

Malaria Rapid Diagnostic Tests Market & Supply Update

UNICEF Supply Division
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1. Summary

- UNICEF procures malaria rapid diagnostic tests (mRDTs) to help programmes achieve early and accurate malaria diagnosis that is essential for effective malaria management and surveillance.
- UNICEF mRDT procurement increased 2.5 fold from 3.8 million tests in 2008 to reach approximately 13 million in 2015. Efforts by UNICEF and other partners to support mRDT scale up, access, and availability have seen the global market grow to an estimated 320 million tests as of 2014. UNICEF procurement represents a 2-3% share of that procurement volume.
- mRDTs are typically not well forecasted or integrated into national annual budget plans compared to other prioritized health products, and procurement is heavily dependent on funding availability. UNICEF anticipates demand to remain at approximately 10 million tests a year through 2016-2017 based on its historical procurement.
- UNICEF mRDT weighted average price (WAP) per test declined by 25% from US\$ 0.60 to reach US\$ 0.44 from 2011 to 2015 making mRDTs more affordable. During this time, the number of suppliers increased from 13 to 19, as new products were available for UN procurement. However, competition remains limited to three early market entrants with significant production capacity compared to other suppliers. Countries with rigid demand for strong product preferences further limit product substitution.
- UNICEF undertook a joint 2016-2017 mRDT tender during 4Q 2015 together with the World Health Organization (WHO), the United Nations Population Fund (UNFPA) and the United Nations Development Programme (UNDP) to ensure affordable, quality assured mRDTs are available through a healthy and stable market. UNICEF will issue 12 long-term arrangements (LTAs) in January 2016 for 30 different mRDTs.

2. General Brief and Background

Malaria is a preventable and treatable parasitic disease. It is transmitted to humans by the female anopheles mosquito infected with *plasmodium* parasites. The parasites cause an estimated 200 million cases of malaria a year, with an estimated 440 thousand deaths.¹ More than 100 *plasmodium* parasite species exist, though only five cause malaria in humans with variable prevalence and severity based on geographical area (Table 1).

Table 1 Malaria Causing *Plasmodium* Parasites in Humans

| <i>Plasmodium</i> species | Observation |
|------------------------------|---|
| <i>Plasmodium falciparum</i> | The most deadly species, responsible for most case fatalities, prevalent in tropical and subtropical areas worldwide, predominantly in Africa. It can cause severe malaria, anaemia, as well as fatal cerebral malaria. |
| <i>Plasmodium vivax</i> | The most widely distributed species, prevalent mostly in Asia, Latin America, and some parts of Africa. It can cause relapses several months or years after initial infection. |
| <i>Plasmodium malariae</i> | Also prevalent worldwide. It can cause life-long, re-occurring chronic infection. The current diagnostic methodology is not able to document reliably the disease burden. |
| <i>Plasmodium ovale</i> | Mostly prevalent in Africa. The current diagnostic methodology is not able to document reliably the disease burden. |
| <i>Plasmodium knowlesi</i> | Prevalent only in South-East Asia. Zoonotic malaria prevalent primarily in monkeys. Gaining attention over recent years as human cases now occurring in South East Asia. |

Source: US Centres for Disease Control and Prevention.

¹ World Health Organization, [Achieving the Malaria MDG Target: Reversing the Incidence of Malaria 2000-2015](#), WHO/UNICEF, Geneva, September 2015, p. 05.

3. mRDTs and Malaria Diagnosis

WHO recommends parasitological confirmation of malaria in all settings prior to treatment using quality assured diagnostics. It recommends countries to use mRDTs or microscopy for clinical malaria diagnosis in all transmission settings.² Malaria diagnosis can be confirmed by good-quality microscopy or with a safe, good quality and optimal performing malaria antigen-detecting RDT for both *P. falciparum* and non-falciparum infections.

