan needs to match the capacity for RDT distribution, storage, training and supervision. Likewise, first targeting outlets and providers that already have the support of public and private stakeholders in the country can help to focus the initial scope of activities. It can be useful to start with activities focused in a pilot area so that lessons can be learned, and if necessary, definitive changes made to policy and regulatory requirements prior to scaling up.



ACTION STEP 14

Pilot before scale-up

Start at pilot scale, involving a limited number of health facilities, retail outlets and provider types. This will enable the country to identify and mitigate possible bottlenecks and challenges before scaling up activities.

Depending on the status of regulations and policies, implementation might require IRB approval, a waiver or legal changes, or other administrative steps to ensure that implementation complies with all national laws and regulations.

A pilot also provides the opportunity to integrate lessons learned and to develop mitigation strategies for potential and real challenges before the programme is scaled up. This can be done through monitoring (for more information see the final section of this Roadmap).



ACTION STEP 15

Assess implementation effectiveness

The national coordinating group should devise review procedures to monitor the progress of the implementation. This could be done in coordination with other existing country review processes, such as Malaria Programme Reviews (MPRs), Rapid Impact Assessment of antimalarial intervention, and Health Facility Assessments.



ACTION STEP 16

Continuously plan for sustainability

Planning for scale-up and the longer term sustainability of private sector mRDTs must happen from the outset. Malaria RDTs will only be available in the country's private sector if the RDT markets are systematically maintained and of appropriate quality. Forward thinking about sustainability should guide the choice of strategies and resources to be mobilized and deployed.

All activities should be guided (i.e. designed and implemented) by a vision of sustainability that is shared and documented by the key stakeholders. This vision will be country-specific and should clarify 'who does what' and 'who pays for what' within a set timeframe in the future (e.g. in 1 year, 5 years and 10 years), with the goal of decreasing reliance on external funding over time. Ideally, in a sustained, healthy market, every key player has the ability and incentive to play their role effectively in order to ensure that the key functions of the market are performed. It is important to keep the entire malaria diagnostic system in mind (i.e. public and private sectors and players) when developing the sustainability plan, as each part of the health system affects every other part. For example, if regulatory requirements are not revised or enforced as needed to support the implementation of quality RDT services, then poor-quality mRDTs might be procured and used in settings, posing safety concerns to patients.



KEY POINT

Summary of key questions for programme planning

Whom is the mRDT market failing to reach (i.e. assess market size)?

The total market size for expansion is the total *actual consumers* (total **USE**) over all *potential consumers* (the total **NEED**). Analysis of this gap through equity lenses such as age, gender, geography, wealth quintile and risk behaviours can help to determine which non-users and users the market is failing to reach and therefore the total potential for market growth.

How is the mRDT market failing (i.e. mapping, situational analysis and gap identification)?

Conduct a robust market mapping and landscape exercise to determine the key players in the relevant health market, the functions they are (or are not) performing, and how the enabling environment influences their capacities and incentives to perform. Measure market performance in terms of health trends, quality of use of health products and services, as well as the availability and use of quality, affordable products and services in the market.

In what areas does the mRDT market need support (i.e. planning for private sector scale-up)?

Determine the areas in which the coordinating group and other stakeholders are best positioned to make market developments, influence the incentives and/or capacities of relevant market players, and create a conducive environment to improve overall market performance.

What support will be provided (i.e. planning for private sector scale-up)?

Determine the steps to achieve the goals of the interventions and the metrics that will track progress in getting there.

Challenge

In Madagascar, despite a national policy to test all suspected malaria cases prior to treatment with ACTs, no legislation or regulation existed to guide which mRDTs to procure and who could use mRDTs, particularly in the private sector. While the availability and use of malaria diagnostics was high in the public sector, availability was much lower in the private sector, particularly in pharmacies and

drug shops (17). In the absence of a registration process for IVDs, the NMCP developed technical specifications to inform the procurement of RDTs in the public sector; however, these specifications were not aligned with [WHO recommendations](#) (18). The requirements for test performance were so high that only one product met the NMCP's criteria, effectively eliminating competition.

Solution

The NMCP convened stakeholder meetings that led to the development of new legislation to allow trained lay providers, such as drug sellers, community health workers and paramedical staff (e.g. nurses), to use and/or sell RDTs, including in the private sector. The legal act was developed in collaboration with the NMCP, WHO, regulatory authorities, private sector representatives, and pharmacists' and physicians' associations. The NMCP visited each director of the relevant MoH departments to advocate for private sector RDTs.

To address the lack of competition for RDTs due to the restrictive technical specifications, Madagascar's private sector mRDT taskforce advocated for a change in policy and a less stringent panel detection score threshold for mRDTs, in line with current WHO recommendations. As a result, RDTs can now be procured from six front-line buyers in Madagascar, thereby fostering a competitive marketplace to keep prices low in both the public and private sectors.

Learning

An aligned and enabling legislative and policy environment – as created in Madagascar – is key to ensuring universal access to diagnostic testing for malaria prior to treatment and stimulating the growth of such a market for sustained commodity supply. The Unitaid project, by way of a strong partnership in country, successfully advocated for legislation to allow sales by outlets (accredited by the

MoH) and the use of such tests by all trained health providers and lay providers. Finally, aligning the RDT technical specifications for procurement with WHO recommendations across both the public and private sectors can help to ensure the availability of quality-assured RDTs at low prices by stimulating market competition.

Drug Shop Policy Forum in Madagascar



Challenge

In Nigeria, several studies (19) have shown that between 60% and 85% of caregivers, especially those in “hard to reach” localities, obtain antimalarial medicines from Patient and Proprietary Medicine Vendors (PPMVs) and community pharmacies. PPMVs provide most of the FCM in informal private settings, but do not have formal pharmacy training.

In 2005, Nigeria revised its schedule of over-the-counter medicines to include ACTs. With ACTs no longer being prescription only, PPMVs could also distribute ACTs. Given their vast network and close-to-client infrastructure, PPMVs substantially increased access to ACTs. Nigeria’s National Policy on Diagnosis and Treatment of Malaria has been

consistent with WHO guidelines, recommending that all suspected malaria cases be diagnosed before treatment either by quality-assured microscopy or through the use of quality-assured RDTs. However, conducting malaria microscopy and RDTs in Nigeria has been the mandate of certified laboratory scientists and technologists. In practice, this meant that there was limited availability of RDT results for making immediate treatment decisions. Furthermore, PPMVs were not permitted by the Pharmacy Council of Nigeria (their regulatory body) to administer RDTs at the point of care, considering it an “invasive procedure” (19). A study found that more than 80% of children who were treated presumptively with ACTs tested negative (20).

Solution

To address this problem, the Unitaid project conducted an assessment of PPMVs that demonstrated their willingness to perform RDTs and to be trained and supervised. The National Malaria Elimination Programme (NMEP) then led a series of consultative meetings with the Pharmacy Council of Nigeria and other in-country regulatory bodies, including the Medical and Laboratory Council of Nigeria (MLCN), Association of Community Pharmacists of Nigeria, and the National Food and Drug Administration Council (NAFDAC). They presented justifications for the need to “task shift” to involve trained PPMVs and community pharmacists in the performance of RDTs. This consultative process culminated in a consensus decision that the Pharmacy Council

of Nigeria remove RDTs from the list of “invasive procedures” and allow registered PPMVs to carry out mRDTs for the detection of malaria before dispensing ACTs.

Subsequently, the Minister of Health drafted a waiver permitting non-laboratory persons to conduct mRDTs. This was an essential milestone in the project, with PPMVs and community pharmacists now permitted to better target treatment of malaria in the country. In turn, professional regulatory bodies and the MoH provided supportive supervision, mentoring and regular monitoring of the implementation of mRDT services in this sector.

Learning

Leadership by a government agency is essential to spearhead any initiative for legal, regulatory and policy change. The implementing agency’s

involvement of all stakeholders from an early stage through increased advocacy meetings and dialogue is important for a unified approach to change.

COUNTRY CASE STUDY

KENYA

SECURING COUNTRY COMMITMENT AND LEADERSHIP TO AMEND POLICIES AND REGULATIONS

Challenge

In Kenya, retail pharmacies and chemist outlets often serve as the first – and sometimes only – point to access care for many people. However, the retail pharmacy business in Kenya is highly fragmented and faces challenges with regard to the quality of products and services it offers. RDT services are conducted by laboratory technicians, but also by community health volunteers (CHVs). To expand RDT services to the private sector, Kenya piloted mRDT diagnosis through pharmacies.

The Kenya Medical Laboratory Technologists and Technicians Board (KMLTTB) and the Pharmacy

and Poisons Board (PPB) are both involved in the regulation of IVDs. The PPB's mandate is to provide regulatory oversight to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices. The KMLTTB's mandate extends to the regulation of all in vitro diagnostics to be used in the country, and the certification and registration of products to be used in laboratory science practice. It also regulates the professional conduct of medical laboratory technologists and technicians.

Solution

After initial consultation, the PPB supported the extension of mRDT services to pharmacists, but the KMLTTB did not authorize non-laboratory personnel to conduct RDTs. However, upon further analysis, it was found that a ministerial circular allowed CHVs to test and treat for malaria using RDTs under the iCCM strategy. This set a precedent and gave trained lay providers an opening for further discussion.

Ultimately, the KMLTTB issued a waiver for the purposes of implementing the project in the Coast

region. The project then arranged field visits for the KMLTTB to observe pharmacists conducting RDTs and to be involved in their training and supervision. The project developed RDT guidelines for non-laboratory personnel and results were shared with the MoH. The project raised the profile of the issue and engaged the Director of Medical Services. Escalating up for discussions with the MoH and presenting evidence were useful in showing that pharmacists could continue testing beyond the waiver period.

Learning

Before rolling out RDTs in the private sector, an assessment of the legal, regulatory and policy environment, key stakeholders and responsibilities will identify who can conduct RDTs and who can provide oversight for training and supervision. Through stakeholder consultations, and innovative pilot projects that draw upon local experience and solutions, concerns can be addressed and safeguards

put in place for successful implementation. The NMCP and the national coordinating group can lead the process of stakeholder engagement and regulatory revision. National and subnational government stewardship is essential. When faced with regulatory challenges, escalation to higher levels of decision-making can help to resolve problems conclusively.



2

Procurement and quality management of mRDT services in the private sector

Overview

Once readiness to proceed has been determined, establishing how to implement quality-assured RDT services to support improved FCM in the private sector is critical to the scale-up. Specific actions must be taken to ensure the quality of the product, the quality and safety of the premises where testing will be conducted, and the quality of end-user training. This section offers considerations for including private sector activities in the context of existing quality assurance (QA) systems for RDTs, or developing systems for both public and private sectors in the absence of existing systems. As in Section 1, this guidance expands on the *Universal access to malaria diagnostic testing manual* (sections 3 to 6).

The Action Steps in this section focus on the anticipated needs pertaining to target product specifications, RDT storage, supervision, referrals and surveillance. At all levels, implementation needs to link with malaria and child survival departments in the MoH and other relevant ministries so as to facilitate engagement with the private sector and vice versa. Specific areas where joint involvement is needed include training, supervision and monitoring.

Most countries have QA manuals for malaria diagnosis that guide the delivery of diagnostic services in the country, inform policies and technical guidelines, and follow existing regulatory requirements. The national coordinating group's situational analysis, as outlined in Section 1, will include a review of quality management systems. As such, it will offer an opportunity to improve existing RDT guidelines or to develop them where they are not yet in place, particularly with regard to engaging the private sector in the health system. Specific areas that need to be addressed are included in this section.

Key Action Steps in Section 2

Quality assurance: RDT products	
17. Determine preferred RDT characteristics and performance specifications	35
18. Conduct lot testing.....	36
19. Ensure that transport and storage conditions respect product requirements	36
20. Establish a plan for reactive and proactive post-market surveillance.....	37
Quality assurance: Providers	
21. Develop/adapt training and supervision support materials.....	39
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23. Implement supportive supervision	41
24. Assess supervision capacity and load	42
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Quality assurance: Premises	
27. Ensure guidelines for suitability and safety of premises	44
28. Implement waste management guidelines	45

CASE STUDIES

The two case studies at the end of this section cover several different issues related to the implementation of QA activities in the private sector.

Uganda: Assigning responsibility for RDT QA

Tanzania: Public-private partnership to improve quality of care of private providers

2.1 QUALITY ASSURANCE: RDT PRODUCTS

In order to ensure the procurement, distribution and use of quality-assured RDTs, a specific set of activities is required, spanning the entire supply chain. These activities should be supported by national QA guidelines and should address both public and private sector needs. The importance of having a body responsible for product-specific QA activities is illustrated in the Uganda case study at the end of this section.

**EXAMPLE****Harmonizing product performance specifications**

Under the Unitaid project, PSI, MC and partners made it an explicit aim to harmonize the private and public sector RDT specifications with WHO recommendations for RDT procurement.

RDT selection: Technical specifications for RDTs should be developed or reviewed by the NMCP sub-committee to ensure compatibility with WHO recommendations (18) (Action Step 17).

