Unitaid end of project evaluation: Creating a private sector market for quality-assured mRDTs

June – August 2016

FINAL REPORT

EXECUTIVE SUMMARY

INTRODUCTION

Unitaid made a USD 34 million grant[1] to support the creation of private-sector markets for quality-assured rapid diagnostic tests for malaria (mRDTs) in five countries (Kenya, Madagascar, Nigeria, Tanzania and Uganda) between 2013 and 2016.

The project sought to address a major gap in how the private sector diagnoses and treats fever. In each country, private providers accounted for between 31% and 66% of fever treatments.[2] In 2010, Unitaid and other donors had launched the pilot of the Affordable Medicines Facility – malaria (AMFm)[3] which funded the provision of affordable quality-assured, subsidised artemisinin-based combination therapies (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 tests for malaria.

Challenges inhibiting private providers from using mRDTs included ingrained consumer and provider behaviour, lack of quality assurance, and restrictive policy environments. Unitaid funded activities to address these challenges in the five target countries and the documentation of evidence to support markets catalysis in other countries.[4] The project's theory of change assumed that (i) increasing availability of quality-assured affordable mRDTs, (ii) building consumer awareness, (iii) training providers, and (iv) ensuring an enabling regulatory and policy environment would lead to an uptake in the use of mRDTs. This in turn would lead to improved fever treatment decisions.

This evaluation assesses the achievements of the project and draws lessons for the future. Unitaid commissioned Dalberg Global Development Advisors to conduct the evaluation. The evaluation combined desk research using documents provided by Unitaid, PSI and MC and other grantees,[5] interviews with 49 stakeholders[6] and visits to Madagascar and Uganda. The evaluation methodology is detailed in Annex 4.

OVERVIEW OF FINDINGS

Dalberg perceives that the project had three overarching objectives:

1. Prove the concept of mRDT provision in the private sector and determining which approaches and interventions are effective
2. Support the development of sustainable private-sector mRDT markets in target countries
3. Build and disseminate knowledge and tools to inform the development of other mRDT markets

[1] USD 34 million was the original grant budget. This was revised in to USD 21 million in late 2015 and early 2016. Actual expenditure was USD 20 million as of June 2016.

[2] DHS Malaria Indicators Survey data, cited in Unitaid end-of-project results presentation, June 2016.

[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

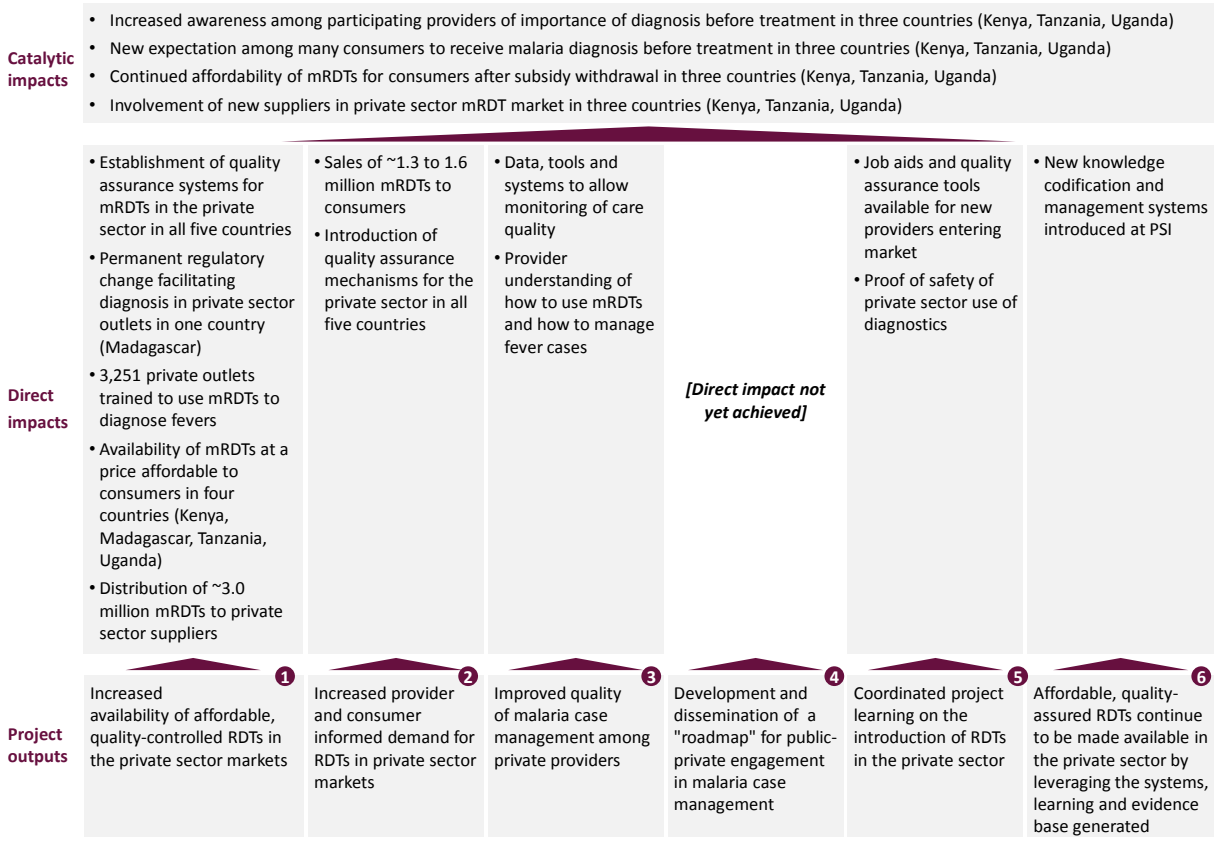
[4] In time, this may include mRDT markets in other endemic countries (identified by Unitaid as potential impact of the project) and markets for rapid diagnostic tests for other diseases (additional potential impact of the project).

[5] The principal grantee (PSI) and sub-grantees (MC, FIND, WHO and JHSPH) are all referred to as "the grantees" throughout this report.

[6] Including Unitaid, grantees, other organisations involved in in-country implementation, and external stakeholders.

