Malaria Diagnostics in the Private Sector

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Definition

Malaria diagnosis in the private sector refers to the case management of malaria with the use of parasitological diagnosis, primarily with microscopy or with a rapid diagnostic test (RDT) (see entry on “▶ Case Management Diagnosis of Malaria, Overview”) at private sector points of care.

Private sector points of care are defined as those operating separately and with no financial support from the public sector (Ministry of Health (MOH)/Government) (Bennett 1992). They are owned and operated by private individuals/groups, nonprofits, and/or faith-based institutions. In malaria endemic settings, they range from large hospitals to mid-level health clinics to pharmacies and drug shops. They are often labeled “formal” or “informal” with the former implying accreditation and registration by the government and the latter implying no accreditation or registration status. Privately financed or nongovernmental community health workers can also be included in this group (Bennett 1992; Standing and Bloom 2002; World Malaria Report 2015).

Introduction

There are several tools for parasitological confirmation of malaria. These are outlined in-depth in the entry “▶ Case Management Diagnosis of Malaria, Overview.” As indicated in that chapter, tools such as LAMP, DNA, PCR, and others are not appropriate for use in low-resourced, endemic settings. They are therefore not considered further here. Light microscopy and rapid diagnostic tests (RDTs) are most appropriate for these settings including in the private sector. Both microscopy and RDTs have distinct advantages and limitations and should be selected for use depending on setting and capacity of the diagnostic technician (see “▶ Malaria Diagnostic Platform, Microscopy” and “▶ Malaria Diagnostic Platform, Lateral Flow Assays”).

Parasitological confirmation of malaria by microscopy is considered the “gold standard” for malaria case management. However, it is time-consuming, labor-intensive, and can be expensive, requiring laboratory equipment and trained personnel available 24 hours a day within close proximity to remote communities where the malaria risk is often highest. An alternative to microscopy is the single-use RDT that can detect circulating Plasmodium antigens in a drop of finger-prick blood. When used correctly, quality-controlled RDTs (i.e., correct pre-and post-market surveillance procedures conducted such as lot quality testing) have been shown to be cost-effective, 98 % reliable, and easy to use by

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nonlaboratory staff. RDTs also have an advantage over microscopy for use in poorly resourced areas, particularly in remote and rural areas where lab equipment, electricity, and personnel with training may be absent (Srinivasan et al. 2000). Additionally, RDTs have lower capital and maintenance costs and require less training than microscopy (Shillcutt et al. 2006). Thus RDTs should be considered a more practical option to enable access to parasite-based diagnosis and the implementation of WHO recommendations in the private sector. For these reasons this chapter focuses on the challenges and opportunities of introducing RDTs as the preferred diagnostic tool for use in the private health care sector.

Rationale for Introduction of Malaria Diagnosis to the Private Health Sector (Health Impact)

Fever is most often equated with malaria in endemic countries (see entry “Case Management Diagnosis, Overview”), despite significant reductions in disease prevalence in the past decade (WHO 2015). As a result presumptive treatment remains the norm in many settings, and febrile illness is routinely treated with antimalarials, leading to mistreatment of potentially life-threatening non-malaria febrile illnesses (NMFI) and to the overuse of frontline treatments for malaria (ACTs) as well as other drugs.

In light of this, the World Health Organization (WHO) recommended in 2010 that every suspected malaria case be confirmed by parasitological testing using microscopy or malaria RDTs. As a result the availability of high-quality, inexpensive RDTs in the public sector has significantly improved and expanded diagnostic testing in the past 5 years (WHO 2015). However, in the private sector, where a large proportion (over 40%) of the population in endemic countries seeks care and treatment for febrile illness, RDTs are commonly nonexistent or more costly than ACTs, driving the provision of treatment without confirmed diagnosis. (WHO 2016).

Special Considerations for Introduction of Malaria Diagnosis to the Private Health Sector (Behaviors)

Challenges to Introducing mRDTs in the Private Sector

As a result of the above, significant efforts have been made by the international malaria community in the last 5 years to scale up access to malaria diagnosis in the private sector. The introduction of malaria diagnosis in the private sector presents specific challenges, and opportunities, unique from the experience to date with scale up in the public sector. Due to the fact that private sector points of care are both points of service as well as profit driven, these challenges may include, but are not limited to:

• **Providers have no incentive to stock RDTs:** Private providers may not see the commercial benefit of stocking RDTs. They may not understand the client benefits of diagnosis before treatment. The RDTs may be too expensive for the provider to stock, since they are not demanded in large enough volumes from clients for them to be able to negotiate low prices from wholesalers/distributers. If providers do not stock RDTs, or are not allowed to sell medications for other febrile illnesses, they may simply make more profit by providing ACTs than any other course of action. Finally, when providers do attempt to stock them, there may be frequent stock-outs due to weaknesses in the supply chain and the short shelf life of RDTs.