**ACTION STEP 17****Determine preferred RDT characteristics and performance specifications**

Based on WHO procurement recommendations, develop a list of RDTs eligible for registration and/or tender. Ensure that specifications are developed to create a market for well-performing tests and that specifications are aligned with WHO procurement recommendations. Share the specifications with national regulators in order to guide product registration, and share a list of products that meet specifications and are eligible for importation with RDT importers.

Conduct lot testing: Testing batches of RDTs before deployment and after deployment into the field is a key quality control measure. Currently, RDTs can be sampled from lots and then shipped for testing against well-characterized reference samples in WHO-recognized international reference laboratories. These laboratories include the Research Institute for Tropical Medicine (RITM) in the Philippines, which serves global needs, as well as the National Institute of Malaria Research (NIMR), New Delhi, India and the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos, Nigeria, which conduct lot verification for RDT batches imported into their respective countries. Anyone can utilize these reference services (e.g. regulatory bodies/authorities, NMCPs, NGOs, distributors, etc.) (21), but there is a discrepancy between the public and private sector in terms of lot testing. In the public sector, lot testing procedures are well developed, as the majority of RDTs are purchased by donor agencies who set a passing grade in lot testing as a requirement for use of funds. This is not the case in the private sector, however, where there are often fewer and less stringent controls on product entry and monitoring after deployment. In the private market, regulatory authorities should conduct post market surveillance (PMS) including lot testing and must directly engage importers in PMS of products destined for the private market in order to ensure that RDT QA activities are coordinated. Once RDT products arrive on the market, there should be processes in place to report concerns about product quality, conduct an investigation and take corrective actions. Importers and distributors should be aware of products that do not meet these requirements, which should ultimately be removed from the market.

Action Step 18 provides guidance on lot testing.



ACTION STEP 18

Conduct lot testing

Develop a process by which RDT quality control checks are performed prior to the release of products into the field/market. Currently, lots can be verified by a WHO-recognized laboratory (20): the Research Institute for Tropical Medicine (RITM) in the Philippines, which serves global needs, as well as the National Institute of Malaria Research (NIMR), New Delhi, India and the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos, Nigeria, which conduct lot verification for RDT batches imported into their respective countries.

Decide who will be responsible for selecting and sending RDTs to the lot testing laboratories and follow up on results. Determine who will pay for the lot testing of commodities imported for use in the private sector.

Agree on the process that will be followed for lot testing RDTs, e.g. who will be responsible for lot testing arrangements, who will act on any lot testing failures, and how. The same process should be followed for both the public and private health care sectors.

Importation, storage and distribution: mRDT performance can be negatively affected by exposure to high temperatures and humidity. Consequently, the manufacturer's instructions for safe storage and transport should be respected. It is therefore recommended that regulatory authorities take responsibility to ensure that minimum standards are established and enforced for the importation, distribution and warehousing of RDTs in public and private sectors alike. This includes setting minimum storage and space standards at the outlet level (Action Step 19). Fortunately, many major private sector distributors already have temperature-controlled warehouses and manage a range of pharmaceutical products safely according to required ISO norms.



ACTION STEP 19

Ensure that transport and storage conditions respect product requirements

Provision and dissemination of practical guidance and training for distributors and providers on the transport, storage and handling of mRDTs based on WHO-FIND manuals (22, 23).

Post-market surveillance: Post-market surveillance is needed to ensure that mRDTs continue to meet the same quality, safety and performance requirements over time. Post-market surveillance can be reactive (i.e. triggered in response to an event involving suspected diminished performance or anomalies) or proactive (i.e. to scan for potential issues prior to field deployment or release into the market, as described under action step 18). Guidelines ideally should address both passive post-market surveillance (e.g. vigilance through reporting of testing anomalies) and

active market surveillance, which involves supervisors physically visiting outlets to investigate testing anomalies experienced in the field (Action Step 20) – see Fig. 3.



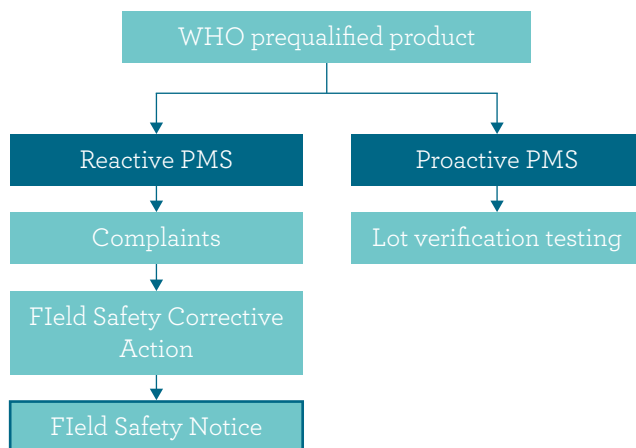
ACTION STEP 20

Establish a plan for reactive and proactive post-market surveillance

Identify a focal point to coordinate proactive and reactive post-market surveillance. This requires selection of RDTs for assessment and shipment to the existing lot testing laboratories.

WHO provides normative guidance on post-market surveillance for IVDs, which is available here: http://www.who.int/diagnostics_laboratory/postmarket/en/. This guidance can be adapted to the country context in order to develop schemes that function for both public and private sectors.

Fig. 3. Steps for post-market surveillance (PMS) of a WHO-prequalified product



Source: Post-market surveillance of in vitro diagnostics, World Health Organization, 2015

2.2 QUALITY ASSURANCE: PROVIDERS

Regardless of the cadre of staff (e.g. nurses, doctors, pharmacists or drug shop owners), mRDTs can only be used by personnel who have explicitly been trained in their use, so as to ensure quality and safety.

Training of health workers and supervisors

To avoid parallel systems and ensure alignment with the public sector, private sector health workers should be trained in using existing national approaches to malaria and fever case management. The key steps for public sector training are outlined in the Universal access manual, section 5, and therefore also apply when designing national RDT training programmes for private providers. These steps include:

- a) Sensitization of key stakeholders (e.g. professional associations, relevant government health managers, those in charge of private laboratories and health facilities, private health workers) before the training begins;
- b) Identification and training of tutors and supervisors (as a part of the national training of trainers [ToT]);
- c) Training of health workers using hands-on, participatory methods; and
- d) Integration of training into pre-service curriculum.

All of these steps are relevant for scaling up training in the private sector, bearing in mind a few key considerations detailed below.



EXAMPLE

Building provider confidence in results

The Unitaid project stressed the importance of building providers' confidence in mRDT results, as providers faced many more negative results than they expected. In settings with decreasing malaria incidence, describing the local epidemiological context as well as performing mRDTs and microscopy within the training demonstrated to providers that mRDT results could be trusted.

The Unitaid experience also underscored the importance of addressing case management of non-malaria febrile illnesses in order to ensure appropriate treatment (i.e. not providing antimalarials for RDT-negative cases). The action to take following the RDT result (especially for negative RDT results) and the integration of malaria testing into the overall management of patients with fever will depend on the private sector channel and cadre providing the testing service and on the nationally approved FCM algorithms.

Target training and training materials to new service delivery channels: Expanding access to RDT services through the private sector may mean that new health worker cadres with different backgrounds will be offering this service for the first time. In many countries, this will require task-shifting from laboratory personnel to non-laboratory personnel. While the overall architecture of the training should remain consistent across all health cadres, the training will need to be adapted to the particular health worker cadre and work environment. All of those planning to offer mRDT services should receive training in the current national guidelines for malaria diagnosis and treatment, as well as practical training on how to perform, interpret and report results and on appropriate waste management.

**ACTION STEP 21****Develop/adapt training and supervision support materials**

Adapt public sector training materials, including job aids, case management algorithms, troubleshooting guides, problem protocols, etc., for different cadres and levels of care. Examples of training materials used in the context of the Unitaid private sector project can be found here: see [PSI's FCM QA manual and toolkit](#) (24); [FIND's Troubleshooting guide](#) (25), which supports providers to identify mRDT anomalies and undertake corrective actions; [FIND's Protocol on responding to problems with malaria RDTs](#) (26), which defines the chain of actions when problems are encountered in the field; and [MC's e-learning training tools](#) (27).

Adapt training to better fit provider needs: Classroom-based training may be a challenge for some private providers to attend, as it may require them to forgo income from a day's work. It may also be difficult for some outlets to send more than one participant at a time so as to not lose business while attending. However, it is important to maximize the number of trained personnel at an outlet in order to avert the loss of capacity due to provider attrition. If a trained member of staff moves on, it may leave no one available to perform RDTs. Innovative solutions may be required to ensure that private providers receive high-quality training (Action Step 22). Simple adjustments to the timing of training delivery (e.g. in non-peak hours) and the modalities used (computer based vs. classroom) may be effective. See the example box below on e-learning and mentorship.

Ensure sufficient training to address negative cases: It is crucial that all training emphasize the correct protocol (based on national guidelines) for the treatment of malaria-negative cases. In some cases, providers may assess signs for other causes of fever (e.g. pneumonia). In other cases, the caregiver may be directed to refer to another facility for further investigation. Programmes are recommended to track the use of antibiotics in order to ensure that the introduction of mRDTs does not lead to increased misuse of antibiotics.

Include procedural steps for switching RDT brands: Compared to public providers, private providers may switch RDT brands if they can get them for a lower price or if there is a stockout. Training should always include a review of how procedural steps differ between mRDT brands on the market.

**ACTION STEP 22****Customize training**

Alternatives to exclusive classroom-based training such as computer-based training, or a mixture of classroom and computer-based learning should be explored to accommodate the work schedules of private providers. A modular curriculum can allow for training to be spread over several weeks, instead of on consecutive days. Furthermore, self-directed computer-based modular training allows participants to study at their own pace and based on their availability. Face to face intensive theory and practical sessions can then be compressed into a shorter time. In addition, training modules can be included as part of a continuous professional education curriculum. Directly engaging mRDT distributors or sales representatives in the training procedures which will foster a collaborative approach.



EXAMPLE

e-learning and mentorship

Under the Unitaid project, two training methods were tested as alternatives to long classroom-based training sessions: i) a 2-day blended e-learning course on febrile case management (led by MC in Nigeria and Uganda); and ii) ongoing mentorship (led by PSI in Kenya, Tanzania and Madagascar).

The blended *e-learning* course provided standardized interactive information and allowed providers to follow the training and revisions of the modules at their own pace. The facilitator part of the course allowed for the review of key topics, role play and practical demonstrations. For more information, see [Malaria Consortium: Diagnose and treat malaria \(Free Self-Paced Course\)](#) (27).

The ongoing *mentorship* approach allowed for continuous on-the-job training of providers and served to build the relationship between provider and supervisor. For more information, see [PSI's FCM QA manual and toolkit](#) (24).

Learning styles and preferences should be considered based on the cadre of staff and other training they have received (logistical arrangements, time available, etc.).

Involve importers and distributors in the training process: At a minimum, importers and distributors should be made aware of training plans so that they can appropriately forecast RDT needs. The Unitaid experience found that some importers and distributors may be willing to finance training, provided there is sufficient market demand. This opportunity could be explored as a more sustainable financing solution for training private providers.

Include private providers in malaria case surveillance reporting: One of the most significant opportunities presented by training the private sector in malaria diagnosis is to improve case surveillance efforts, which is a crucial component of effective malaria control. However, each country must consider how to incentivize private sector reporting – whether through financial or non-financial incentives, or as a requirement for registration. See Section 4 for a detailed discussion of malaria surveillance as a component of the M&E system.

Supportive supervision

As outlined in the Universal access manual, section 6, supervision is conducted at points of care in order to assess the quality and performance of diagnostic testing at all levels of service delivery. Supervision should address the work environment, RDT procedures and case management competencies. Supervision techniques include direct observation of procedures, verification of recorded data, identification of challenges, provision of on-the-job training and mentorship, provision of recommendations for improvement and implementation of corrective measures (see Action Step 23).

**ACTION STEP 23****Implement supportive supervision**

Adapt [supervision assessment checklists](#) (24) to new service delivery channels, e.g. drug shops should only be assessed on whether malaria-negative cases are referred, while private health facilities should be assessed on their management of malaria-negative cases and/or their referral practices. Meanwhile, identify a supervision body to use the checklists and ensure a system that gives them the mandate to perform their supervisory functions.

**EXAMPLE****Sanctions**

Ensuring that the supervision body has the authority to sanction an outlet in the case of substandard performance is critical to enforcing good quality standards of practice; this will allow the supervision visits to truly influence provider performance.

Under the Unitaid project, different supervision modalities were explored: In Uganda and Nigeria, professional bodies were mandated to supervise private providers within their profession, while regulatory authorities carried out inspections of premises and medicine availability. In Uganda, the district authorities, National Drug Agency and professional associations developed an integrated supervision plan. In Tanzania, Kenya and Madagascar, joint supervision visits were conducted by PSI-supported franchise supervisors and NMCP representatives, which enabled buy-in for the supervision system.

Avoid parallel supervision approaches: The same scope and approach to supervision should be applied to both public and private health workers. The NMCP, implementing partners, professional associations, and regulatory bodies should consider who has the time, resources and capacity to supervise the private sector and report the findings and recommendations back to the government. This may require the contracting of NGOs, professional bodies or others, and initial financing.