The project had different levels of success across its objectives. With regards to the first objective, the project created a large body of insights and learnings that helped build the proof of concept and learning. The project demonstrated the safety and effectiveness of mRDTs in the private sector, and showed in which contexts private sector distribution is more challenging to implement (e.g. with regards to required subsidies) and mitigating steps that might be required. On the second objective, there was partial success. Providers were trained, mRDTs were imported, and consumers bought and used mRDTs, although at lower levels than expected. The supply chain has been strengthened in some countries and there has been permanent policy change in Madagascar. There is high likelihood that the markets that have been developed to date in Kenya, Tanzania and Uganda will continue at their current size. It is possible that they might expand further if support from other donors materialises. In Madagascar, support from the Global Fund might enable the continuation of the market. The project had little long-term influence in Nigeria. Regarding the third objective, a range of documents are being prepared to draw out and share insights from the project; these will likely inform private sector engagements in other countries. The figure below summarises the key achievements of the project.

Figure 1. *Key changes to which the project contributed*



SUPPLY

The project increased the availability of affordable quality-assured mRDTs to some degree, but we estimate that approximately half of the mRDTs procured remained on wholesalers' or retailers' shelves as of the end of the project.

Availability: Of the 3.1 million quality-assured mRDTs procured by Population Services International (PSI) and Malaria Consortium (MC), an estimated 1.3 to 1.6 million were used by customers at

private outlets during the project. There was significant overstocking. Approximately 1.3 to 1.7 million mRDTs remained in warehouses at the end of the project (predominantly in Madagascar and Nigeria). Several factors led to this overstocking.[7] Despite challenges, by the end of the project, Kenya, Uganda and particularly Tanzania appear to have fostered markets for mRDTs. Sustainable markets have not yet been created in Madagascar and Nigeria.

Affordability: It was challenging to find an unsubsidised price that was low enough for consumers but high enough for retailers. The subsidies differed by country but most led to affordable prices during the project.[8] In Kenya, Tanzania and Uganda the markets have evolved and currently have unsubsidised prices that consumers are willing to pay and that provide sufficient profits to suppliers. In Madagascar, affordable pricing might not be sustainable when subsidies are withdrawn.

Quality of mRDT kits: In all countries, grantees worked with the public sector to establish quality assurance (QA) systems for private-sector mRDTs. All mRDTs provided directly during the project were quality assured through such processes.[9]

Quality of mRDT handling and care: There was less provider supervision than originally planned. Nevertheless, most private outlets targeted demonstrated knowledge of the correct steps for diagnosing malaria with an mRDT.

DEMAND

The project built demand for quality assured mRDTs among consumers. There is evidence of growth in consumer demand across most countries. The growth was, however, lower than targeted in Kenya, Madagascar, and Nigeria. Consumer marketing efforts (behaviour change campaigns and branding of quality-assured products and providers) seem to have contributed to demand growth. Price was a key driver of consumer demand. In particular, demand was sensitive to the price of mRDTs relative to ACTs. Behaviour change campaigns appear to have contributed to sustainable demand in Kenya, Tanzania and Uganda (more than in Madagascar where price remains a challenge).

Demand appears to have been built among providers. Providers participated due to two reasons: profit and appeals to professionalism. In countries where single packs were available, providers preferred them as they found them easier to use.[10] The lack of supply of single packs will likely be an issue. Standard Diagnostics (SD), the only manufacturer of WHO-approved single-pack mRDTs, does not intend to supply single packs to African private-sector supply chains.[11]

POLICY AND REGULATORY CHANGE

[7] Initial demand forecasts were based on flawed or incomplete market information in Kenya and Nigeria. UNITAID's assessment that there was lack of clarity and incomplete information provided on the procurement and management of 'bundled RDTs' led to extensive clarification communication between Unitaid and grantees, which delayed approvals and affected procurement timelines, leading to shorter implementation timeframes. In some countries, delays in regulatory approvals or in gaining the support of interest groups constrained execution, reducing the time available for demand building.

[8] With the exception of Nigeria.

[9] While there were problems with single packs used in all countries but Tanzania, these were identified and addressed.

[10] In Kenya and Madagascar some single packs were available. In Nigeria and Uganda, only single packs were made available through the project.

[11] Interview with Standard Diagnostics.

Temporary regulatory waivers were agreed with the governments of Uganda and Kenya.[12] A permanent regulatory change was achieved in Madagascar.[13] Although Nigeria saw policy changes and Tanzania is likely to see policy changes, these were not directly linked to the project but rather to longer-term engagement between government and global health actors, including MC and PSI's Nigerian partner. In all five countries, governments have updated policies to include private sector mRDTs in QA systems and product specifications. In addition, grantees and their partners engaged in advocacy, evidence sharing and system strengthening in each of the five countries, which has informed the policy debate and may lead to further policy change in time.

IMPACT

The project's impact in terms of its reach during implementation was limited. The targeted number of fevers diagnosed with mRDTs according to the logframe was not reached. The proportion of fevers diagnosed with mRDTs and treated appropriately varies by country but in many cases exceeded the original targets at project outset.[14]

- The percentage of fever cases diagnosed using mRDTs in the private sector is above the target of 30% in Kenya, Tanzania and Uganda, but the absolute number of people reached appears to be below target in all countries.
- According to surveys,[15] the percentage of positive malaria cases treated correctly was above targets in all countries, although Dalberg modelling indicates that absolute targets have not been reached. The high rates of adequate treatment may not be a result of the project. At the outset, the percentage of adequate treatment of positive malaria cases was already higher than targets; progress decreased or levelled off over the lifetime of the project in some countries.[16,17]
- The proportion of negative malaria cases treated correctly was high across all countries at project outset and increased across all countries.[18]

FUTURE PROSPECTS

It is probable that, if no additional market development activities take place, the markets in Kenya, Tanzania and Uganda will remain at their current levels while gains in Nigeria and Madagascar will reverse. PSI gradually changed its role over time in the Tanzanian and Kenyan markets by moving from direct distribution to support of other actors. This has increased the likelihood of market sustainability. In other countries, the role of PSI and MC remained the same

[12] In each country, there had been restrictions – either in law or in practice – on certain private sector providers such as pharmacies and drug shops playing a role in diagnosis.
[13] The project did not directly target policy change but aimed to generate evidence to support later policy change.
[14] Grantees report that Unitaid agreed to consider only proportional targets and not absolute targets, given the difficulties of recording or modelling the total number of fever cases treated, but that this decision was not reflected in Unitaid's documentation. This report considers absolute as well as proportional targets to assess the magnitude of the impact achieved.
[15] Project survey results provide insufficient and inconclusive data on whether treatment decisions improved for both positive and negative malaria cases as a result of the diagnoses. As a result, we are cautious about our ability to draw conclusions from these survey results.
[16] Round 1 surveys exceeded first-year targets for under fives in Nigeria, Tanzania and Uganda, and for people five and over in Madagascar, Tanzania and Uganda.
[17] Achievement against this indicator fell over the course of the project in Nigeria and Tanzania for children under five, and in Kenya and Tanzania for people five and over.
[18] The high rates of adequate treatment were already higher than targets at the outset.

over time. The abrupt end of Unitaid funding may have jeopardised market development in the absence of other donor funding.[19]

Taking into account potential work by other actors in developing these markets, future prospects are more positive. In all countries relationships have been built and governments and private stakeholders have committed to driving change. Moreover, other donors have indicated interest in taking forward private sector markets in Madagascar, Nigeria and Tanzania.