mRDTs are immunochromatographic in vitro diagnostics and often come in a dipstick or cassette format, providing results in approximately 20 minutes. Current recommended mRDTs for use in malaria-endemic countries can detect four types of malaria parasite antigens (*P. falciparum*; *P. vivax*; *P. ovale* and *P. malariae*). mRDTs offer a useful alternative to microscopy in situations where reliable microscopic diagnosis is not readily available or provided in a timely manner, as is often the case in most malaria-endemic settings. Microscopy requires laboratory conditions and the necessary equipment for the preparation and analysis of malaria blood slides, including a x100 objective and x10 ocular grid reticle microscope with electrical light source.³ The use of mRDTs does not eliminate altogether the need for malaria microscopy, as they may not detect some lower parasite titer infections, and less common species of malaria may be misdiagnosed (*P. ovale* and *P. malariae*). WHO recommends patients with negative mRDT results to follow up and confirm the results with microscopy where available, and patients with positive mRDT results not responding to initial antimalarial treatment, to be re-assessed for other febrile illnesses or potential antimalarial drug resistance.

At present, several complementary mRDT quality assurance initiatives are ongoing. They each provide certain sets of comparative data on the different mRDTs available submitted for assessment. They guide countries to determine suitable mRDT products for their programmes (Table 2).

Table 2 Different mRDT Product Testing and Quality Assurance Programmes - Continued overleaf

| mRDT Quality Assurance Programme | Description |
|---|--|
| WHO / Foundation for Innovative New Diagnostics (FIND) mRDT Product Testing Programme | <ul style="list-style-type: none"> - Laboratory test evaluation programme directly comparing mRDT performance between tests. - Uses standardized panel of specimens for each round and standard operating procedures. - Only available for capillary whole blood-based mRDTs targeting antigens produced by malaria parasites. - Results published in a report format available through an online tool accessible here. It assists users to filter data to identify particular mRDTs that meet specific criteria. - WHO/FIND have completed five rounds of testing, evaluating 147 mRDTs, as of November 2015. - A sixth round, evaluating 41 mRDTs from 22 suppliers is pending release. - Suppliers are now required to resubmit products for testing every five years to remain listed in WHO's product testing report, and therefore eligible for UN procurement. |
| WHO Global Malaria Programme (GMP) | <ul style="list-style-type: none"> - Issues mRDT selection guidance and recommendations. - Forms the basis for WHO mRDT procurement and shared through an information note for use by countries and organizations, published on WHO's GMP website. |
| WHO Prequalification of In Vitro Diagnostics Programme | <ul style="list-style-type: none"> - WHO prequalification assessment of products that successfully meet WHO/FIND mRDT product testing programme acceptance criteria through dossier review and site inspection and prequalification for UN procurement. - As of November 2015, WHO has 12 prequalified mRDT products from 4 suppliers: <ul style="list-style-type: none"> • 7 <i>P. falciparum</i>. • 2 <i>P. falciparum</i> / pan malaria. • 2 <i>P. falciparum</i> / <i>P. vivax</i>. • 1 Pan malaria. |

² World Health Organization, [Policy Brief on Malaria Diagnostics in Low-Transmission Settings](#), WHO, Geneva, September 2014.

³ World Health Organization, [Microscopy for the Detection, Identification and Quantification of Malaria Parasites on Stained Thick and Thin Blood Films in Research Settings](#), WHO, Geneva, 2015.

| mRDT Quality Assurance Programme | Description |
|----------------------------------|--|
| WHO / FIND mRDT Lot Testing | <ul style="list-style-type: none"> - Independent mRDT quality control testing, pre or post shipment of consignments. - Consistently reports variations between lots tested. - Currently, the only practical mechanism for checking mRDT performance in post-market phase as quality control material is not yet available for end-users to utilize (e.g. positive control wells). |

Source: UNICEF Supply Division.

Table 3 describes WHO’s mRDT selection criteria for procurement consideration.⁴

Table 3 WHO mRDTs Selection Procurement Criteria

| Selection Criteria | Considerations |
|---------------------------|--|
| <i>P. falciparum</i> PDS† | PDS against <i>P. falciparum</i> should be minimum 75% at 200 parasites / μ L. |
| <i>P. vivax</i> PDS | PDS against <i>P. vivax</i> should be minimum 75% at 200 parasites / μ L. |
| False positive rate | False positive rate should be <10%. |
| Invalid rate | Invalid test rate should be <5%. |
| Temperature stability | mRDTs with high thermal stability are recommended in areas with very high temperatures. |
| Ease of use | Product choice / decision making considerations should include: Blood safety, quality, number of procedural steps, time to result, blood transfer device, format, and kit completeness. |
| Price | Price consideration should be after all other above factors. |
| Programmatic needs | Diagnostic performance is dependent on the above mentioned parameters, including: Training effectiveness, supervision, supply chain delivery, quantification, budgeting, monitoring and evaluation. |

Source: WHO.