Allocate appropriate resources to supervision and mentorship: Supervisors should act as mentors and build long-term relationships with private providers in order to facilitate a supportive environment for their work. They can also coach providers in their diagnostic skills for ongoing quality improvement. As such, appropriate resources and time should be dedicated to building up the systems and capacity of supervisors to undertake their mentoring and coaching tasks. For more information, see the case study from Tanzania at the end of this section.

Develop a cost-effective supervision system: Introducing mRDTs into the private sector greatly increases the scale and diversity of the networks of providers offering diagnostic services. Therefore, it becomes even more critical to establish a supervision system that offers the greatest return on investment, i.e. provides optimal quality of FCM at the lowest possible cost (see Action Step 24). Supervision needs to respond to providers' needs and be targeted to their performance and potential client volume (see case study from Tanzania at the end of this section).



ACTION STEP 24

Assess supervision capacity and load

Once supervisors' caseloads have been defined, efforts should be made to increase their capacity before full scale-up to the private sector is achieved. Consider a system that targets supervision visits based on quality and client load (volume of clients seen by outlet type), bearing in mind that cost-effectiveness is the goal of tailored supervision.



EXAMPLE

Tailored supervision

PSI in Madagascar, Kenya and Tanzania worked in partnership with the NMCP to pilot a structured supervision system under the Unitaid project that scheduled supervision visits based on need (i.e. based on quality of care [QoC] assessment scores). All outlets were visited immediately after the training and then subsequent visits were scheduled based on the outlet's overall QoC score, as measured by a [supervision checklist](#) (24). Class C (poorest performing) outlets were prioritized and visited in the following month; high performing (class A) outlets were visited after 6 months; class B outlets were visited the following quarter. This allowed supervisors to develop their plans based on the needs of the providers.

Routine data collected by participating outlets in the Unitaid project found that roughly 70% of cases were seen by 30% of the outlets (15). This pilot experience informed the subsequent establishment of the Health Network Quality Improvement System (HNQIS), designed to support quality improvement delivered by health providers. The electronic android open source tablet-based app can work off-line and can link with the information management system Demographic Health Information Software 2 (DHIS2). It is principally focused on enabling quality assurance officers (QAOs) to:

1. Effectively plan their support visits prioritizing where support is required, and where it will have most impact
2. Undertake assessments with comparable scoring and benchmarking mechanisms
3. Consistently and effectively provide feedback and coaching following assessments
4. Monitor performance of providers over time in order to understand the return on their support efforts and conduct mid-course corrections (such as refresher trainings).

HNQIS additionally helps managers to more effectively manage large networks of health workers and has been adapted to monitor quality in diverse groups of health workers, such as drug sellers, social franchise workers, private clinicians, pharmacists, and mobile malaria workers.

HNQIS is currently live in more than 15 countries and supports various health services including family planning, post abortion care, HIV, tuberculosis, hypertension, IMCI, and malaria.

These innovations, if implemented with support of the NMCP, offer an opportunity to improve supervision systems within the public and private sectors in the most cost-effective manner.

1 **QoC Score:** Assessment of danger signs, RDT procedure, classification of patients' illness, provision of treatment as per guidelines, and counselling of patients

Integrate QA and surveillance data: While many national programmes have established information systems to gather case surveillance data (some of which also extend to the private sector), few have implemented systems that gather and analyse QoC data; even fewer have such systems in place for the private sector. Ideally, public and private sectors should join efforts to improve routine information systems for collecting both case surveillance data and QoC data.



EXAMPLE

Integrating surveillance and QA data

Through the outlets enrolled in the Unitaid project, PSI integrated both case surveillance data and QoC assessment results into the [DHIS2](#), an open-source health management information system (HMIS) (see the case study in Section 4 on monitoring systems in Tanzania). This information was presented in the form of dashboards, which allowed supervisors, PSI management/technical staff, and government counterparts to monitor the progress of each outlet, and to adjust supervision and training plans based on needs. This approach could be considered in order to equip supervisors and managers to better manage and improve the quality of care provided in the outlets they oversee.

In Uganda and Nigeria, MC piloted a smartphone application that included individual patient data and photos of the RDT result. This information was then uploaded into a database with the same indicators as the DHIS2 platform maintained by the MoH. These data enabled supervisors to remotely monitor provider competencies without going into the field. [Uganda also piloted Deki-readers® \(FioCorp\), a sophisticated step-by-step procedure with automated reader for RDTs linked to a web portal](#) (28). In the future, MC is working towards direct integration of the Deki-reader's routine data and supervision results within the DHIS2 platform.



ACTION STEP 25

Consider measuring quality of care

QoC data measurement systems for both private and public sectors could feed into the surveillance systems and allow for better targeting of supervision interventions.

Referrals

Training, supervision visits and all supporting materials (curricula, algorithms, etc.) should consistently address how to recognize danger signs and review the referral protocols specific to each health facility. Records of referrals should be kept by the provider. Expanding diagnostic capacity to the private sector may result in referrals from a private sector outlet to a public hospital or vice versa, depending on the availability of microscopy, second-line malaria treatment, and treatment of severe malaria. Setting up a referral protocol is needed (Action Step 26).



ACTION STEP 26

Implement referral protocols

Private providers must follow referral protocols:

1. Providers need to specify precisely where to transfer patients so that this information can be passed on accurately to patients.
2. Any patient with fever and danger signs of severe disease should be immediately referred by private providers (who do not have the capacity to manage severe cases) to an in-patient facility.
3. Patients returning for a follow-up visit in which treatment failure is suspected should also be referred to an in-patient facility with greater diagnostic capabilities.
4. Management of RDT-negative cases should be in accordance with provider training and competency.

Implementation needs to connect private sector RDT services to both private treatment facilities and the public health care system, specifically malaria and child survival departments of the MoH and other relevant ministries.

2.3 QUALITY ASSURANCE: PREMISES

Most countries have guidelines and policies for premises to follow in order to receive the requisite licence to operate. Private sector outlets performing mRDTs may need to have their licensing revised and/or comply with additional guidance over their premises.



ACTION STEP 27

Ensure guidelines for suitability and safety of premises

The guidance and licensing for premises need to be reviewed to ensure that they align with global best practices and include both public and private sectors. Ideally, guidelines should specify designation of private areas for testing in order to safeguard patient confidentiality; proper RDT storage; a well-lit, clean surface for performing the test; sufficient space for all the materials required; and appropriate waste management.

Introducing blood testing with RDTs at private sector points of care that have not previously managed such testing will increase the volume of both infectious waste (blood-contaminated sharps and non-sharps) and general waste on the premises (Action Step 28). To address these issues, NMCPs can consider the following:

- Explore the involvement of local health authorities and health committees in ways to safely dispose of waste locally. For example, the private sector outlet can take full sharps bins to the nearest public health facility incineration site.

- Involve a private waste management company to pick up sharps bins from outlets and take them to the nearest incineration site. A fee could be paid by the private outlet as part of the registration process in order to help cover costs.
- Pilot the production of individual incineration units at private outlet sites. Guidance is available on the construction and operation of small-scale incinerators in low-resource settings (29). Based on the volume of waste and needs of the specific context, these approaches can be piloted to expand the evidence base for their potential effectiveness.



ACTION STEP 28

Implement waste management guidelines

Review existing national guidelines to incorporate feasible solutions for waste disposal in urban and rural settings in the private sector. Ensure that each private sector outlet has sharps boxes and gloves.



EXAMPLE

Dealing with hazardous waste

Under the Unitaid project in Uganda, the RDT distributors provided sharps boxes (ensuring a spare was also available) and the providers themselves bought gloves. During training and ongoing supportive supervision, adherence to national guidelines, biosafety and separation of waste were emphasized. In the urbanized district of Wakiso, two certified hazardous waste service providers were contracted to collect the waste and dispose of it in established incineration facilities – initially every month and then quarterly once demand for the services was established. In rural mid-west Uganda where certified service providers were not available, providers were orientated to take their waste to the nearest public health facility with an incinerator or pit for burning. While this service was provided as part of the project, the health providers have indicated that they are willing to pay for approximately half of the cost going forward.

Challenge

At the onset of the project in Uganda, there was no routine approach to assure the quality of RDTs in-country. Furthermore, medical devices including mRDTs were not covered by the existing National Drug Authority (NDA) Act, which mainly applied to drugs and cosmetics. Each profession was regulated by a professional board set out by an act of law, but the responsibility for regulating drug shops was

not clear. Malaria RDTs could only be performed by qualified laboratory personnel under existing regulations. During project implementation, routine support supervision by the professional bodies revealed several RDT quality issues, including false-negative test results and insufficient buffer volume in some test kits.

Solution

To work within the restrictions of the existing laws and regulations, MC submitted the project proposal for ethics review, which was granted. Then, the MC project led a process to bring all stakeholders with a role or responsibility in mRDT to agreement on a strategy for mRDT quality control in the country. The NDA is responsible for IVD regulation, including post-market surveillance. They aligned mRDT technical specifications with those of the MoH NMCP. The NDA and MC signed an MoU outlining all of the issues related to the quality control of RDTs in Uganda. In addition to NDA officers at the ports of entry, an additional liaison officer was assigned at the Office level to facilitate QA activities, including compliance with technical specifications for importation/registration, pre-distribution lot testing, following up on complaints and implementing corrective actions upon confirmed product defects.

Despite passing initial lot verification procedures, complaints of RDT quality arose during implementation. Issues included false-negative results and buffer vials with variable volumes and

dispensing problems. The project assessed over 170 randomly selected single-pack RDTs using the lot QA sampling methodology (30). All RDT cassettes were present in all of the packs opened and appeared adequate. No anomalies were found during evaluation of the RDTs against reference blood samples. However, some abnormalities were encountered with the single-use buffer vials. These potential problems and how to address them were covered at subsequent training workshops. To address insufficient buffer volumes, the project team launched an official complaint to WHO, trained the health outlet providers on how to monitor the buffer vial volume using a visual aid (supplied by the manufacturer as part of a corrective action plan), and replace inadequate vials with new ones. The team agreed that any problematic lots were to be sent for re-testing at the WHO-FIND-recognized laboratory in the Philippines. A complaint form was developed to record future anomalies. A warehouse monitoring tool was also introduced to continually assess the buffer volumes.

Learning

Private sector providers have to be confident about the quality of products being used and the results generated in order to be able to promote the use of the products. Consequently, routine quality control

procedures are needed. Clear roles, responsibilities and mechanisms to investigate complaints are also needed.

COUNTRY CASE STUDY

TANZANIA

PUBLIC-PRIVATE PARTNERSHIP TO IMPROVE QUALITY OF CARE OF PRIVATE PROVIDERS

Challenge

To improve the case management of malaria in Tanzania, the focus is to maintain high coverage of the parasitological diagnosis of malaria in both public and private facilities. To ensure provider quality across the health system, government supportive supervision is supposed to address both public

and private health facilities. However, in practice, the private sector is not consistently supervised or supervision is not rigorous enough in relation to the quality of services delivered. The Unitaaid project seized an opportunity to standardize the quality system for FCM in private health facilities.

Solution

PSI/Tanzania and WHO, in collaboration with the NMCP, sought to develop a comprehensive approach to [improve quality of care for FCM \(24\)](#). The system was piloted with a view to expand beyond the project if the system proved successful.

Following a condensed two-day training (as providers were not willing to leave their clinics for long periods of time) that was aligned with the national mRDT curriculum, providers were supervised by PSI QAOs with standardized checklists addressing the mRDT procedure, diagnosis and treatment. This information was entered on android tablets with offline data collection capability and assessment data was

uploaded to DHIS2 (the open-source software used by the government of Tanzania under their HMIS), automatically when a connection was available. This allowed supervisors, PSI management/technical staff, and the government to monitor progress and adjust supervision and training plans based on need.