Other private-sector markets for mRDTs might be catalysed through the roadmap and learnings. The WHO roadmap is intended to provide recommendations to national malaria programs on how to build private-sector mRDT markets.[20] Moreover, a range of materials were developed or will be developed to support other actors that engage in diagnostics markets.

OPERATIONS

Grantee selection: Unitaid did not have tools in place to fully assess grantees' capacity, and hence understand where project structures (e.g. delegation of authority, risk management) might need to be adjusted**.** Unitaid has already established new processes to more critically analyse its grantees' capacity.

Defining the grant and its overarching objectives: As discussed above, the project had three implicit, overarching objectives. There was a degree of tension between these implicit objectives, particularly between the first two objectives. Given this tension and the inherent trade-off, it was critical that Unitaid and the grantees had a shared and aligned understanding on how to manage this balance. However, Unitaid and its grantees had different understandings of the weight of each objective and the balance between them. Despite attempts, these different understandings were not fully reconciled during project planning and as a result continued to play a role during design, implementation, and reporting.

Setting national targets and planning country operations: The logframe was not contextualised and in many cases did not have appropriate targets or a realistic timeframe. Grantees' project planning was comprehensive and addressed the full range of relevant issues. However, there were weaknesses in the evidence gathered by grantees to inform project plans. Grantees developed strategies to recognise and manage risks that are inherent to market development but these did not address all relevant risks due to the incomplete market information. As they define project logframes and targets, both Unitaid and grantees need to ensure that logframes are responsive to the facts on the ground, and that a good understanding of the market informs planning.

Delegation of authority: As the funder, Unitaid had to define which decisions it would delegate and which ones it would maintain. Unitaid's decision to retain authority for approving procurement reduced the overall project risk ex-ante, and turned out to be an important risk management tool during the project. However, it did cause bottlenecks in project implementation. Unitaid's approval processes were relatively slow and the underlying criteria were sometimes unclear to the grantees. It is difficult to separate the decisions on the delegation of authority from the grantee selection and the capabilities and risks of grantees. Going forward, Unitaid will likely want to make an integrated

[19] In Madagascar, private sector interventions to support the mRDT market introduced under the Unitaid grant have been rolled into a project funded by the Global Fund. DFID continues to invest in private sector case management in neighbouring counties in Kenya. In Uganda, a six-month transition period is operating as the project closes out.

[20] There are delays in finalising the roadmap.

decision on grantee selection, project structure, and the possible levels of delegation of authority, to determine the optimal balance between risk, flexibility and speed.[21]

Monitoring and reporting: Grantees completed routine monitoring and evaluation, with some challenges. The extensive use of surveys also posed practical constraints to grantees. Moreover, inventory data was not systematically gathered on a project-wide basis until June 2015.[22] Grantees submitted detailed semi-annual procurement, financial and programmatic reports although there were some inaccuracies. Unitaid felt that grantees did not proactively share information on emerging risks and challenges until problems became apparent. Going forward, Unitaid could further emphasise the norms and expectations that it has with regards to the proactive sharing of challenges and issues by its grantees.

CONSIDERATIONS ON THE NO-COST EXTENSION

Unitaid denied grantees' request to continue operations for six months past the original end date (the "no-cost extension request"). This decision was based on Unitaid's assessment of project results to date.[23] However, not extending the timeline reduced the time available to grantees to operate at full scale, given delays in project set-up. This may have reduced grantees' ability to achieve some, but not all, of the project's goals:

1. **Prove the concept of interventions in private-sector mRDT markets:** The project generated a large body of learnings on the challenges and possibilities of introducing mRDTs in the private sector. Granting the no-cost extension might have generated further learnings on challenges specific to national scale-up and further enriched the learnings with further details and insights, but many of general insights on private sector scale-up were likely already captured.
2. **Support the development of sustainable private-sector mRDT markets in target countries:** The implementation of pilots was partially on track in most countries and some pilot targets had been achieved. The scale-up was only partially implemented and most scale-up targets were not achieved. Despite limited scale-up, some markets grew and appear to be sustainable at local scale, the no cost extension could have increased the scale further.
3. **Build and disseminate knowledge and tools to inform the development of other mRDT markets.** The project resulted in knowledge and tools that could be used by other actors, including the roadmap. However, the richness of content could have been further enhanced if the project duration was extended.

VALUE FOR MONEY

Value and impact achieved to date: The project has proven the concept and possibility of incubating private sector markets for RDTs, resulted in some sustainable markets at sub-national scale, and it has generated many materials that capture the project learnings and that are starting to be adopted by other actors. In terms of impact, the project funded the distribution of mRDTs to private-sector customers who might not otherwise have had access to diagnostics. Given that an estimated 1.3 to 1.6 million mRDTs were distributed, the project has likely averted hundreds of thousands of cases where non-malarial fevers would have been treated with antimalarials.[24] As a result, unnecessary

[21] In extremis, Unitaid might decide that certain setups are not possible with some or all possible grantees.
[22] PSI and MC had been tracking stock separately since 2014.
[23] Unitaid based its decisions on UNITAID's assessment of (i) the complex project implementation challenges faced and the lack of reliable mitigating actions, (ii) the inclusion of Nigeria, where the project faced elevated challenges, and (iii) unsatisfactory mitigating actions/strategy by the grantee.
[24] The majority of fever cases diagnosed with mRDTs were negative for malaria, according to project reporting.

use of ACTs was reduced in target areas. This is likely to lead to reduced stock-outs of ACTs and therefore to improved health outcomes for malaria patients who would otherwise not have had access to ACTs. The cost of achieving this immediate impact is approximately USD 11 to 14 per mRDT distributed.

Value and impact in the medium term: The project has also built momentum which will extend the value generated across the above-mentioned areas. In terms of impact, if recent sales volumes are maintained in Kenya, Tanzania and Uganda, future sales of mRDTs in the private-sector market could increase, ensuring longer-term availability of mRDTs to consumers. Over the coming five years, expenditures per mRDT distributed would fall to below one dollar as the number of sales to consumers in Kenya, Tanzania and Uganda increases.