• **Caregivers and patients do not ask for an RDT:** He/she may be lacking in knowledge and understanding of the benefit of RDTs. For example, he/she may not know that her or her child’s fever could be caused by other life-threatening febrile illnesses such as pneumonia, bacterial meningitis, and diarrhea. RDTs may be too expensive for her to afford. The median costs of *P. falciparum* tests at the point of purchase range from <US$0.50 to $2.50 across key malaria endemic countries, making them unaffordable or less desirable,
especially when subsidized ACTs are available at lower prices (WHO and UNITAID 2016).

- Private providers and clients lack confidence in RDT results: Providers may not have confidence in the accuracy of the test results and may also feel pressure from the patient to provide malaria treatment, particularly if the client also lacks confidence in the accuracy of the results. Results from Kenya and Zambia have shown continued poor targeting of ACTs when providers encountered negative RDT results (Hamer et al. 2007).

- The regulatory environment is not conducive: The regulatory environment in specific settings may not have national policies that require mandatory testing before treatment with antimalarials – where such policies have been adopted, they may not be enforced. Or the regulatory environment may not allow the private sector points of care that are closest to febrile clients to stock and sell RDTs for malaria even though they may be permitted to stock and sell malaria treatment. In addition to considerations around testing with RDTs at specific points of care there also needs to be an understanding of the registration and importation regulations for RDTs to private sector markets. Registration and importation for new products can be costly, acting as a barrier/disincentive to front line buyers to supply national markets, dampening demand.

Opportunities to Introduce RDTs in the Private Sector

Despite these challenges, the introduction of RDTs into the private sector in malaria endemic countries presents an opportunity to leverage the power of the market to ensure sustainable access to RDTs for appropriate febrile case management. It is now possible to increase access without relying solely on international donor and public sector financing because of three key factors:

1. There is large-scale availability of high quality, easy to use rapid diagnostic products at the manufacturer level.
2. Products are affordable: ~.30 USD at the manufacturer level (WHO).
3. There is market size potential, which stimulates private sector interest, assuming all fevers in malaria endemic countries should be tested (WHO and UNITAID 2016).

The global health community can make investments in global health goals more attractive for the private sector, while appealing to its profit-driven motives. By combining business and global health aims (profit and reduced mortality and morbidity, respectively) the burden on the public sector can be reduced. Initiatives aimed at unlocking the potential of markets to transform the current malaria diagnosis landscape have begun in key endemic countries. Their success will depend largely on continued support from the international community until a time when market sustainability can be achieved in concert with country governments and available public sector financing.

Guidance for Introducing RDTs in the Private Sector

The following sections outline considerations for how to engage the private sector to introduce RDTs in a sustainable way and with the aim of achieving coverage at scale. Ideas for engagement and implementation are categorized according to the key market functions of supply and demand, the supporting market functions of quality assurance (QA), monitoring and evaluation (M&E), and policy and rules.

The Roles for Microscopy and/or RDTs in the Private Sector (Core Function: Supply)

Quality control for RDTs requires attention to single pack versus hospital pack size suitability, waste disposal, and environmental issues.

As noted above, microscopy and RDTs are the most appropriate diagnostic tools in the private sector. While RDTs have certain advantages, microscopy still has an important role to play in settings with trained technicians and reliable equipment, such as at referral facilities to diagnose severe malaria (WHO 2010).
Furthermore, it is important to note that RDTs also require quality control efforts to ensure their reliability which will in turn promote provider and client trust and confidence in their results. The WHO Malaria RDT Product Testing Program provides independent comparative data on RDT performance to guide procurement (WHO 2011). It has evaluated over 200 RDT products from 60 manufacturers supplying their products to malaria endemic countries. Complementing this program are tools aimed at quality control pre- and post-market:

1. Lot quality testing (pre and post shipment)
2. Maintaining appropriate storage and transport conditions
3. Positive control wells
4. Anomaly reporting mechanisms

Alongside the use of the above quality control tools should be efforts aimed at improving availability of quality assured RDT single packs (see entry “Malaria Diagnostic Platform, Lateral Flow Assays”). Historic single-pack quality issues have included the instability of individual single-use buffer vials and led to a purchasing restriction on single packs from three large manufacturers (WHO 2014). Quality issues such as these are especially problematic for private sector market development at a national level, and global demand more broadly, as many private sector points of care, with limited capital and commitment to a new product, prefer purchasing 5–10 single packs at a time rather than entire box of 25 tests (the most common hospital pack box size available). Interventions that can overcome the quality issues associated with single packed test kits and offer a smaller box of hospital packs could stimulate significant demand from distributors and private sector providers where the market has the most untapped potential.