†NB: mRDT performance data is assessed against a panel detection score (PDS). A PDS is a combined positivity-rate parameter measure against different parasite panels.

4. Current Market Situation

mRDTs are a nationally regulated product, and country mRDT procurement, channelled through UNICEF, is dependent on national product registration, several performance evaluations and national testing protocols. While WHO/FIND’s Product Testing Programme in 2009 contributed to increasing the acceptance of mRDTs, supported by malaria diagnostics advocacy from the Roll Back Malaria (RBM) Partnership, WHO guidelines for the treatment of malaria in 2010 drove mRDT adoption and scale-up by recommending universal diagnosis. A growing number of countries subsequently adopted a policy of providing diagnostic testing to all age groups (88% of endemic countries in 2011, up from 85% in 2010, and 74% in 2009). The mRDT market’s rapid growth over recent years reflects these changes in policy.

In 2012, the RBM Partnership undertook an mRDT country requirement forecast analysis of 42 African countries for 2013 through 2016, to understand how countries plan to scale-up mRDT diagnostics. The RBM Partnership projected the total need to reach 1.4 billion tests, of which six countries (DR Congo, Ethiopia, Mozambique, Nigeria, Tanzania and Uganda) accounted for the largest share. However, there was a noted difference between the identified needs and actual mRDT demand. The availability of financing heavily influences actual demand and appears more indicative of actual procurement than do the needs. The latest data, published in WHO’s 2014 World Malaria Report, states that the mRDT market has grown from 45 million tests in 2008 to reach 320 million in 2013.⁵

4.1 Pricing and Supplier Base

Manufacturers make mRDTs to order and do not maintain an inventory, given the absence of any accurate country forecasts and shelf life validity.

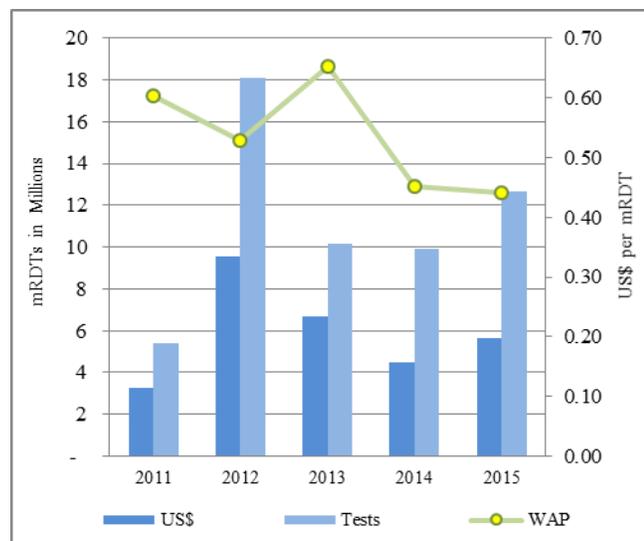
⁴ World Health Organization, [WHO Global Malaria Programme Information Note on Recommended Selection Criteria for Procurement of Malaria Rapid Diagnostic Tests \(RDTs\)](#), WHO, Geneva, 20 March 2012, p. 2.

⁵ World Health Organization, [World Malaria Report 2014](#), WHO, Geneva, 2015, p. 22.

The number of suppliers increased from 13 in 2011 to 19 in 2014, as new products were included after the release of WHO/FIND’s fifth round of product testing. However, competition remains limited to the three early market entrants that have a higher production capacity to produce and deliver ad hoc requests, as compared to other newer and often smaller suppliers.

UNICEF does not consider global production issues to be a limiting factor in mRDT availability. On average suppliers only need five weeks lead-time for mRDT delivery, ranging from one to eight weeks and depending on the product and the supplier. mRDTs are a temperature-controlled products that must be kept between 4-40°C or 4-45°C through the whole supply chain.⁶ WHO issued guidance for the transport, storage and handling of temperature sensitive products, which can be accessed [here](#).