Value and impact in the long term: In time, the project may also inform the development of private-sector mRDT markets in other countries. The research has also generated knowledge and processes that will improve the effectiveness of grantees, Unitaid, and potentially the sector. Finally, it is likely that the lessons and hence impact of this study will be used in other health-commodity markets.

CONTENTS

ACRONYMS AND ABBREVIATIONS USED

ACT	Artemisinin-based combination therapy
ADDOs	Accredited drug dispensing outlets
BDH	BDH Laboratory Suppliers Uganda
CHAI	Clinton Health Access Initiative
DALY	Disability-adjusted life year
DFID	UK Department for International Development
FIND	Foundation for Innovative New Diagnostics
KES	Kenyan shillings
MC	Malaria Consortium
M&E	Monitoring and evaluation
MOU	Memorandum of understanding
mRDT	Malaria rapid diagnostic test
NDA	Ugandan National Drug Authority
NGO	Non-governmental organisation
NMCP	National Malaria Control Programme
PATH	PATH, formerly the Program for Appropriate Technology in Health
PMC	Premier Medical Corporation
PSCM	Global Fund Private Sector Copayment Mechanism
PPMVs	Patent and proprietary medicine vendors
PSI	Population Services International
SD	Standard Diagnostics
SFH	Society for Family Health
SUNMAP	Support to the National Malaria Programme
UHMG	Uganda Health Marketing Group
USD	United States dollar
WHO	World Health Organization

1. INTRODUCTION

Unitaid made a USD 34 million grant[25] to support the creation of private-sector markets for quality-assured rapid diagnostic tests for malaria (mRDTs) in five African countries between 2013 and 2016. This grant funded a consortium led by Population Services International (PSI) with the Foundation for Innovative New Diagnostics (FIND), Malaria Consortium (MC), Johns Hopkins School of Public Health and the World Health Organization (WHO) as sub-grantees. The project countries were Kenya, Madagascar, Nigeria, Tanzania and Uganda.[26]

The project sought to address a major gap in how the private sector diagnoses and treats fever. A substantial number of patients in malaria-endemic countries seek fever treatment in the private sector.[27] However, private outlets do often not adhere to global and local policies and guidelines for fever case management. [28,29] Many outlets prescribe or provide treatment without prior diagnosis. Overuse of antimalarials increases the risk of resistance and of unavailability of antimalarials for patients that need them. [30] Unitaid sought to address this situation by increasing the use of malaria diagnostics (specifically mRDTs) by private outlets, and by catalysing functioning markets for mRDTs in each target country. By improving use of diagnostics, the project intended to improve malaria case management.

The project's theory of change targeted the main reasons for limited use of mRDTs in the private sector. The theory of change for the project assumed that by (i) increasing availability of quality-assured affordable mRDTs, (ii) building consumer awareness, and (iii) training providers, there would be an uptake in the use of mRDTs, which in turn would lead to improved fever treatment. Moreover, Unitaid aimed to influence the regulatory and policy environment to ensure that the markets created were sustainable. The project also included the development of a roadmap that distilled the learnings from the five countries to help other countries build mRDT markets. Annex 1 presents Dalberg's understanding of the theory of change based on the logframe and conversations with Unitaid and grantees. Annex 2 outlines Dalberg's evaluation of the logframe.

Grantees engaged in a variety of activities to support market development by improving supply, demand and the policy environment. PSI and MC used two different models:

- **In Kenya, Madagascar and Tanzania, PSI procured mRDTs and provided a range of services to actors along the supply chain.** PSI and MC country offices managed their own procurement processes separately. A different manufacturer supplied each country office. PSI was able to procure diagnostic kits at more advantageous prices than individual wholesalers by buying in large volumes.[31] Kits were predominantly procured in bulk packs or "hospital packs". PSI procured some individually wrapped mRDT kits (each containing the accessories required for one

[25] The original grant budget was USD 34 million. This was revised in to USD 21 million in late 2015 and early 2016. Actual expenditure was USD 20 million as of June 2016.
[26] All countries selected had participated in the AMFm.
[27] From approximately one third in Kenya to two thirds in Nigeria. MIS/DHS data, Cited in end of project results presentation, 2016.
[28] World Health Organization, 'World Malaria Report 2014'.
[29] Malaria Consortium, 'Managing illness through better diagnosis of malaria'.
[30] World Health Organization, 'World Malaria Report 2014'.
[31] PS Kenya was able to secure an additional discount by accessing rates negotiated earlier by CHAI.

diagnostic test) in Kenya and Madagascar.[32] The stock was then sold to various market players.[33] PSI and its in-country partners also provided a range of services to build demand, including training for providers and marketing to consumers.[34]

- **In Uganda and Nigeria, MC procured both mRDTs and services from manufacturers.** In each country MC worked with two different consortia of manufacturers, importers and wholesalers. MC procured mRDT "bundles" of commodities (individually wrapped mRDT kits) and ancillary services (such as training, waste management and demand creation). In each country, manufacturers used their in-country importers and distributors to provide these services. MC was not directly involved in supporting distributors or providing ancillary services. [35,36]

In each country, a multi-stakeholder task force oversaw implementation. National project task forces included PSI or MC, government stakeholders, WHO, professional associations and others. National malaria control programmes were involved in planning, securing regulatory approvals, and project execution (at differing degrees). The division of responsibilities varied in each country.

The project was planned in two phases: a pilot phase and a scale-up phase. Project plans anticipated an 18-month pilot phase in a small number of regions in all countries, followed by a scale-up to a larger number of regions in four of the five countries.[37] Grantees experienced several delays, including in signing agreements with national authorities, in receiving procurement approvals from Unitaid, and in the delivery of mRDTs. The first implementation start date was April 2014 (in Kenya and Madagascar) and the last September 2014 (in Nigeria), compared to original plans for approximately October 2013.[38] Given the delays at the outset of the project, the time available for implementation was shorter than originally planned. As a result, in April 2015 PSI made a request to Unitaid to extend the duration of the project by six months (the "no-cost extension request").[39] The no-cost extension would have allowed a scale-up phase of approximately one year in four countries. As PSI and MC waited for Unitaid's decision, teams in Madagascar, Nigeria, Tanzania and Uganda began to scale up.

Due to limited uptake of mRDTs, the extension was denied and Unitaid ordered a scale-down of activities in some countries, and restrictions including budget reductions in others. Unitaid

[32] In Madagascar, 60,000 mRDTs were procured in single packs and 716,000 in hospital packs. In Kenya 162,500 mRDTs were procured in single packs and 87,500 in hospital packs.