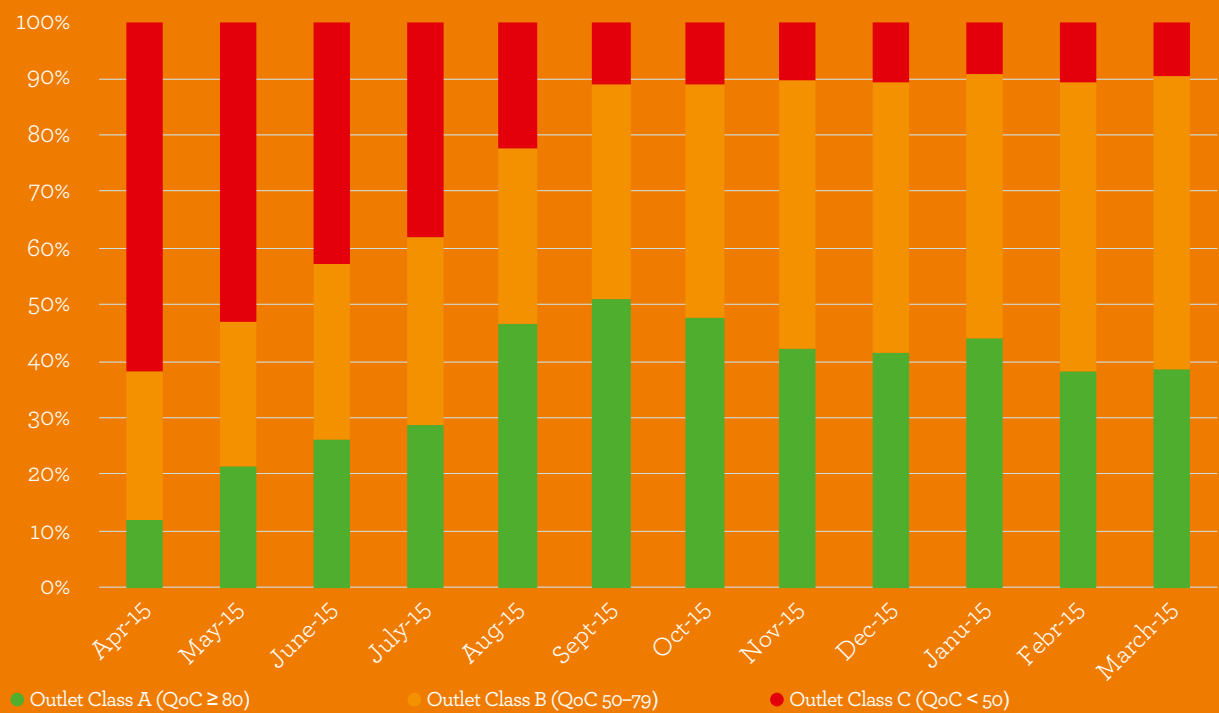
All outlets were visited immediately after the training and subsequent visits were scheduled based on the outlet's overall QoC score, as measured by the [fever case management assessment checklist \(31\)](#). The poorest performing outlets were prioritized and visited the next month; higher performing outlets were visited after a longer period.

Learning

Overall, this training and approach to supportive supervision (conducted in partnership with the NMCP and WHO) improved the QoC of providers (see Fig. 4). More importantly, this approach offers an example of how to align a QoC monitoring system across public and private sectors through joint supervision visits and entering/analysing data

through the DHIS2. For authoritative supervision and project oversight, the government needs to take over the leadership role from the very beginning of the project. Spot checks are not sufficient; systematic supervision and mentorship are required to improve quality of care.

Fig. 4. Improvements in QoC scores over a 1-year period among 546 enrolled private health facilities in Tanzania







3

Stimulating supply and demand for mRDT services

Overview

In addition to establishing QA procedures, key stakeholders need to develop a plan to incentivize the engagement of the private commercial sector. This section outlines some of the key activities needed to ensure the supply and demand of mRDTs by incentivizing the private sector.

This section provides guidance on how to engage with private sector supply chain actors, such as manufacturers, importers, service providers, retailers and consumers (i.e. those in the orange box in Fig. 2) in order to stimulate supply and demand for mRDT services.

Key Action Steps in Section 3

Supply chain stimulation

- 29. Make a business case for mRDTs to supply chain partners.....52
- 30. Address leakage and stock management54
- 31. Create easily recognizable packaging and labelling for quality RDTs.....54

- 32. Consider the need for price intervention.....55

Demand generation

- 33. Develop a demand creation strategy ...57

CASE STUDIES

At the end of this section, there are three case studies addressing different issues related to the supply chain for mRDTs.

Uganda: Strengthening supply chain systems

Kenya: Supply chain stimulation

Nigeria: Leakage of public sector RDTs into the private sector

3.1 SUPPLY CHAIN STIMULATION

The aim of supply chain stimulation is to create a competitive marketplace. This includes increased demand and availability of affordable, quality-assured RDTs at a global, national and subnational level. A key challenge is understanding how to stimulate the supply chain such that the priorities of both public sector and private sector stakeholders are met within the regulatory context (refer back to Fig. 2 in Section 1).

This section describes how the various stakeholders in the supply chain can be engaged; in what ways the availability and affordability of RDTs can be achieved in the supply chain and how demand – the ultimate driving factor in creating a sustainable supply chain for RDTs – can be generated.

Stakeholder engagement

Because demand and use of RDTs in the private sector has remained low in most endemic countries, RDT manufacturers and their agents and distributors have largely focused on public sector contracts. Manufacturers and importers will therefore need to be convinced that sufficient demand for RDTs exists in the private sector.

At the top of the supply chain, manufacturers and importers are attracted by a clear business case (Action Step 29). Therefore, it may be useful to show them the estimated market size for RDTs in the private sector (Action Step 10; Section 1), as well as the potential revenue and hence profit available. Other motivations may include the prospect of more favourable regulations for registering or distributing RDTs (Section 1.4), the roll-out of training and supervision programmes targeting private sector providers (Section 2), or the anticipated effect of behaviour change communication (BCC) campaigns on client behaviour. Given their limited market visibility, RDT manufacturers may need to be linked with importers who are interested in procuring RDTs. Refer to the case study from Kenya at the end of this section to see how the supply chain was stimulated under the Unitaid project.



ACTION STEP 29

Make a business case for mRDTs to supply chain partners

Manufacturers and importers will have to be convinced that sufficient demand exists for RDTs. Specifically, they may want to know the number and type of outlets that exist in the private sector, either registered or not, that are allowed to sell and/or perform RDTs. If importers are interested in registering a specific brand and type, they may want clarity on the process and costs involved in registering the RDT, and whether there are associated taxes and tariffs. All of this information should be available from the situational analysis (Section 1), specifically the assessment of total market size (Action Step 10).



EXAMPLE

Linking importers and manufacturers

In Tanzania and Kenya, the Unitaid project collaborated with CHAI to negotiate prices and introduce importers to RDT manufacturers. Interested importers included not only large pharmaceutical importers, but also smaller ones who were looking to expand their business to new distribution channels. Even the smaller importers were able to place orders at low prices without a minimum order quantity.

Over time, it was found that market forces led to consolidation, with only the most successful RDT brands and importers remaining at the top of the supply chain.

Without efforts to spur demand (such as provider training and case management supervision, medical detailing and BCC/awareness campaigns of the need to test before treatment), manufacturers or importers may not be willing to enter the market.

The lower end of the supply chain engagement can take the form of provider training on RDT use and case management and/or detailing visits made by wholesalers to help market the mRDTs. Innovative approaches can be used to attract interest and encourage participation in these activities, such as provider training certification, accreditation of outlets, free biosafety services (sharps boxes, gloves and waste management services), branding of outlets, promotional materials, access to promotional deals, etc. Questions of who should be responsible for implementing these activities, who pays and for how long are dependent on the individual country context and private sector supply chain structure. As such, these aspects should be considered jointly and agreed upon with all stakeholders. These considerations should be incorporated into work plans during the situational analysis phase in Section 1.



EXAMPLE

Bundling services

Bundling is a marketing strategy that joins products or services together in order to sell them as a single combined unit. Bundling allows for the convenient purchase of several products and/or services from one company.

Under the Unitaid mRDT project in Uganda and Nigeria, MC proposed an ‘enhanced RDT’ commodity that resembled the marketing strategy of product/service bundling. Specifically, the manufacturer was requested to offer the RDTs, medical detailing, product demonstration, product literature and marketing, product performance monitoring and waste management services as part of the negotiated agreement costs. The negotiated cost also included a direct subsidy to the manufacturer.

The attractiveness of this model for the manufacturer centres around the opportunity to forge strong relationships with governments and other national stakeholders; engage in social responsibility programmes; harness valuable technical skills in the production of communication materials; and build capacity. In the long term, manufacturers will be seen as providers of quality RDT commodities and services, such as detailing, training, waste management and promotion, which should in turn increase the demand for RDTs from distributors and outlets.

Availability

Efforts to promote availability could include a number of diverse activities and may target manufacturers, importers, wholesalers or retailers. Large supply leakages from the public sector (whose warehouses may be overstocked) may result in a saturated market, thereby undercutting the market price for RDTs and making it difficult to maintain a competitive market. As a result, it would be less attractive for any supply chain actor to enter or stay in the market (see Nigeria case study at the end of this section, and Action Step 30).



ACTION STEP 30

Address leakage and stock management

Prevent leakage from the public sector into the private sector, as this may cause major disruption in the private sector markets. This can best be done by having a strong public-private partnership with regular communication.

Regular market intelligence should be collected and, if leakage from the public sector is seen to be a problem, a joint investigation between MoH inspection services and distributors should be carried out and appropriate action taken. The same procedure would apply in the case of black market RDTs from neighbouring countries.

The introduction of RDTs also provides the opportunity to guide training sessions and on-the-job training on stock management for providers, including FIFO (first-in, first-out) and FEFO (first-expired, first-out) principles, storage conditions, stock inventory methods and stock ordering. Logos or preferred packaging sizes may make it easier for supply chain actors to promote specific products or to sell in small or large quantities. Logos and distinct packaging also allow for differentiation between private and public sector market items, which is important for consumers (see Action Step 31).



ACTION STEP 31

Create easily recognizable packaging and labelling for quality RDTs

Create recognizable labelling and packaging and publish a list of quality-assured RDTs for providers. The labelling should ideally differentiate between private and public sector products, and may include logos that are linked to materials presented and circulated during demand creation activities.

A symbol denoting that the RDT brand is a quality-assured product could be applied to the boxes of the mRDT products designated for national use.

Logos require promotion such that both supply chain actors and patients can recognize the logo and understand what it stands for. Most brands can be packaged in single packs (all components and accessories included in a single package), or in multiple (or hospital) packs of 5, 10, 15 or 25 RDTs in one box with one or two buffer bottles. Smaller drug shops will likely prefer pack sizes that are smaller than the hospital pack. However, single-packaged RDTs are

slightly more expensive than hospital packs and at risk of being sold for self-testing, which is not their intended use. Some single-packaged tests come with a small vial that contains the correct volume of buffer, potentially reducing the risk of applying the incorrect number of drops or swapping buffers with other test kits.

Although providers normally have one or two brands that they prefer, they will realistically switch products if stockouts occur or if prices between products differ significantly. Sensitization methods, such as detailing visits by company representatives, training and clear instructions on the various brands and their differences, are essential for providers so they do not make procedural errors when changing products. The NMCP should draw up a list of approved brands, which the National Drug Authority should enforce.

Ultimately, availability is driven by the demand of the end user. Retailers/providers, wholesalers and importers will only stock products if they anticipate that they can offer and sell the product immediately.

Affordability

The selling price of the RDT may need to include other costs associated with providing the RDT service (e.g. gloves, waste disposal, human resources to conduct the test). In addition, understanding the value-added costs and mark-ups required throughout the supply chain from manufacturer to provider and client will help to determine whether some form of price regulation could stimulate the market, at least temporarily.

Often, importers, wholesalers and retailers will use blanket percentage mark-ups across a range of products, making it difficult to influence the pricing of a specific product like an RDT. For there to be a sustainable market, any subsidies should be time-limited and/or reduced gradually over time, thereby allowing market forces to establish the “true” price. Any subsidies should be nationwide or cover a distinct geographic scope in order to prevent leakage to areas that are not covered (Action Step 32).



ACTION STEP 32

Consider the need for price intervention

Consider whether price interventions are needed, such as marketing in tiers (e.g. discounts offered for higher volumes), temporary subsidies to prime markets, or even offering free RDTs for a limited time.

It is, however, important for profit margins to be maintained throughout the supply chain and for the price of an RDT to the client to be set lower than that of the first-line adult-strength ACT, so as to discourage presumptive treatment.

Ultimately, competition among importers, wholesalers and retailers will contribute most to a low yet sustainable end-client price. Below are a number of potential methods that can be used to ensure affordability at the client level. These methods are not mutually exclusive and can be used in combination to achieve best results.



EXAMPLE

Methods to improve the affordability of RDTs

1. **Negotiate low input prices and low supply chain mark-ups:** Providing importers with access to low negotiated prices from the manufacturer can be used as an incentive to keep mark-ups at a low but sustainable level. This mechanism ensures that the lower price is passed on to the wholesaler or retailer. It has been used in Kenya and Tanzania with some success (CHAI projects (32), Unitaid PSI projects (15)). The approach's success is dependent on the degree to which the manufacturers are willing to reduce their profit margins and the importers, wholesalers and retailers are willing to adhere to the agreed low mark-ups. As prices are negotiated, it is important to understand that it will not be an attractive proposition to all manufacturers, particularly when the negotiated price comes close to the manufacturing cost. Smaller scale manufacturers will find it difficult to compete at these prices and will potentially exit the market. It is also critical to ensure that the quality of the RDT is not compromised in an attempt to reduce manufacturing costs and improve profitability at the new lower price point.
2. **Set a recommended retail price (RRP):** In countries where permitted, an RRP, whether enforced or not, can help to keep mark-ups low throughout the supply chain. However, care must be taken when setting the price. Since most RDTs are purchased in U.S. dollars, local currency fluctuations will affect the price in local currency and hence the supply chain mark-ups on the RDT. The RRP also needs to be communicated to a wide consumer base. Finally, expansion into more rural areas will increase distribution costs that could possibly lead to different end prices for rural customers (unless a subsidy is put in place).
3. **Provide a subsidy for the products:** Subsidies can be in the form of a co-payment to the manufacturer, as done under the Affordable Medicines Facility–malaria (AMFm) or under the Unitaid RDT project in Madagascar, Uganda and Nigeria. Under the Unitaid project, the subsidy amount was calculated using value chain analysis (VCA), allowing the supply chain partners to maintain their profit margins. PSI did not pay the subsidy to the manufacturer directly, but rather sold the directly procured RDTs to importers and wholesalers at a subsidized price.
4. **Removal or waiver of tariffs:** In some countries, IVDs are subject to value-added tax (VAT), while therapeutics are not. In most countries, an administrative importation charge is also levied. These types of additional costs will make the RDT more expensive, with the cost being passed down to the client. Clients meanwhile will tend to avoid costly testing if the medication is well tolerated and less expensive. In these cases, advocacy with the MoH through the Ministry of Finance or other relevant ministries to remove VAT and other taxes/fees could create a more favourable situation, decreasing the cost for importers by potentially 15% to 20%.