To further ensure quality of care in scaling up access to RDTs at nonclinic private sector points of care, such as pharmacies and drug shops, special consideration must also be given to issues of waste management, client privacy, and quality lighting. Such outlets are often only selling medicines and not offering clinical services such as blood tests. They therefore do not have the resources to appropriately dispose off infectious waste, space to offer their clients to receive tests and wait for results privately, or appropriate lighting by which to read tests results. Such conditions must be assessed before RDT introduction.

**Engaging with Private Sector Providers and Clients**

**Core Function: Demand**

*Demand for malaria diagnosis has been low, but can be improved by provider and client demand side interventions.*

Provider and client demand side interventions are recommended. Intervention learning and qualitative research to date suggests providers can be convinced of RDT trustworthiness with proper training and supportive supervision. This trust is then passed down to clients most effectively to generate demand in situations where providers are serving regular clients with whom they already have trusted relationships. In this same vein, word of mouth and interpersonal communication efforts seem to have the most impact in generating demand over and above mass communication approaches. Drop-in clients where no provider/client relationship previously exists are more challenging in terms of creating demand; however, mass and mid-media efforts aimed at “sensitizing” populations to the importance of testing before treatment appear beneficial. For example, clients who recall such messages may be more open to being offered a test by unfamiliar providers. Such findings indicate that efforts focused on sensitizing populations and provider behavior change to test before treatment may be the most efficient use of limited resources.

At the point of care level, experience to date indicates that consumers don’t recognize and respond to the promotion of RDTs. “Malaria testing available here” is clearer and has generated better demand in the private sector. Quantitative survey data and further qualitative research in key malaria endemic countries is forthcoming to provide further evidence regarding these initial findings.
Supporting Function: QA

Quality of care among private providers can be achieved, but QA efforts must take into consideration the unique characteristics of the private sector, which may require adapted tools and shorter formal trainings, in addition to ongoing supporting supervision.

Quality of care among private providers, irrespective of point of care type, can be achieved with training and routine supportive supervision (Marquez et al. 2002; Patouillard et al. 2007). Furthermore, the introduction of RDTs for correct febrile case management can improve the proportion of malaria positive patients who receive an effective antimalarial and decrease overprescription of antimalarials to malaria negative patients. This finding in fact points to the cost-effectiveness of introducing RDTs in the private sector.

Building on existing private sector network capacity to introduce RDTs and ensure quality through the existing QA systems is key to create efficiencies and avoid QA fatigue. Similarly integrated febrile case management trainings and algorithms should be adapted from existing national/public sector standards to avoid different approaches and ensure government buy-in. Important to note, however, is that trainings and algorithms for pharmacies and drug shops often do not currently exist for the public sector and may need to be developed. For example, national training curricula of 5 days are too long for many private providers to afford to attend (given the opportunity cost of time away from their business). Even 2-day curricula have resulted in private providers not attending all sessions or not sending a second provider, but rather training them informally on the job. At the start of each program to introduce RDTs into the private sector it is suggested that adaption of materials and curriculums to accommodate private provider’s needs without compromising on quality of training be discussed and decided upon. In some countries the opportunity to involve Professional Associations further in guaranteeing provider attendance and sustainability has helped.

With regard to pharmacies and drug shops, referral for danger signs, management of negative test results, and investigation of comorbidities remain a challenge. Training and algorithms at these levels of care must ensure clients are appropriately referred for differential diagnosis and not sold medicines that would leave clients to believe they are being properly managed. While the business/profit aspect of the private sector may complicate this situation, it is important to remember that private providers are health providers and in the business of keeping their clients alive. If correctly trained and supervised evidence to date shows that these private points of care can manage fever with RDTs safely.

Regular supportive supervision is key to ensuring the impact of training and adherence to algorithms. The capacity to implement and the sustainability of implementing competency-based supervision is often questioned though for private sector points of care, which can number in the tens of thousands in some countries such as Nigeria (Beyeler et al. 2015). New systems however, which leverage digital communications (mHealth) solutions such as mobile phones for case surveillance and tablets to complete assessments, can ensure limited resources are best targeted and, for example, private outlets with the highest caseloads and lowest assessment scores are visited more frequently than others.