[33] In Madagascar to wholesalers, in Tanzania to regional distributors, and in Kenya at first directly to retailers and later to wholesalers.

[34] In Kenya, Madagascar and Tanzania, PSI worked with wholesalers and distributors it had worked with for other health commodities. PSI Tanzania further built trust and guaranteed demand by sharing market data and its stock data with suppliers to prove market viability.

[35] By design, in Nigeria and Uganda, MC did not assume control or responsibility for building relationships between distribution partners. Instead, the manufacturers (and the distributors the manufacturers contracted) built demand as they chose. This led to a variety of models. For instance, in Uganda, one manufacturer-distributor consortium paid for services such as waste management in advance, while another paid these in arrears. The latter model inhibited demand by adding short-term costs for wholesalers and retailers.

[36] MC provided a subsidy for the mRDTs and the services required by paying a sufficiently high price. This price allowed manufacturers to provide each bundle at a price that was affordable for customers and allowed sufficient margins for all actors.

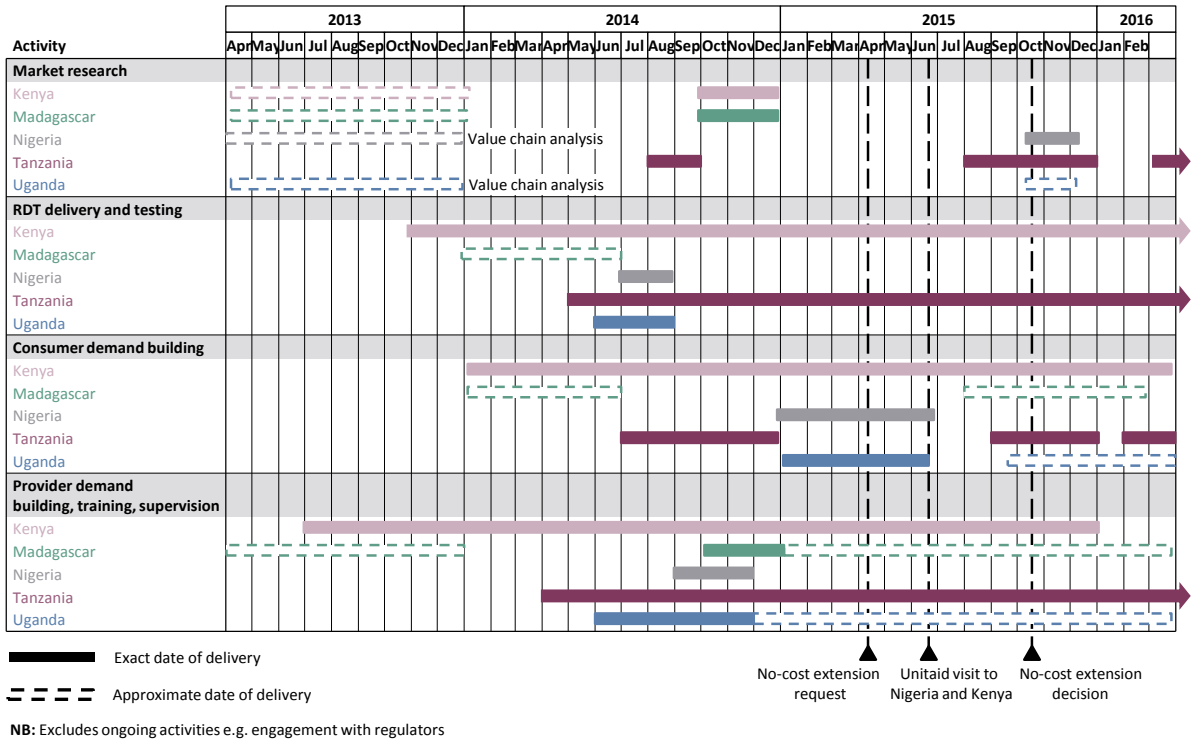
[37] Project plans included a scale-up phase in all countries except for Kenya.

[38] Project annual and semi-annual reporting

[39] The no-cost extension requested permission to make expenditures of USD 2.9 million in the six months after the original project closure date. These expenditures would have been funded from the underspend in previous accounting periods, and would not have added to the total costs faced by Unitaid.

concluded that it would be difficult for grantees to achieve the results expected from the no-cost extension.[40] In October 2015 Unitaid decided not to grant the extension. Unitaid also ordered a significant scale-down of activities in Nigeria and Uganda, and reduced the project budget accordingly. In Madagascar and Tanzania (and in Kenya, where no request for an extension was made), the scale-up phase was limited to approximately six months and budgets were also reduced. Following the denial of the no-cost extension, PSI and MC have engaged in various activities to use up excess stock before they expire, including distribution to parties other than private sector distributors and outlets.[41] In total 27,150 mRDTs were recalled for destruction due to expiry.[42]

Table 1. *High-level summary of project activities*



NB: Excludes ongoing activities e.g. engagement with regulators

Following project closure, Unitaid engaged Dalberg Global Development Advisors to conduct its final evaluation of the grant. This evaluation assesses what was achieved and compiles learnings. The evaluation combined desk research,[43] interviews with 49 stakeholders,[44] and visits to Madagascar and Uganda. The evaluation was completed between June and August 2016. The evaluation methodology is detailed in Annex 4.

[40] Project planning initially envisaged a pilot period of 18 months followed by a scaled-up period of 18 months. The first 18 months of the implementation period (which started from the date of deployment of mRDTs procured) had not been completed in all the countries when the no-cost extension was requested.

[41] This includes working with new private outlets in Uganda and donating mRDTs to the National Malaria Control Programme in Kenya.

[42] 13,450 mRDTs expired on the shelves in Nigeria and 13,700 in Uganda. These are due to be destroyed.

[43] Using documents provided by Unitaid, PSI and MC and other members of the grantee consortium

[44] Including Unitaid, grantees, other partners involved in in-country implementation, and external stakeholders.