3.2 DEMAND GENERATION

Much like importers, private sector providers and patients are often unaware of the need for confirmatory diagnosis of malaria before initiating treatment. While the provider must be aware of the business case and the surrounding legal, regulatory and policy issues, the client must first be aware of how testing with an RDT benefits him or her directly and understand the public health benefits of testing before treatment. This is best done through demand creation strategies (see Action Step 33).



ACTION STEP 33

Develop a demand creation strategy

Demand generation activities must focus on both the provider and the client in order to ensure that they both understand the benefits of testing with an RDT before treatment.

Mass media campaigns should coordinate the national public health message with messages that will influence the behaviour of providers.

Initial campaigns can run for 3–6 months, followed by a maintenance period to keep awareness high.

With proper training and supervision, providers who can be convinced of RDT trustworthiness, in turn, communicate this to their clients.

Mass media campaigns

The timing of mass media campaigns is extremely important. Campaigns should start immediately after providers are trained and RDTs are available in the outlets. All campaigns should be evaluated to see if the messages have had the desired impact or if any changes are warranted.

Mass media activities should be organized by the MoH and funded as appropriate, while other marketing initiatives (such as point of sales, posters, etc.) could be conducted or partially funded by the manufacturers or other implementing organizations.

Below-the-line activities

Other marketing activities (often referred to as ‘below the line activities’) focus on provider behaviour change and interpersonal communication (e.g. product/brand positioning for consumers and providers, communications objectives, message selection). Providers’ confidence in RDTs can effectively generate demand in situations where providers are serving regular clients with whom they already have trusted relationships.

It is more challenging to create demand in settings where providers serve drop-in clients and therefore no provider–client relationships have been established. In such cases, the provider will have to use interpersonal communication to convince the client to take a test; at the same time, the provider must consider the time and profit factors related to loss of other clients who are waiting to be served. Since the time it takes to provide quality malaria diagnostic testing services may outweigh the profits from selling the RDTs themselves, demand creation activities focusing on the service being provided rather than exclusively on the product itself could be essential for increasing availability and uptake.

Provider behaviour change communication (PBCC) is a key approach to generating demand for mRDTs. PBCC builds on the literature review and situational analysis to uncover and address barriers to providing malaria diagnostic services with mRDTs. It is also useful to examine analogous situations in which people’s biases have been overturned and norms around diagnosis have shifted. PBCC approaches must be developed with the understanding that providers do not operate in vacuums and are often influenced by those around them, including those in more powerful positions (e.g. supervisors, health administrators, policy makers, etc.). The landscape analysis will also help to uncover the contextual factors and various influences that might contribute to bias or provider ignorance, in addition to personal barriers. Solutions should then be tested in order to ensure that providers are able to operate within an enabling environment that will help them to sustain their learning and agency.



KEY POINT

Key considerations for generating demand:

- As in other health areas, interpersonal communication, and in particular word of mouth from trusted community members or family members, seems to have the most impact in generating demand from the consumer's perspective when supported by mass communication approaches.
- Keep messages and communication objectives simple. For example, the acronym 'RDT' is not clearly understood; consequently, consumers may fail to recognize and respond to the promotion of RDTs. "Malaria testing available here" is clearer and has generated better demand at project outlets. Messaging should also focus on the benefits to the customer, such as speed, simplicity, reliability and affordability.
- Make differential use of various mass media and interpersonal communication channels. For example, follow up radio messaging with roadshows or door-to-door promotions.
- Engage trainees: Offer Continuing Medical Education, job aids, troubleshooting guides, etc.
- Consider distribution of promotional clothing (e.g. shirts, badges, caps) to providers.

Examples of promotional materials for both clients and providers

Kenya



Madagascar



Tanzania



Uganda



3.3 ONGOING MARKET LANDSCAPING

As described at the end of Section 1, during the pilot phase, a continuous assessment of the market is needed in order to test assumptions, identify lessons learned and respond to unexpected challenges. This process needs to continue during scale-up. Some challenges are more frequent in the private sector (e.g. RDT leakage), but others are shared across public and private sectors (e.g. high staff turnover and perceived discordance between mRDT and microscopy results). Wholesalers and in-country distributors could be tasked with ensuring the

sustainability of the private mRDT market. Sustainability will, in the longer term, depend largely on the programme's market stimulation and a conducive policy and regulatory environment. Implementation activities should help to build private providers' confidence in and clients' acceptance of RDT results, e.g. through medical detailing, mentoring and BCC. Private sector providers are profit-driven and need to make sales. If sales of antimalarials are low in the context of changing malaria epidemiology or seasonal transmission, sales of RDTs could help boost profits. In many cases innovative solutions may be required as illustrated in the case study in Uganda at the end of this section.



EXAMPLE

Common implementation challenges encountered in the private sector

RDT leakages from other markets: As mentioned, additional commodities entering the market and not being controlled or accounted for by the project can create several problems. Markets are driven by incentives for distribution based on profit margins on the one hand and consumers demanding access to testing at affordable prices on the other. When commodities such as RDTs leak from the public sector into the private sector markets, these market constellations and incentives change such that they may reduce demand. For example, lower priced or free RDTs “leaking” from the public sector may adversely impact the incentives for distributors to distribute testing devices and for consumers to buy them at a price that is higher than that of the “leaked” commodities. Furthermore, storage and transport conditions for leaked products are unknown and therefore quality may be compromised.

Reporting and surveillance in the private sector: Private providers may not be prepared to take over functions outside of their profit-making activities. While public sector RDT providers often accept reporting of patient data as part of their job profile, private providers often lack adequate capacity (training, education, infrastructure) to contribute data to dedicated, often complicated HMISs. In these cases, the project needs to create incentives and mechanisms for private providers to collect and report data (see Section 4 on M&E).

Provider attrition: Attrition of trained providers is a common problem that has hindered private sector efforts to date. Outlets sometimes only have one salesperson to sell RDTs and provide testing; or, when there are multiple staff, often only the principal salesperson has received RDT training. During implementation, the aim should be to train several providers per outlet in anticipation of attrition. For obvious reasons, there may be lower attrition rates with providers who both own and work in their shops.

Procurement and logistics challenges involving stockouts of commodities, supply of poor-quality mRDTs and inappropriate storage of mRDTs should also be anticipated. The information from the situational analysis should be used to address these challenges.

COUNTRY CASE STUDY

UGANDA

STRENGTHENING THE SUPPLY CHAIN

Challenge

In Uganda, a market analysis was conducted by Malaria Consortium to better understand the dynamics of the private sector market for mRDTs. A supply chain analysis (VCA) established the actors present, their responsibilities and their possible pricing strategies. Local distributors who were affiliated with manufacturers' representatives in the country were assigned to participating outlets. It was assumed that these distributors would use their existing networks to ensure continuous product availability.

Implementation was met with significant challenges. Three months after RDT distribution commenced in

participating outlets, it was noted that stockouts were prevalent. On average, 60% of outlets experienced stockouts within a period of two weeks. It could take up to four days for the sales representatives to deliver RDTs in order to restock. Distributors also raised complaints about increasing operational costs, as outlets were spread across large geographical areas. The majority of outlets did not place orders that exceeded one pack of 25 RDTs. This meant travelling long distances (over 10 km) to deliver a single pack of RDTs. As a result, RDT sales remained low and lagged far behind initial expectations.

Solution

To address these challenges, MC assigned supervisors the additional task of medical detailing (i.e. to educate providers about mRDTs and to offer more products if needed to replenish RDT stocks). To cater for the expansion of RDT services into rural areas, the number of supervisors (now also undertaking the task of medical detailing) was increased from 10 to 22. Sub-distributors were also introduced under the direct supervision of the distributors. These measures, together with a timely mass media campaign, contributed to substantial stimulation of the market. Sales increased by a factor of more than 10, from a monthly average of fewer than 4,500 kits to more than 56,000 mRDT kits. Setting up sub-

distributors in major trading centres further cut operational costs, as there was no longer a need for long-distance travel. Simultaneously, these activities led to increased competition among supervisors/detailers to ensure that their respective outlets had products at all times; stockouts implied losing sales to other detailers or worse to other mRDT brands on the market, thereby losing out on their sales commission. To promote their products, distributors' representatives offered to conduct training sessions for the detailing team on their product range and marketing skills. They also offered to occasionally engage the detailing team and assimilate them into their system as part of a sustainability plan.

Learning

This case study identifies a few creative solutions to address low sales and stockouts, namely by expanding the scope and number of supervisors (i.e. adding the role of medical detailing plus additional recruitment) and adjusting the supply chain to

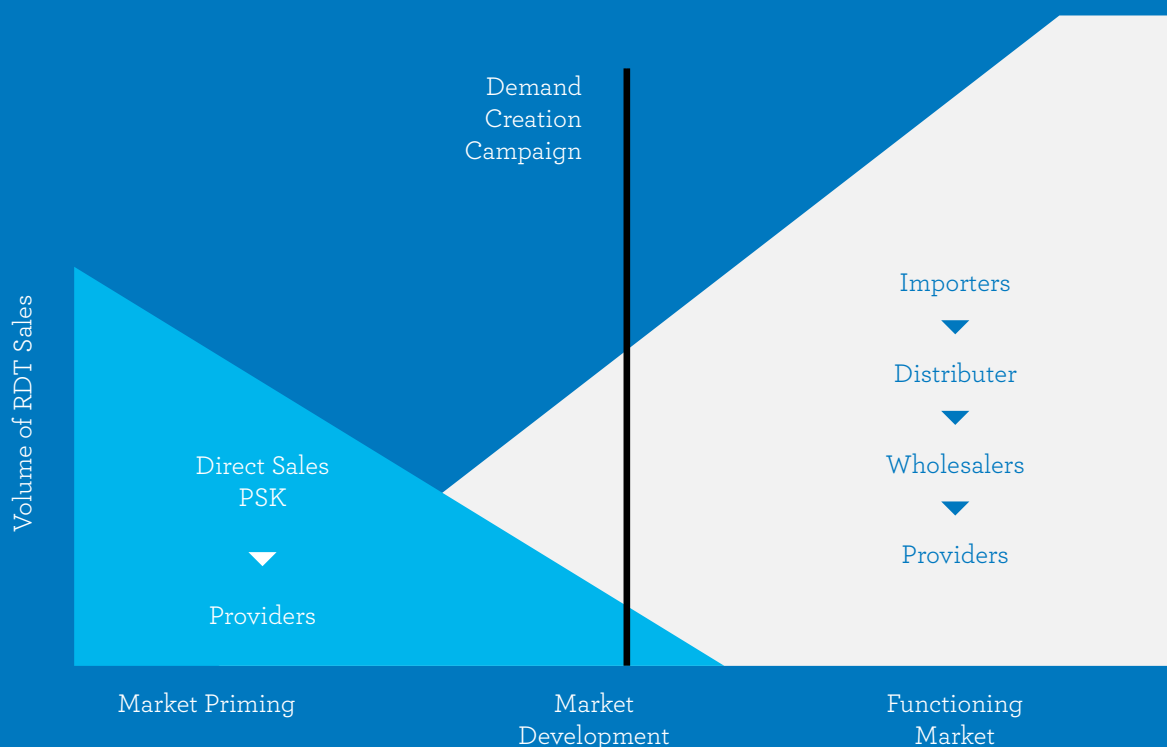
include sub-distributors, thereby reducing the cost of transport. Other organizations should collaboratively discuss innovative solutions to similar challenges in other country contexts, drawing on the experience in Uganda.

Challenge

Historically, the availability of mRDTs in Kenya’s private sector has been low. In 2014 availability was 29% in private health facilities and 15% in registered pharmacies, compared to 68% in public health facilities (33). Population Services Kenya’s (PSK) total market analysis identified several constraints that were contributing to market underperformance. One constraint was related to the unwillingness of importers to import RDTs and of wholesalers and distributors to stock RDTs. The reason given was the

low profit margins and low demand from consumers, who preferred to be given antimalarials without testing. Related to this lack of interest was a lack of communication to drive demand for testing prior to treatment. Another constraint was inadequate quality systems and labour capacity. Potential private sector providers were not aware of the national malaria test and treat policy, and private providers were not trained to perform RDTs.