Figure 1 UNICEF Procurement and WAP Data



Procurement through UNICEF during 2015 reached approximately 13 million during 2015, from approximately 10 million tests a year during 2013 and 2014 (Figure 1). The notable peak in 2012 was on account of an exceptional procurement request for Kenya. The Government of Kenya requested 7.2 million mRDTs with funds from The Global Fund (formerly known as the Global Fund to Fight AIDS, Tuberculosis and Malaria). UNICEF’s mRDT WAP per test declined by 25%, reducing from US\$ 0.60 per test in 2011 to US\$ 0.44 per test in 2015 on account of growing global market maturity and demand. UNICEF anticipates the mRDT WAP to decline further over the next tender period (2016-17).

Source: UNICEF Supply Division.

The number of countries procuring through UNICEF (24) has remained the same over the past two years (2013-2014). Most countries depend on donor funding to procure mRDTs and lack sufficient resources to try out alternative available tests in the market.

UNICEF has 30 products from 12 suppliers available through its catalogue, available [here](#). To date, demand patterns concentrated 99% of UNICEF’s procurement over 2013-2015 (November) on four suppliers only. UNICEF’s country office programmes account for 50% of UNICEF’s mRDTs supply; followed by procurement on behalf of developing country governments/implementing partners (Procurement Services), accounting for 40%. UNICEF packs the remaining 10% for use in medical kits, held as stock items in UNICEF’s warehouse in Copenhagen for emergency preparedness and response, and in case of need for set packing with other goods destined to primary care health settings.

4.2 UNICEF’s View of Demand

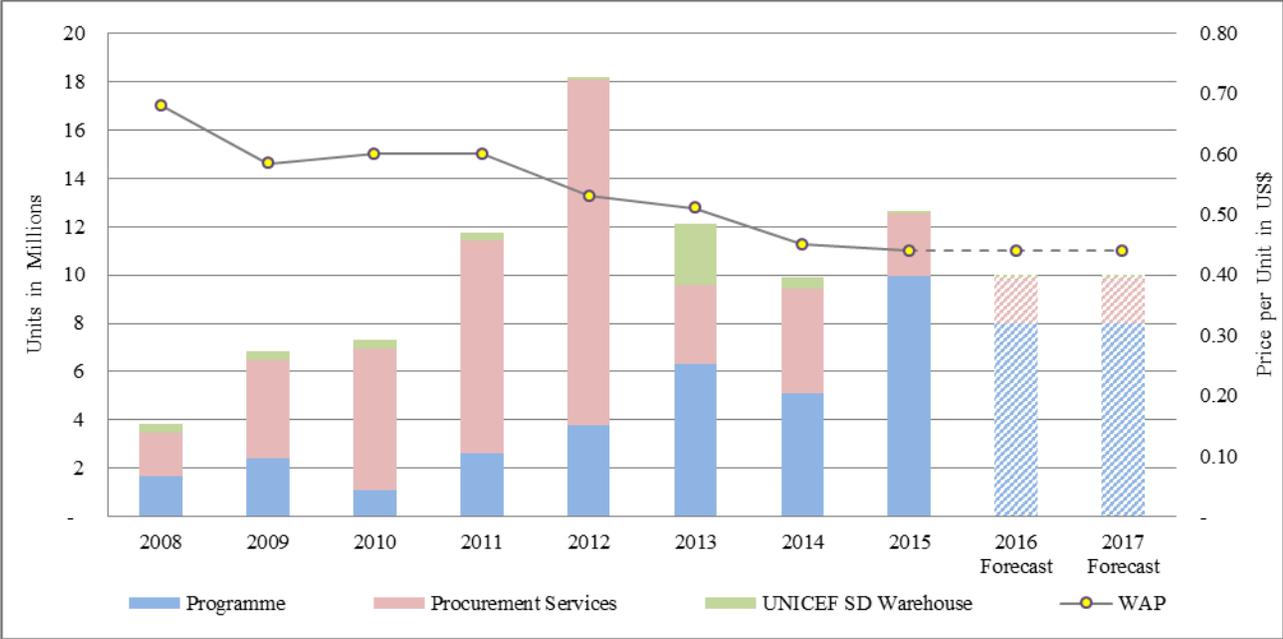
UNICEF bases its 2016-2017 mRDT procurement forecasts primarily on country historical offtake. The demand from UNICEF evolved from a more Procurement Services agenda to increasing demand from UNICEF country programmes. The demand driven by UNDP decreased as UNDP increased its self-procurement post 2012. However, current forecasts include volumes from UNDP/The Global Fund-administered programmes where mRDT procurement is channelled through UNICEF as sub recipient, as well as demand administered by UNICEF country programmes (i.e. in Burundi, Central African Republic, Niger, and Somalia).