Reporting and Data Use (Supporting Function: M&E)

The private sector should be engaged to ensure case surveillance and quality of care data is integrated and reported into the national health management information system (HMIS).

Disease surveillance systems are essential for providing public health decision makers at the local, national, and international level with the necessary information to manage health systems and design appropriate interventions. In malaria and febrile case management they are particularly important to ensure (a) all cases of malaria which present themselves within the healthcare system are recorded and (b) all febrile patients are diagnosed, treated, and/or referred according to national algorithms and globally recognized
standards of quality care. As noted above, private sector points of care play a significant role in managing malaria patients and can be the first or only contact point for febrile patients seeking treatment. Incorporating these actors into a national health system is critical on two different levels:

1. **Case Surveillance Data**
   
   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. By including case surveillance reporting in the RDT training, private providers can help ensure that all cases of malaria presenting within the healthcare system are recorded. However, each country must consider how to incentivize private sector reporting into the national HMIS – either through financial incentives, or as a requirement for registration, or other nonfinancial incentives (Bennett et al. 2014).

2. **Quality of Care Data**
   
   While many national programs have established information systems to gather case surveillance data (some of which also extend to the private sector), few have systems which gather and analyze quality of care data and even fewer have that system in place for the private sector. Efforts should be made to integrate both case surveillance data (described above) as well as quality assurance data into DHIS2, to monitor both occurrence of malaria in the private sector as well as the safety and accuracy of febrile case management in the private sector. Information can be presented in the form of visual “dashboards” to allow supervisors, management, technical staff, and government counterparts to monitor progress of each outlet and to adjust supervision and training plans based on needs. This approach can equip supervisors and managers to better manage and improve the quality of care provided in the outlets that they oversee. Smart phone apps and photometric readers with individual patient level data and photos of RDT results can also enable supervisors to remotely monitor provider competencies without going into the field. These data can also be incorporated into DHIS2.

**Policy Environment (Supporting Function: Policy/Rules)**

*Competing provider and regulatory interests must be understood and proactively managed to create a conducive policy environment.*

In order to effectively address restrictive policy and regulatory situations when present there is a need to understand competing interests among different health care provider types and regulatory authorities. For example, physicians may be reluctant for pharmacists to perform RDTs and pharmacy owners may consider drugs shops to be illegal competitors.

To address these situations, it is necessary to conduct a systematic review of the regulatory and policy environment before introduction of RDTs, after which a task force with key stakeholders, inclusive of the appropriate government agencies, regulatory bodies, professional associations, and/or private sector businesses, can be formed to create and ensure a conducive policy environment going forward.

**Sustainability**

The private health sector is an important part of the overall health system: It can alleviate some of the burden on already stretched public sector points of care and potentially stimulate private sector investment to complement limited public sector financing. Introducing malaria diagnosis into the private sector requires a coordinated and holistic approach to address the above issues. A WHO Roadmap (forthcoming at the time of this writing) to guide malaria endemic countries interested in implementing this recommended and cost-effective intervention includes guidance and tools developed from the experience to date in malaria endemic countries. An important part of this guidance is the need to ensure overall country government stewardship of such initiatives.
Effective stewardship requires a coordinated effort between the public and private sectors to ensure that each sector is setting and adhering to regulations which protect clients and appropriately contributing resources to expand access to malaria diagnosis.

An example of sustainable malaria diagnosis in the private sector may be one where the public sector sets policies, regulations, and standards that includes all private sector outlets to be able to sell and administer RDTs. In return, private sector manufacturers/front line buyers finance training of private providers and pay a “tax” to the government to conduct supportive supervision and waste collection and disposal. While such sustainability visions may seem a long way off in malaria endemic countries, programs aimed at introducing RDTs to the private sector should begin with this vision in mind.

Future Priorities

In order to achieve the sustainability vision outlined above more research and evidence is needed on:

1. Cost-effective QA/QC systems for private sector case management and clinical service delivery in particular at pharmacies and drug shops.
2. Effective activities to stimulate private sector investment with the aim of first ensuring quality assured, affordable RDT supply security and secondly a vibrant and competitive market place that assumes costs for demand creation through medical detailing and promotional activities.

Research on the above will further the evidence base on how to effectively engage with the private sector in support of the WHO’s goal of universal access to malaria diagnosis before treatment.

References