Fig. 5. Schematic of market development activities facilitated by Population Services Kenya (PSK)



Solution

Since importers and wholesalers were not willing to stock RDTs, PSK first decided to prime the market through direct sales to health facilities and pharmacies. In the interim, they continued to engage the suppliers in order to demonstrate the

increasing market potential. PSK then tapered off direct sales by linking providers to wholesalers and wholesalers to distributors within the project areas (Fig. 5). Once providers started testing, patients began to demand a test prior to treatment. Subsequently,

the providers were interested in continuing to offer RDT services after the Unitaid project period ended. Based on this experience, PSK approached importers and distributors who were then introduced to wholesalers and also linked to providers.

With regard to demand creation, PSK engaged the MoH in developing a communications campaign

to promote testing prior to treatment. The MoH is now planning to scale up the campaign country-wide. The project also advocated with the MoH to include private providers in their case management training that previously focused exclusively on the public sector.

Learning

A total market analysis (refer back to Fig. 2 on market development) can help the project to anticipate the key systemic constraints leading to market failure and underperformance. Both supply-side and demand-side constraints should be addressed

for a market to be functional. Where there is little penetration of RDTs, a two-pronged demand creation campaign targeting both providers and consumers will be useful.



Challenge

In Nigeria, through the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), 25 million mRDTs were procured for the public sector and a private sector initiative covering a total of 2,400 Patient and Proprietary Medicine Vendors (PPMVs) – 100 in each of 24 high-impact states. Subsidized RDTs and ACTs were distributed to the trained providers and initially, in order to stimulate demand, the RDTs were distributed **free-of-charge** to PPMVs and private clinics. The Unitaid private sector mRDT project targeted three of the same states, and project implementers chose to provide subsidized bundled RDT services as an alternative model for generating a private sector market. While the Unitaid project members were aware of the free RDT distribution via

the GFATM private sector initiative, the magnitude and level of the impact the free RDTs would have on sales of commercial RDTs was not known.

Coupled with the distribution of free RDTs, there was significant leakage of RDTs from the public to the large wholesale markets, causing market saturation. The leaked RDTs were sold at very low prices, significantly undercutting the price of RDTs imported through the Unitaid mRDT project supply chain partners. This, in turn, prevented the Unitaid private sector initiative from moving RDT stock and hindered the establishment of a sustainable and profitable mRDT market.

Solution

Two national stakeholder meetings were convened by the NMEP and WHO to discuss the factors posing serious challenges to market stimulation and sustainability. Participants at the meeting represented professional associations, regulatory authorities, and the Federal MoH. Supply chain partners were provided with solid evidence that stock movement was lower than expected, and requested to develop alternative stock management plans to circumvent the negative impact of the leaked public sector procured products on the open market.

The NMEP initiated discussions with state governments to mitigate the pilfering from state stores caused in part by large volumes of stock being delivered to the stores but not distributed

to lower health facilities or stores due to lack of funds. The NMEP emphasized the serious need to provide funds for distribution and logistics in order to guarantee RDT delivery to service delivery points. The NMEP also resolved to improve the quantification for mRDT procurement in future GFATM funding rounds.

Partners also resolved to support the NMEP in its efforts to stem the leakages by providing information on any confirmed incidence of public sector supply on the open market. This included an agreement to obtain information on actual quantities of available mRDTs sorted by product type, brand and expiry date in order to support investigations and guide decision-making.

Learning

Government procurement of mRDTs should be based on a thorough quantification exercise using reliable consumption data and not just the number of fever cases. The NMEP should further engage supply chain partners a source of information on the prevailing market situation with regard to the types of RDTs on the market and their sources. These interventions will

help to improve stock monitoring at the government stores around the country. RDT leakage may be very difficult to resolve over a short period of time. Understanding RDT procurement methods in both the public and private sector is key for undertaking supply chain interventions.





4

Surveillance, monitoring and evaluation

Overview

The monitoring and evaluation of mRDT services plays a dual role in informing both malaria case management and surveillance. The former directly impacts patient care and the latter influences planning and implementation of malaria control and elimination interventions. Evidence gaps in terms of the quality of malaria case management pose a risk to planning interventions designed to optimize health outcomes. Gaps in malaria surveillance data pose a challenge in targeting malaria control interventions. Efforts to improve malaria case management and surveillance in the private sector should be coupled with equal efforts to increase private sector reporting via the routine health facility mechanism (i.e. HMIS) or a system that integrates or aligns with the public sector.

The challenges associated with implementing monitoring, evaluation and surveillance systems in the private sector are somewhat distinct from those of the public sector. Routine data collection may be part of the for-profit portfolio (e.g. private health care providers), but not necessarily at all levels (e.g. retail outlets). The design and implementation of non-routine studies should consider how the mandates and operating practices differ between private and public providers (e.g. different attitudes to participating in research, different opening hours). Finally, including the private sector in activities that have been solely based in the public sector implies a substantial difference in scale. As such, the M&E approach must seek to monitor and assess a heterogeneous sector comprised of many more facilities, retail outlets and testing personnel. As with other areas outlined in this document, M&E resources, roles and responsibilities all need to be agreed upon and allocated and should be a key consideration in planning for sustainability when including the private sector.

Key Action Steps in this section build on the activities from section 8 of the Universal access manual and section 2.7.2 of [Malaria surveillance, monitoring and evaluation: a reference manual](#) (34).

Key Action Steps in Section 4

Planning for M&E; 4.2 Routine data	
34. Integrate the private sector M&E strategy for malaria with the public sector strategy 68	
35. Adapt existing data collection tools..... 69	
36. Adapt routine monitoring and surveillance 70	
37. Consider incentives for data collection and reporting..... 71	
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	Non-routine data
	39. Collect non-routine data 72
	Data quality assurance
	40. Carry out data quality assurance activities..... 74

CASE STUDIES

The final case study highlights some of the challenges and opportunities in using M&E not only to track market performance, but also as an intervention to improve quality.

Tanzania: Piloting improved routine monitoring systems

4.1 PLANNING FOR M&E

Several categories of activity need to be considered as part of the planning process.

Systems alignment

The private sector M&E strategy must be aligned with the overarching national M&E strategy and framework, in line with the Paris Declaration principle on harmonization of country systems. It is important to align the data flows with those in use in existing national systems (Action Step 34).



ACTION STEP 34

Integrate the private sector M&E strategy for malaria with the public sector strategy

Align and integrate the private sector M&E strategy with the existing public sector strategy. This includes adapting and harmonizing tools, approaches and indicators for the private sector.

Ensure that there is a policy mandate for M&E activities covering private sector outlets and providers.

Identify the required human and financial resources to implement an integrated M&E strategy.

Policy mandate

The roll-out of private sector M&E activities requires a conducive policy environment to avoid ambiguity around the mandate of each stakeholder. In some countries, the policy mandate for engaging with the private sector has clearly defined structures to support an integrated M&E strategy (see case study from Tanzania at the end of this section). In other countries, particularly where the private sector has a small share of the health market, policies may need to be adapted to guide the M&E functions of the private sector, bundled together with the public sector. Such policies could relate to the appropriate collection, reporting, transmission, storage and ownership of data. Furthermore, the scope of private providers covered under the policy should be clearly defined.

Human capacity

M&E in the private sector can be a daunting task, requiring considerable human and financial resources. Given the potential higher number of testing sources (e.g. pharmacies, drug shops, private clinics and hospitals) in the private sector than in the public sector, implementers need to appreciate the differences that private sector engagement may bring in terms of heterogeneity and scale. Even in countries where there are dedicated M&E staff for the public sector, the inclusion of private sector data requires human capacities to be augmented in order to match the additional demands that come with scale-up.

Indicators and tools

New private sector data collection systems should be aligned with and embedded in the existing national systems. Consequently, the planning stage should include considerations for adapting existing data tools and approaches to accommodate private sector needs (Action Step 35). Similarly, indicators and their definitions may need to be revised or simplified to accommodate private sector specificities (e.g. the reporting of referred negative cases at retail outlets). Data terminology and definitions will likely need expanding to cover new outlet or provider types.



ACTION STEP 35

Adapt existing data collection tools

Expand existing information management systems to collect and collate data from private sector providers performing RDT services.

4.2 ROUTINE DATA

Performance monitoring framework

Governments incorporating RDT services into the private sector need a performance monitoring framework to gauge the strength and functionality of this sector. A set of M&E performance indicators at output, outcome and impact levels needs to be agreed upon for both public and private sectors. Indicators should be aligned with international standards such as those from [WHO](#) (34) and [GFATM](#) (35). [Special considerations](#) should be made when planning interventions for the private sector in order to address gaps identified in the performance monitoring framework, as these can differ from the public sector (e.g. the routine renewal of operating licenses is an issue for private sector providers but not for public sector facilities).

Data collection tools

To the extent possible, health information system tools should be aligned across public and private sector providers to ensure the consistency and quality of data collected. During the Unitaid private sector project, private-sector-specific information dashboards presenting common indicators were shared with national government counterparts (e.g. NMCPs) in order to monitor uptake of services in the private sector (Action Step 36).



ACTION STEP 36

Adapt routine monitoring and surveillance

Link private sector data to the local HMIS and the district health information management system (DHIS) where this is in place.

Supervise and mentor the private sector as part of HMIS activities.

Develop a performance monitoring framework for the private sector that is aligned with public sector quality performance standards.



KEY POINT

Routine data collection tools should:

- Be kept as simple as possible, focusing on minimum mandatory data elements as suggested in WHO's [Malaria surveillance, monitoring and evaluation: a reference manual](#) (34);
- Offer a simple format for data entry, e.g. ticking categories, rather than writing alphanumeric text;
- If paper-based, be kept short and physically small (no greater than A4 size).

Data reporting

Roles and responsibilities for data reporting should be clarified. Where possible, data reporting on RDT services from the private sector should build on existing private sector reporting channels for other health areas (i.e. notifiable diseases). When there are no other channels in place, efforts should be made to build an electronic data reporting system that pushes data to the existing national system. National bodies, such as associations of private health professionals, can play a role in facilitating data reporting from private facilities and outlets to the national HMIS. In some cases, public health centres can also represent a valid alternative for collating data from nearby private facilities and outlets and reporting it to the routine HMIS.

Incentives for data collection and reporting

As the private sector has traditionally not reported RDT service data, providers might need support to meet data collection and reporting requirements. It is possible that they may be reluctant to share information, feeling that it is proprietary or not wanting to lose any competitive advantage. One measure that may improve collection and reporting is the use of performance-based incentives (Action Step 37), such as the provision of branding materials, phone credit

vouchers or eligibility for free government commodities (e.g. vaccines for immunization) upon timely submission of complete reports.

Another option is to make licensing contingent upon complete data collection and reporting; however, this may be challenging to enforce regularly (e.g. for monthly reporting, since licence renewal is done only annually). A third possibility is to engage with professional associations to which the facilities/providers subscribe and leverage their support for routine data collection processes. Outlets may tend to respond more positively to requests from their member associations.



ACTION STEP 37

Consider incentives for data collection and reporting

Consider performance-based incentives for data collection and reporting, such as free promotional materials, free government commodities, discounts on national health insurance systems, etc.

Consider tagging operational license renewal to meeting data collection and reporting requirements.

Involve professional associations and local implementing partners in order to encourage timely data collection and reporting.

Data collation

Programme implementation teams need to weigh the advantages and challenges associated with the level of aggregation to be introduced in data collation and transmission to higher levels. Submission of individual patient data provides a rich dataset that allows indicator disaggregation for any data element. However, it is immensely challenging to implement systems that allow for the efficient submission of such detailed data to higher levels. Alternatively, reporting of aggregated data is less challenging, but prone to aggregation errors. The timing of moving from aggregated data to individual patient data needs to be carefully considered and informed by the level of malaria transmission (Action Step 38).

Considering the key role played by the private sector in governments' successful achievement of their malaria elimination goals, countries should aim to have at least a solid and well-functioning system in place to report aggregated data by the time they would like to transition to individual patient data.



ACTION STEP 38

Decide data aggregation detail, frequency and collation

According to malaria transmission levels, choose the level of data aggregation, reporting frequency and collation.

Decisions are required on the frequency and mode of data collation. More frequent collations, e.g. monthly collations, require significantly more resources. However, more frequent contact with private providers increases opportunities for feedback that may improve compliance with

guidelines. The processes under which data will be transported form a key component of the system, and a decision must be made early in the planning stage on the transmission mechanism. Electronic data collection and reporting brings benefits in terms of data quality (through internal logic checks) and timeliness, but can have significant technical and budgetary implications.

4.3 NON-ROUTINE DATA



ACTION STEP 39

Collect non-routine data

Quantitative non-routine studies can be used to inform programme outcomes, such as population-level access, coverage, equity, use and quality of use of RDT services.

Qualitative data can explore motivations, barriers and actions of individuals or groups of individuals around RDT services in the private sector.