⁶ World Health Organization, [WHO publishes interesting new Guidance for the Storage and Transport of Pharmaceutical Products](#), ECA Foundation, Manheim, June 2015.

UNICEF attempted an inaugural mRDT annual forecasting exercise in 2015, which unfortunately generated a response rate too low to be useful. In many countries, mRDT needs are poorly integrated into national annual budgets compared to other prioritized health commodities, and most countries depend on donor funding to finance mRDT procurement. As such, countries continue to face funding gaps and patient access to diagnostics remains low. Most countries also lack sufficient resources to try out possible alternative tests on the market. As such, countries’ demand preferences are often rigid, limiting substitution.

Even though UNICEF country demand forecasts are not yet available, UNICEF does not anticipate demand through UNICEF to increase significantly given other procurement options, most notably The Global Fund’s Pooled Procurement Mechanism (PPM) and The Presidents Malaria Initiative (PMI). Annual procurement through UNICEF will likely remain stable at around 10 million mRDT tests per year, with an approximate annual value of US\$ 4 million based on the current WAP (Figure 2).

Figure 2 UNICEF mRDT Procurement and Forecast 2010-2017



Source. UNICEF Supply Division.

5. Issues and Challenges

- The lack of a robust country mRDT forecast based on forward-looking analysis from country programme managers risks undermining the ability of UNICEF and suppliers to meet any increases to country demand efficiently and effectively. mRDTs are made to order and therefore are not kept in stock. As such, any large unplanned country orders risk long lead-times for delivery if not forecast in advance. Long lead-times for delivery could be mitigated by staggering the deliveries of orders generally made on an annual basis. It would also mitigate risks related to storing large quantities of mRDTs in accordance with manufacturer instructions. Furthermore, larger orders with short delivery times generate higher production risks for manufacturers.
- mRDTs are not well forecasted or integrated into national annual budgets compared to other prioritized health products, and procurement is heavily subjected to funding availability. As such, countries continue to face funding gaps and patient access to diagnostics remains low despite guidelines recommending wide use in endemic countries.
- A limited product range in some countries due to national regulatory requirements can result in limited product availability and accessibility, as most countries have rigid product preferences: i.e. for a particular brand of mRDT, which stymies competition.

- Initiated by the RBM Partnership and the Institute of Tropical Medicine, Antwerp, WHO is harmonizing mRDTs and reviewing the comparability of mRDTs and their compliance with international standards and best practice for labelling, and instructions for use. It will determine how to harmonize mRDTs to increase their inter-changeability and ease of use.

6. Steps Forward

- UNICEF concluded a joint tender with WHO, UNFPA and UNDP for mRDTs end-December 2015 to ensure access to affordable and assured quality devices. UNICEF will issue 12 LTAs during January 2016 (Table 4).
- UNICEF is planning a global forecast to improve future procurement strategies and tenders. It will be based on country product selection decisions, product pipelines and country readiness to adopt new products, product performance and funding availability.
- UNICEF will attempt to undertake again a more detailed country forecasting exercises for future procurement efforts, based on country mRDT selection, product selection decisions, pipeline products, country readiness to adopt new products, product performance, funding availability, as well as other factors and risks.

Table 4 Expected mRDTs Tender Timeline and Milestones

| Date | Activity |
|---------------------|--|
| 2-3 November 2015 | Invitation to bid issued jointly with WHO and other UN agencies. |
| 13-16 November 2015 | Tender closed. |
| November 2015 | End of clarifications and evaluation. |
| December 2015 | Announcement of awards. |
| January 2016 | LTA issuance. |

Source: UNICEF Supply Division.

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Other UNICEF information notes can be found at: http://www.unicef.org/supply/index_54214.html.