2. FINDINGS ON PROGRAMMES

2A. INGOING SITUATION AND NEED FOR THE PROJECT

In each country, private providers treated a large number of suspected cases of malaria. Each of the five priority countries had a high malaria burden. Combined, they accounted for over 77 million suspected malaria cases in 2013 – or over 20% of the total of suspected cases globally.[45,46] Private facilities, including small owner-operated drug shops, larger pharmacies and private clinics, accounted for between 31% and 66% of fever treatments.[47]

Private providers in the five countries had access to subsidised ACTs but faced obstacles in offering diagnostic tests for malaria. In 2010, Unitaid and other donors launched the AMFm pilot project. The pilot was implemented in seven countries: Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.[48] The AMFm funded the provision of affordable, quality-assured, subsidised ACTs through the public, private not-for-profit and private for-profit sectors. As a result, affordable ACTs were readily available in the private sector. WHO and governments recommend that suspected malaria cases should be diagnosed before treatment.[49] This recommendation aims to ensure the availability of ACTs for those needing them and to reduce the risk of resistance due to overuse of antimalarials.[50] However, the private sector faced obstacles in offering diagnostic tests for malaria.

Obstacles that private providers were facing included ingrained consumer and provider behaviour, lack of quality assurance (QA), and restrictive policy environments. The Unitaid grant funded activities to address each of these challenges.

- **In all countries, consumer preferences inhibited demand for mRDTs.** For over a decade consumers in malarial areas had received the message that presumptive treatment with antimalarials was the best course of action. This message was based on prior WHO guidelines that recommended that all fevers in children under five in Africa be presumptively treated with antimalarials.[51,52] ACTs and other antimalarials were often easily available over-the-counter in the private sector. The AMFm and its successor, the Private Sector Co-payment Mechanism, made ACTs more affordable. ACTs were often cheaper than diagnostic tests, making presumptive treatment cheaper. There was also a common assumption that all testing in pharmacies was for HIV, introducing an element of stigma for consumers.
- **While mRDTs were available in the public sector, only Nigeria had relevant private sector distribution of mRDTs.** Each country had a public sector supply chain for mRDTs**.** However, the

[45] World Health Organization, 'World Malaria Report 2014', Annex 6a.
[46] 2014 data on suspected malaria cases reported worldwide and in target countries.
[47] DHS Malaria Indicators Survey data, cited in Unitaid end-of-project results presentation, June 2016.
[48] The AMFm was launched in 2010 and ran through to 2013. Sources : http://www.unitaid.eu/en/amfm, http://www.theglobalfund.org/en/news/2012-11-15_Board_Approves_Integration_of_AMFm_into_Core_Global_Fund_Grant_Processes
[49] The governments of all the countries in scope had adopted WHO's ambition to ensure all malaria cases are tested before treatment.
[50] Interviews with the national malaria control programmes of Kenya, Madagascar, Nigeria and Tanzania and the National Drug Authority of Uganda.
[51] Unitaid, 'Malaria diagnostics technology and market landscape', 2016.
[52] D'Acremont V1, Lengeler C, Mshinda H, Mtasiwa D, Tanner M, Genton B. 'Time to move from presumptive malaria treatment to laboratory-confirmed diagnosis and treatment in African children with fever.' PLoS Med. 2009 Jan 6: 6 (1).

suppliers and distributors did not supply private providers due to a vicious cycle of low demand and high prices.

  - **In four of the five countries, there were limited markets for mRDTs.** In Kenya, Madagascar and Tanzania, there was no significant market servicing private health facilities and pharmacies with mRDTs. In Uganda, there was a private sector market in private health facilities and pharmacies, but there was no significant market among smaller drug shops.[53,54] Providers who were not used to working with mRDTs did not have experience managing the services required to operate diagnostics safely, in particular medical waste disposal. They therefore required training on how to administer and manage diagnostics, including accessories such as gloves, lancets and buffer. Providers were also reluctant to risk their business by turning down customers' requests for treatment in favour of a diagnostic product customers were not demanding.

  - **In Nigeria, a private sector market for mRDTs already existed – including a large illicit market.** Initial market research indicated a small private sector market concentrated in private clinics and laboratories.[55,56] During the project, MC and Unitaid discovered a larger market than anticipated. This larger market-segment included non-quality-assured mRDTs and illicit supplies leaked from the public sector to the private market. Competitive pricing was therefore challenging, especially for high-quality products.

- **National authorities did not perform QA for mRDTs that were intended for private outlets.** The lack of QA compounded the difficulties in building demand, as it increased the risk that kits could be faulty or of low-quality.

- **Despite governments' intentions to increase access to diagnostics, regulatory barriers hindered private outlets from providing mRDTs.** In most countries, laws and regulations restricted private providers from providing diagnostic tests. In Madagascar, while there was no prohibition, there was no clear legal basis that allowed private outlets to offer diagnostics, which inhibited providers from doing so.

[53] Sustainability is defined here as use of mRDTs at scale that allows commercial viability. In Kenya, Madagascar and Tanzania mRDTs were available in fewer than 10% of all private-sector outlets in a 2011 survey. In Uganda, mRDTs were available in fewer than 10% of all drug shops. In Nigeria, mRDTs were also available in fewer than 10% of all private-sector outlets but subsequent project experience indicated that there was a larger market than previous research found.

[54] Poyer et al., Tropical Medicine, 'Availability and price of malaria rapid diagnostic tests in the public and private health sectors in 2011: Results from ten nationally representative cross-sectional retail surveys.' 2015

[55] In Nigeria, mRDTs were also available in fewer than 10% of all private-sector outlets but subsequent project experience indicated that there was a larger market than previous research found.