The national coordinating group and NMCP should consider the periodic collection of additional data through non-routine studies. Dedicated surveys can be used for a variety of purposes at different stages of the intervention in order to complement routine monitoring systems. These should be aligned with public sector surveys as much as possible.

Planning for non-routine surveys needs to be addressed in tandem with planning for routine systems in order to identify where leadership, budget and human capacity for conducting the studies fall under existing country and partner organizational structures. Indicator definitions and data elements should be aligned between routine systems and quantitative surveys in order to ensure the complementarity and comparability of results. While surveys allow for the capture of a broader range of data elements compared to routine systems, managers must ensure that key definitions are consistent (for example, *suspected fever case*).



KEY POINT

There are four project stages at which a country may wish to add non-routine data to meet their information needs:

1. During a pilot phase, preceding full implementation of RDT services in the private sector, to provide independent evidence of diagnostic uptake and compliance to care algorithms in certain segments of the private sector;
2. In advance of or during the roll-out of routine M&E systems, to address the acute need for information on private sector RDT services and malaria case management;
3. Once routine M&E systems have been implemented, as an independent verification of the routine health system information in tandem with other data quality assurance activities;
4. Once routine M&E systems have been implemented, as a source of complementary information on RDT services and malaria case management not provided by routine systems, and to focus on specific coverage or quality issues identified by the routine data.

**KEY POINT****Survey types**

Initiatives to support the public and private sector roll-out of RDTs have used three non-routine study types, below are (examples of the first three quantitative surveys):

[Client exit interviews](#) (36) involve interviewing febrile clients or adult caretakers of febrile children as they leave a facility or outlet. These can be included as part of a broader health facility survey – such as a Service Provision Assessment (SPA) or WHO Service Availability and Readiness Assessment (SARA) – which may also include clinical encounter observation and patient re-examination components.

[Mystery client studies](#) (37) can use known test-negative volunteers acting out the role of a patient with suspected malaria in order to assess the quality of case management offered by providers. Due to the covert nature of the interaction, the results may offer a more realistic representation of provider behaviour than that recorded through exit interviews and supervision visits. This may be the case particularly for behaviours that providers know to be deviant, such as non-adherence to a negative malaria test result. However, the studies may be difficult to implement at scale due to the need to find volunteers willing to receive a blood test for malaria.

[Population-based household surveys](#) (38) that include information on diagnostic testing and treatment are now widely available for malaria-endemic countries, either through the DHS Program, Malaria Indicator Surveys, or the UNICEF Multiple Indicator Cluster Surveys. Programmes can use the data from these sources to inform the initial needs assessment and to track national and subnational population trends over time.

Qualitative studies can help to illuminate and explain patterns or unexpected results observed in available routine or non-routine data. Qualitative data collection may involve interacting with members of the national coordinating group, the government, supply chain actors, private providers, or clients and patients, depending on the specific research question. The following illustrative examples describe scenarios in which qualitative research methods could be used to inform or modify programme approaches: when routine reporting levels are persistently low and the national coordinating group wants to understand factors that influence providers' adherence to reporting protocol; or when implementing partners want to better understand the factors that influence RDT use among non-lab providers in order to enhance outreach and BCC efforts in the retail sector.

4.4 DATA QUALITY ASSURANCE

Any outcome informed by the HMIS is only as good as the quality of data contained in the information system. Ensuring that the data available in the local HMIS are of good quality is the cornerstone of every M&E system and increases data users' confidence and trust in their local HMIS. Data quality assurance (DQA) activities for the private sector need to be carried out as part of the routine monitoring system and, where possible, aligned with the DQA guidelines in place for public sector data. The quality of data from the private sector should be held to the same standards as in the public sector.

Where possible, countries are encouraged to develop automatic quality checks for data completeness, validity, consistency, timeliness and accuracy, and validate data only after the standards for these checks are met. M&E systems should be designed to enable regular quality

checks of the data generated by the private sector. As with the previous steps, it is important to examine where public and private systems can align their DQA mechanisms (Action Step 40).



ACTION STEP 40

Carry out data quality assurance activities

Consider promoting the inclusion of private facilities in the scope of public sector DQA activities.

COUNTRY CASE STUDY

TANZANIA

PILOTING IMPROVED ROUTINE MONITORING SYSTEMS

Challenge

The HMIS of the MoH collects routine health facility data from both public and private health facilities. Data are submitted in paper copy, but managed through the DHIS2, an electronic open-source platform

used by the government of Tanzania and 61 other countries around the world. However, reporting rates from the private sector are lower than from the public sector and neither report routinely on QoC data.

Solution

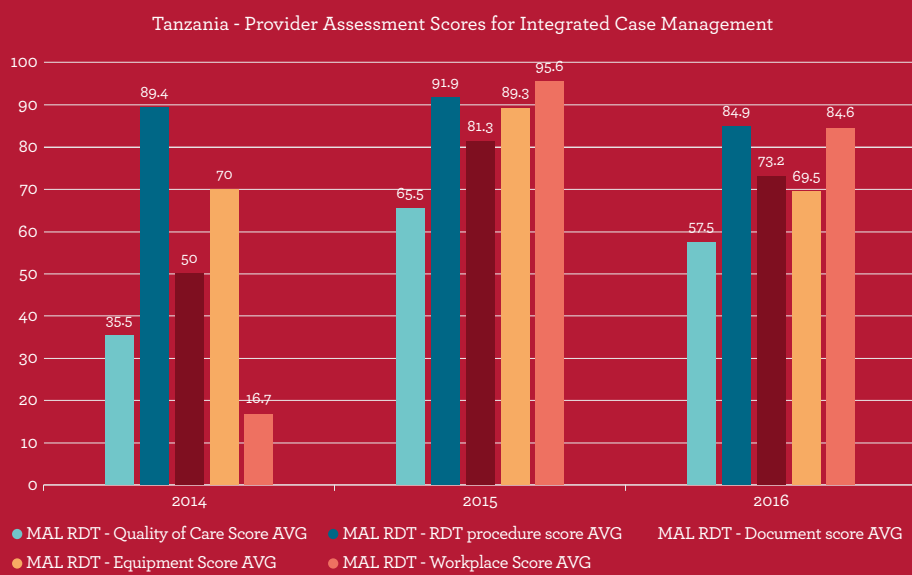
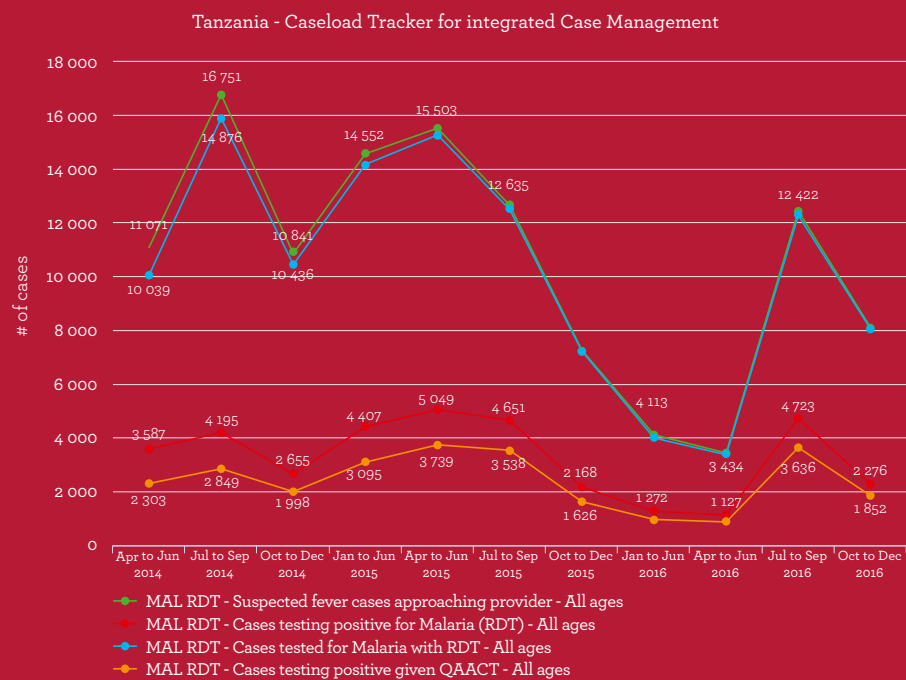
The NMCP and PSI/Tanzania along with partners sought to use the DHIS2 platform to systematically monitor both malaria case surveillance and the quality of FCM in the private sector. They piloted a system to improve the monitoring and reporting of case surveillance and QoC data through the DHIS2. The new approach introduced tally sheets that could track and measure treatment by diagnosis and for the first time included information on testing.

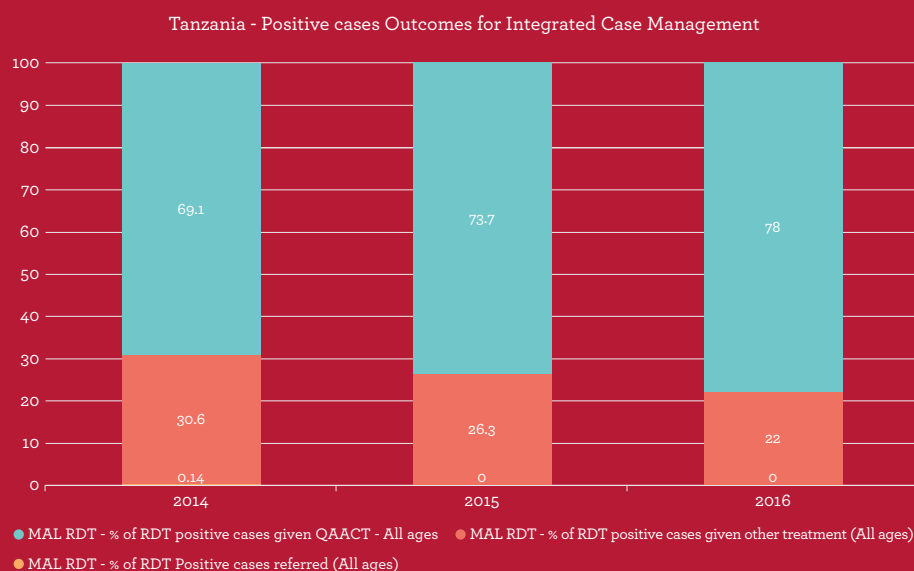
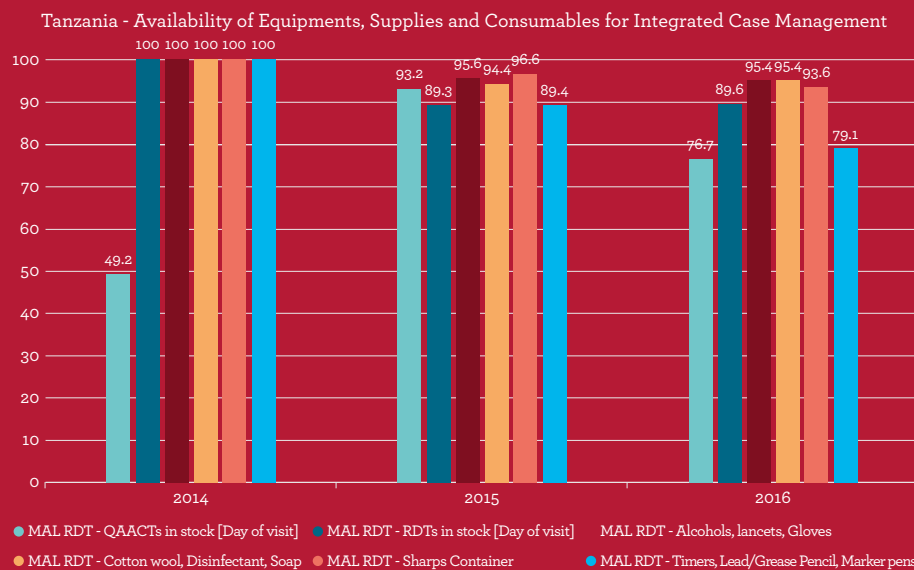
To reduce the time lag associated with data entry from paper-based forms, PSI/Tanzania engaged an IT firm, Mango Inc., to develop a mobile application that would enable providers to report tally sheet

summary information on mobile phones. Tally sheets recorded data for a one-month period, and providers reported monthly data directly into DHIS2 at the month-end through the mobile app.

Finally, tablet-based assessment checklists on FCM enabled supervisors' QoC data to automatically integrate into the DHIS2. This enabled managers (both public and private) to track and use the data related to surveillance (provider-reported) and QoC (supervisor-reported) to make evidence-based decisions. This resource is available online: <https://mis.psi.org/using-dhis2-to-improve-health-service-quality/?lang=en>.

Fig. 6. Tanzania DHIS2 Reports for case surveillance, quality of care, stock management and patient outcomes





Learning

The introduction of tally sheets reported through mobile phones into the DHIS2 dashboards enabled near real-time tracking of diagnostic testing levels and treatments prescribed based on diagnosis status – all key indicators to monitor for malaria control. Integrating supervisor-generated QoC data into the DHIS2 improved the routine monitoring of provider FCM performance. This example shows the feasibility of collecting this information with the right investment and support. Further scaling of

these improvements should be considered, but would require several key changes, including aligning the NMCP malaria reporting forms across public and private sectors, revising the NMCP summary forms to track treatment by diagnosis status, including public sector supervision checklists in the DHIS2, and facilitating public–private sector collaboration on mobile data entry of case surveillance data.



Summary

Conceptually, public-private partnerships are an instrument to respond to market failures while minimizing the risk of government failure. Inclusion of the private sector, if implemented well, can help to overcome constraints and allow for coverage of the total population in a particular health area. Given their respective strengths and weaknesses, neither the public sector nor the private sector alone can fulfil the needs of the health system, and this is also true of mRDT services. To reach the goal of universal access to malaria testing, it is fundamental and necessary for mRDT services to be provided in private sector outlets - from health facilities to retail outlets - where patients routinely seek care and treatment for febrile illness.

However, to reach this universal access goal, and to include and scale up mRDTs in the private sector, there needs to be harmonization and alignment in three key areas: policy, supply and quality. To this end, the legal, regulatory and policy framework must be compatible with both private sector and public sector realities; all relevant stakeholders need to be engaged, mapping out roles and responsibilities; a comprehensive QA system must be in place; and methods should be used to stimulate the supply and demand for mRDTs.

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Resource Document List

Document (oldest to newest)	Link	Summary
Rapid Diagnostic Testing		
1 d'Acremont, V, et al., <i>Time to move from presumptive malaria treatment to laboratory-confirmed diagnosis and treatment in African children with fever.</i> PLoS Med, 2009. 6 (1): p. e252.	http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050252	A paper which examines whether enough evidence exists to support abandoning presumptive treatment and whether African health systems have the capacity to support a shift toward laboratory-confirmed rather than presumptive diagnosis and treatment of malaria in children under five. It called for the policy to be changed even if all conditions for perfect implementation were not fulfilled. The paper shows that in areas where RDTs have been deployed at scale, clinicians have understood that the performance and usefulness of RDTs is not different in a child under five years than in an adult. They recommended staggered implementation according to country capacity.
2 WHO, T3: <i>Scaling up diagnostic testing, treatment and surveillance for malaria.</i> 2012	http://www.who.int/malaria/publications/atoz/t3_brochure/en/	The WHO Global Malaria Programme's T3: Test. Treat. Track. initiative supports malaria-endemic countries in their efforts to achieve universal coverage with diagnostic testing and antimalarial treatment, as well as in strengthening their malaria surveillance systems. The initiative seeks to focus the attention of policy-makers and donors on the importance of adopting WHO's latest evidence-based recommendations on diagnostic testing, treatment and surveillance, and on updating existing malaria control and elimination strategies, as well as country-specific operational plans.
3 Albertini, A., et al., <i>Malaria rapid diagnostic test transport and storage conditions in Burkina Faso, Senegal, Ethiopia and the Philippines.</i> Malar J, 2012. 11 : p. 406	https://malariajournal.biomedcentral.com/articles/10.1186/1475-2875-11-406	Malaria rapid diagnostic tests (RDTs) must be highly reliable at point of use, but exposure to adverse environmental conditions during distribution has the potential to degrade tests and accuracy. This study assessed temperature and humidity throughout supply chains used to transport and store health commodities, such as RDTs. Malaria RDTs were regularly exposed to temperatures above recommended limits for many commercially-available RDTs and other medical commodities such as drugs, but rarely exceeded the recommended storage limits for particular products in use in these countries. The results underline the need to select RDTs, and other commodities, according to expected field conditions, actively manage the environmental conditions in supply chains in tropical and sub-tropical climates.

Document (oldest to newest)	Link	Summary
<p>4 Albertini, A., et al., <i>Preliminary enquiry into the availability, price and quality of malaria rapid diagnostic tests in the private health sector of six malaria-endemic countries</i>. Trop Med Int Health, 2012. 17(2): p. 147-52.</p>	<p>http://online.library.wiley.com/doi/10.1111/j.1365-3156.2011.02904.x/full</p>	<p>This enquiry aimed to provide a snap-shot of availability, price and quality of malaria rapid diagnostic tests (RDTs) in private health facilities at selected sites in six malaria-endemic countries in Africa, South East Asia and South America. In the private outlets sampled, the availability of RDTs was limited. Some of the RDTs whose quality we tested demonstrated inadequate sensitivity. This presents a number of risks. Given the more widespread distribution of antimalarials currently planned for private sector facilities, parasite-based diagnosis in this sector will be essential to adhere to the WHO guidelines for effective case management of malaria. Considerable regulation and quality control are also necessary to assure the availability of accurate and reliable RDTs, as well as adequate case management and provider adherence to RDT results. Public sector engagement is likely to be essential in this process.</p>
<p>Poyer, S., et al. (2015), <i>Availability and price of malaria rapid diagnostic tests in the public and private health sectors in 2011: results from 10 nationally representative cross-sectional retail surveys</i>. Tropical Medicine & International Health, 20: 744-756</p>	<p>http://online.library.wiley.com/wol1/doi/10.1111/tmi.12491/abstract</p>	<p>This article describes the state of the public and private malaria diagnostics market shortly after WHO updated its guidelines for testing all suspected malaria cases prior to treatment three thousand four hundred and thirty-nine rapid diagnostic test (RDT) products from 39 manufacturers were audited among 12 197 outlets interviewed. Availability was typically highest in public health facilities, although availability in these facilities varied greatly across countries, from 15% in Nigeria to >90% in Madagascar and Cambodia. Private for-profit sector availability was 46% in Cambodia, 20% in Zambia, but low in other countries. Median retail prices for RDTs in the private for-profit sector ranged from \$0.00 in Madagascar to \$3.13 in Zambia. The reported number of RDTs used in the 7 days before the survey in public health facilities ranged from 3 (Benin) to 50 (Zambia). It found that eighteen months after WHO updated its case management guidelines, RDT availability remained poor in the private sector in sub-Saharan Africa.</p>
<p>5 WHO, <i>Universal access to malaria diagnostic testing – An operational manual</i>. 2013.</p>	<p>http://www.who.int/malaria/publications/atoz/9789241502092/en/</p>	<p>This operational manual, provides practical guidance to national malaria control programme managers and other stakeholders for rapidly increasing access to malaria diagnostic testing with RDT and microscopy in malaria endemic countries. It includes the core elements of policy setting, strategy development, and planning as well as practical tools to deploy malaria diagnostic testing at all levels of the health care system, including the community. The manual emphasizes full integration of malaria diagnostic testing in the clinical management of febrile illnesses and the contribution to overall efforts in strengthening laboratory services. It provides strong emphasis on quality management systems and the need for supervision, and clear guidance on roles of both RDT and microscopy for different clinical situations and settings, recognizing that in most countries both tests are needed.</p>

Document (oldest to newest)	Link	Summary
6 WHO TDR & FIND, <i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests</i> . 2014	http://www.who.int/malaria/publications/rdt-manual/en/	<p>The manual details a protocol for the product testing of antigen-detecting malaria rapid diagnostic tests (RDTs) using samples of frozen parasites prepared for this purpose. The manual describes a protocol to:</p> <ul style="list-style-type: none"> • assess sensitivity and specificity of RDTs against a specimen bank consisting of recombinant antigen, culture-derived parasites and wild-type parasites, and parasite-negative blood samples; • assess the stability of RDTs at various temperatures; • describe aspects of RDTs affecting ease of use in the field; and • record results in a database. <p>The manual is intended only for use in laboratories conducting product testing for the WHO.</p>
7 Meeting report of the WHO Evidence Review Group on Low-Density Malaria Infections. 2017	https://www.who.int/malaria/mpac/mpac-oct2017-erig-malaria-low-density-infections-session2.pdf?ua=1	<p>WHO convened a meeting to revise current recommendations based on a review of the natural history, prevalence, contribution to transmission, and ultimate public health importance of low-density <i>P. falciparum</i> and <i>P. vivax</i> infections</p>
8 Visser, T., et al., <i>Rapid diagnostic tests for malaria</i> . Bull World Health Organ, 2015. 93(12): p. 862-6	http://www.who.int/bulletin/volumes/93/12/14-151167/en/	<p>This bulletin describes recent developments that have spurred the growth in demand for rapid diagnostic tests for malaria, identify challenges that could limit further progress and make recommendations that could help mitigate these challenges.</p>
9 <i>Malaria rapid diagnostic test performance: results of WHO product testing of malaria RDTs: round 6 (2014-2015)</i>	http://www.who.int/malaria/publications/atoz/9789241510035/en/	<p>This report provides a comparative measure of their performance in a standardized way to distinguish between well and poorly performing tests. It can be used by malaria control programmes and guide WHO procurement recommendations for these diagnostic tools.</p>

Document (oldest to newest)	Link	Summary
10 Harmonization of rapid diagnostic tests for malaria and implications for procurement. Meeting report November 2015	http://www.who.int/malaria/publications/atoz/9789241509978/en/	This document reviews the comparability of malaria rapid diagnostics tests (RDTs) and their compliance with international standards and best practice for labelling and instructions for use.
11 Ochodo, E., P. Garner, and D. Sinclair, <i>Achieving universal testing for malaria</i> . BMJ, 2016. 352 : p. i107	http://www.bmj.com/content/352/bmj.i107	Rapid diagnostic tests have the potential to reduce the overtreatment of malaria by 95%, but time and extensive logistical, behavioural, and technical interventions may be required to achieve this Universal testing for malaria will take time and extensive resources to fully implement across sub-Saharan Africa. This paper calls for interventions to overcome logistical health system constraints and change the beliefs and behaviour of health workers and patients as well as further developments to improve the accuracy of tests.
12 <i>Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs)</i> March 2016	http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/	There is increasing demand for countries to improve malaria diagnosis in view of wide-scale introduction of expensive antimalarial medicines and the decreasing malaria trends in many countries. Guidance is therefore required to ensure the selection of rapid diagnostic tests (RDTs) for malaria that meet quality standards. This WHO information note provides an updated list of recommended criteria for selecting RDTs for malaria, and highlights the performance of RDTs evaluated by the WHO malaria RDT product testing programme. It also provides an overview of additional considerations in the procurement of rapid tests.
13 <i>Malaria microscopy quality assurance manual</i> – Ver. 2 January 2016	http://www.who.int/malaria/publications/atoz/9789241549394/en/	This manual is designed primarily to assist managers of national malaria programmes and national reference laboratory responsible for quality assurance of malaria microscopy control. The information is also applicable to non-governmental organizations and funding agencies investing in quality management systems for malaria microscopy.
14	http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0173093	Many patients with malaria-like symptoms seek treatment in private medicine retail outlets (PMR) that distribute malaria medicines but do not traditionally provide diagnostic services, potentially leading to overtreatment with antimalarial drugs. To achieve universal access to prompt parasite-based diagnosis, many malaria-endemic countries are considering scaling up malaria rapid diagnostic tests (RDTs) in these outlets, an intervention that may require legislative changes and major investments in supporting programs and infrastructures. This review identifies studies that introduced malaria RDTs in PMRs and examines study outcomes and success factors to inform scale up decisions.

Document (oldest to newest)	Link	Summary
General Malaria Guidance and Treatment		
1 d'Acromont, V, C. Lengeler, and B. Genton, <i>Reduction in the proportion of fevers associated with Plasmodium falciparum parasitaemia in Africa: a systematic review</i> . Malar J, 2010. 9 : p. 240.	https://malariajournal.biomedcentral.com/articles/10.1186/1475-2875-9-240	The objective of this systematic review was to estimate the change in the Proportion of Fevers associated with Plasmodium falciparum parasitaemia (PFPf) over the past 20 years in sub-Saharan Africa. The review shows that the decline in malaria provides evidence for the policy change from presumptive anti-malarial treatment of all children with fever to laboratory diagnosis and treatment upon result.
2 White, N.J., et al., <i>Malaria</i> . Lancet, 2014. 383 (9918) : p. 723-35.	http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60024-1/abstract	A review of the epidemiology, clinical features, pathology, prevention, and treatment of malaria.
3 WHO, <i>World Malaria Report 2015</i> .	http://www.who.int/malaria/publications/world-malaria-report-2015/en/	Summarizes information received from malaria-endemic countries and other sources. It assesses global and regional malaria trends, highlights progress towards global targets, and describes opportunities and challenges in controlling and eliminating the disease.
4 WHO, <i>Guidelines for the treatment of malaria, third edition</i> . Geneva, WHO. 2015	http://www.who.int/malaria/publications/atoz/9789241549127/en/	The document provides guidance on early diagnosis and prompt, effective treatment; rational use of antimalarial treatment to ensure that only confirmed malaria cases receive antimalarials; the use of combination therapy in preventing or delaying development of resistance; and appropriate weight-based dosing of antimalarials to ensure prolonged useful therapeutic life and an equal chance of being cured for all patients.



Population Services International
1120 19th Street, NW, Suite 600
Washington, DC 20036
www.psi.org
malaria@psi.org