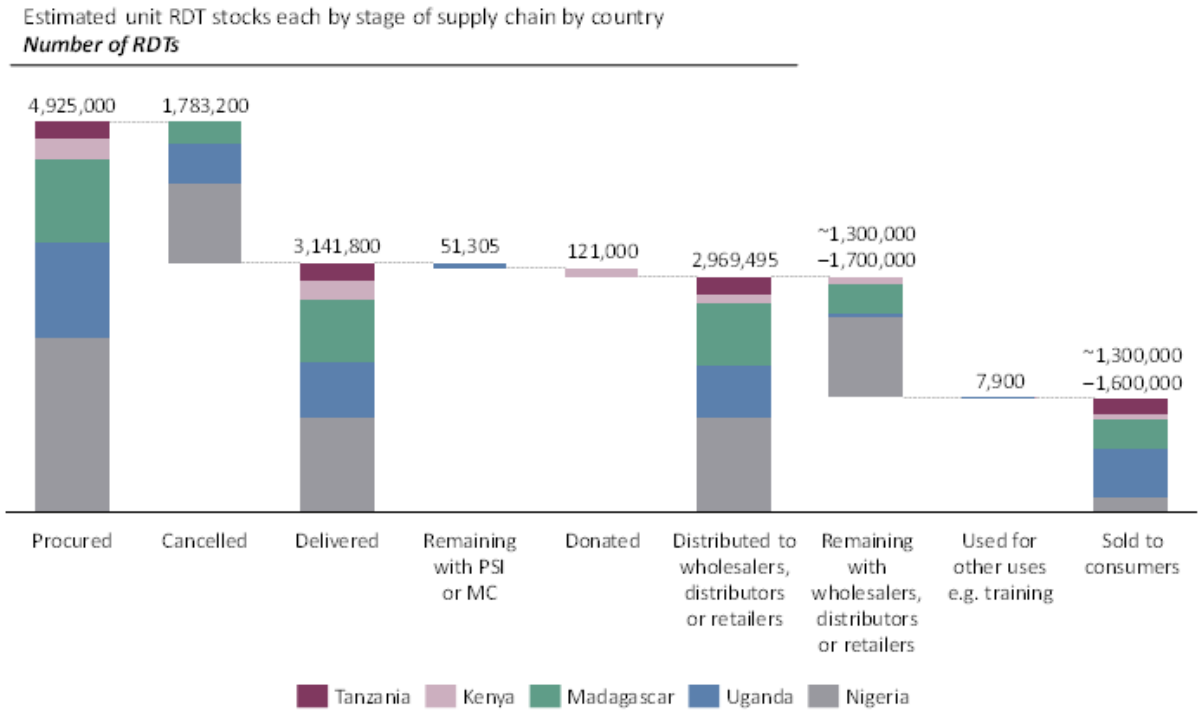
[56] Poyer et al., Tropical Medicine, 'Availability and price of malaria rapid diagnostic tests in the public and private health sectors in 2011: Results from ten nationally representative cross-sectional retail surveys.' 2015

2B. SUPPLY CREATION (AVAILABILITY, AFFORDABILITY, QUALITY)

The project increased the availability of affordable quality-assured mRDTs by approximately three million mRDTs, but we estimate that approximately half of the mRDTs procured remained on wholesalers' or retailers' shelves as of the end of the project.

AVAILABILITY

Figure 2. *Estimated stock volumes by stage of distribution, end of project (April 2016)*



Of the 3.1 million quality-assured mRDTs procured by PSI and MC, an estimated 1.3 to 1.6 million were used by private sector customers during the project. 4.9 million mRDTs were planned to be procured according to original project plans, but orders for 1.8 million were cancelled at Unitaid's direction.[57] According to Dalberg's estimates, of the 3.1 million mRDTs actually delivered[58] an estimated 3.0 million mRDTs were distributed to wholesalers, distributors or retailers. Of these, approximately 1.3 to 1.6 million[59] were likely sold to consumers during the project period.[60] In all

[57] These were intended for Madagascar, Nigeria and Uganda. The UNITAID decision to cancel the orders was due to (a) lack of prior formal approval of the quantities procured, and (b) low consumption of RDTs, overstocking at country level and risk of RDT expiry and (c) lack of clarity on the market challenges and the coordination with country level stakeholders.

[58] Worth approximately USD 1.9 million.

[59] Worth approximately USD 0.8 to 0.9 million.

project countries stock-outs at outlets were rare and targets for availability were generally exceeded.[61]

There was significant overstocking; approximately 1.3 to 1.7 million mRDTs remained in warehouses at the end of the project – predominantly in Madagascar and Nigeria.[62] In Nigeria the majority of the overstock was sold at a discount or distributed through state programmes after the end of the project. 13,450 mRDTs expired before they were used and were therefore destroyed. In Madagascar, the overstock does not expire until 2018 and might still be sold.[63] In Kenya 117,000 mRDTs[64] were donated to the National Malaria Control Programme (NMCP) for use by the Global Fund in training private providers and for national distribution to private outlets.[65] In Uganda, MC planned for the destruction of up to 200,000 mRDTs. Most stock destruction was avoided due to a tenfold increase in sales following the rapid expansion of the project from one district to nine in late 2015. 13,700 mRDTs were destroyed in Uganda.

Unitaid cancelled the procurement of 1.8 million mRDTs due to the overstock. Of the 4.9 million mRDTs originally planned to be procured, Unitaid denied the procurement of 1.8 million mRDTs for Madagascar, Nigeria, and Uganda. [66]

Several factors contributed to flawed demand forecasts which resulted in overstocking:

- **Oversupply of mRDTs in the Nigerian market.** Grantees did not recognise the extent of public sector leakage, the availability of low-quality substitutes, and the availability of counterfeits through their initial research in Nigeria. Additionally, in mid-2015, the Global Fund geographically expanded a project which donated free mRDTs to private facilities. The expansion included the three states targeted by the Unitaid project. MC lobbied the Global Fund not to include project states in its distribution plan but was not successful.[67] The Society for Family Health Nigeria (SFH),

[60] Dalberg has estimated the volume of mRDT sales to consumers based on available sales data, procurement plans, reporting from private outlets, and qualitative assessments provided by PSI and MC. These are outlined in Figure 2 and the methodology is detailed in Annex 5.

[61] It appears that there was no significant leakage or illicit sales to suppliers or providers not enrolled in the project. Grantees are confident that leakage was avoided because most outlets enrolled were small-scale and because there was intensive oversight through training and supervision**.** Our estimates therefore assume that all stock delivered to wholesalers, distributors or retailers was sold or remains with those suppliers.

[62] Worth approximately USD 0.9 to 1.0 million, or about half the expenditure on mRDTs delivered.

[63] Dalberg estimates that the stock currently with wholesalers and retailers could be sold to consumers in approximately 23 to 47 months following project closure. At the lower end of this estimate, all mRDTs in stock would be sold before expiry; at the upper end approximately half would be. This based on an assumption of 11,000 mRDT sales per month, derived from average monthly sales per outlet in 2016 and the number of provider outlets currently operative. This estimate does not include potential increases in the number of outlets consumer that might result from the ongoing work funded by the PSCM.

[64] Worth approximately USD 68,000.

[65] mRDTs are still available for use in the private sector market but costs were not recouped. If they had not been donated, the stock would likely been destroyed as they were due to expire in 2016.

[66] In Madagascar, permission for the final round of 283,000 mRDTs was denied by Unitaid after PSI had made the order. PSI Madagascar was liable for payment and sold its stock to PSI Angola to avoid making a loss. In Nigeria, Unitaid cancelled the delivery of one million mRDTs planned for December 2015 following its assessment that the Nigerian market was saturated. In Uganda, 500,000 of the 1.2 million mRDTs procured were not delivered following a similar assessment by Unitaid that the market was saturated. Unitaid clarified that the orders for Uganda and Nigeria had not been approved.

[67] A market research commissioned by MC that analyses the Nigerian supply chain notes the existence of the Global Fund donation project and its role in supplying mRDTs to patent and proprietary medicine vendors

PSI's Nigerian network member, implemented the Global Fund grant. PSI and SFH are operationally independent, and SFH's understanding of the Global Fund project appears not to have informed MC's or PSI's project planning. PSI interviewees say that it was not feasible for SFH to use its relationship with the government or the Global Fund to affect the decision to expand the donation programme.

- **Delays in procurement approvals.** Delays in Unitaid's procurement approvals affected timelines, leading to shorter implementation time-frames. These delays were particularly pronounced in Uganda and Nigeria (reaching four to five months compared to PSI countries). In these countries, MC procured a novel "bundle" of mRDTs and related services, resulting in extensive clarifying communication between Unitaid and MC.
- **Delays in regulatory approvals.** In Madagascar, there was a delay before the legal basis for private-sector mRDT testing was established in 2014. In Tanzania, the Ministry of Health needed eight months to complete the process to sign a memorandum of understanding.
- **Other legal restrictions**. Tanzania did not allow in-pharmacy testing and the project could only be implemented in officially recognised private sector health facilities (such as clinics and hospitals). PSI procured mRDTs in Kenya assuming a reach of 100 outlets, but only 40 outlets were officially registered and eligible.
- **Demand was lower than expected.** See section 2c on demand.

Despite challenges, by the end of the project, Kenya, Uganda and particularly Tanzania appear to have fostered markets for mRDTs. In each of the three countries, private sector operators are active in wholesale, distribution and retail. In Kenya, the supply market now consists of three wholesalers, five distributors and 168 retail outlets operating in the coastal region. Distributors expect further market growth.[68] In Uganda, 1,502 outlets have been trained, and two of the distributors participating in the project have increased their share of the market for mRDTs,[69] and a Ugandan manufacturer has started to sell to the Ugandan private sector.[70] In Tanzania, the supply market was self-sustaining by 2015. There were additional sources of quality-assured mRDTs besides PSI. As a result, PSI stopped distribution activities and shifted to a facilitation role in which it supported others' commercial relationships. Three wholesalers, ten regional distributors and 868 outlets are now estimated to be active in the market.[71]

Sustainable markets in Madagascar and Nigeria have not been fostered to date. In Madagascar, the project enrolled approximately 450 private outlets and five wholesalers. However, sales volumes are lower than anticipated due to low demand. Demand and ability to pay are so low that interviewees report that without a future subsidy, there is no prospect of a market in the next five

(PPMVs). However, MC interviewees report that they were taken by surprise when the project started reaching PPMVs in project areas.

[68] Due to PS Kenya's DFID-funded work in contiguous Mombasa and Kilifi counties, some of the market infrastructure developed in the region is also attributable to DFID funding.

[69] A third distributor involved in the project left the mRDT market.

[70] Astel Diagnostics, which manufactures its mRDTs in Lugogo in Kampala, sells approximately five percent of its stock to private-sector suppliers, according to MC.

[71] Data on mRDTs sold by these other source during the project duration is not available.

years.[72] In Nigeria, the landscape of private providers does not appear to have changed significantly, and fewer outlets than targeted operate in the market (868 compared to 3,000 targeted).

AFFORDABILITY

It was challenging to find an unsubsidised price that was low enough for consumers but high enough to give sufficient margin to retailers. Private providers require a minimum margin. In some cases, this margin made mRDTs unaffordable without subsidy. There were challenges on both the supply side and the demand side.

- **Oversupply of mRDTs from the public sector, from the black market, and from other countries resulted in the availability of cheaper alternatives.** In Nigeria, recommended retail prices were set with reference to ACT prices but without regard to the price of the other mRDTs that were available. The pricing strategy was affected by unanticipated increases in the supply of mRDTs due to leakages from the public sector and free mRDTs as result of the Global Fund grant. The greater availability of mRDTs depressed retail prices for quality assured mRDTs and retailers had to accept smaller than anticipated margins.
- **Consumers' willingness to pay for mRDTs depended on their own ability to pay and on the cost of ACTs.** This is detailed in section 2c below on demand.

There was diversity in the level and form of subsidies by country. Most subsidies led to affordable, prices with the exception of subsidies in Nigeria. In each market, grantees attempted to set prices at affordable levels**.** Grantees used various levels and forms of subsidy. In most countries, goals for affordability were met with the exception of Nigeria.[73] In Kenya, subsidy levels were increased to ensure affordability. In Madagascar the value of subsidies was held constant and mRDTs remained affordable throughout the project. In Tanzania, prices remained affordable despite the fact that no direct subsidy was paid and that the average retail price increased once stock was exhausted. In Uganda, a high level of subsidy ensured affordability. Due to severe price competition, in Nigeria, mRDTs were not affordable despite levels of subsidy that were comparable to other countries.

Prices in Kenya, Tanzania and Uganda have since reached levels that consumers are willing to pay and that provide sufficient profits to suppliers (approximately USD 1.00, 0.40 and 1.00 respectively), despite the end of the subsidies. In Madagascar, commercial prices remain unaffordable to consumers without subsidies.[74]

[72] The Global Fund is likely to fund price subsidies until 2018.
[73] For details on subsidies please refer to country profiles in Annex 3.
[74] Nigeria did not reach adequate subsidised pricing during project implementation.

QUALITY OF mRDT KITS

All mRDTs provided were successfully quality assured according to processes devised for the project. Pre-shipment and post-shipment testing was completed on time in all countries.[75,76]

In all countries, grantees worked with the public sector to establish QA systems for private sector mRDTs. Project activities improved QA by: (i) increasing the public sector's capabilities to oversee the private-sector market, (ii) improving providers' ability to handle and quality assure their stock, and (iii) building consumers' demand for high-quality products. Grantees engaged national authorities to develop national private-sector QA systems or to incorporate private sector mRDTs into public sector assurance systems.

FIND also developed tools to help private providers conduct QA of their mRDT stock.[77] These tools included a new QA technology (positive control wells), a troubleshooting guide describing problems often encountered with RDTs and solutions, and visual guides to promote appropriate use of mRDTs by providers.

Problems with single-pack kits were identified and addressed. The buffer solution needed for the diagnostic tended to evaporate in single-pack mRDT kits, possibly due to the packaging used. [78] PSI, MC, FIND, WHO and the national authorities in each country collaborated on quality testing to identify the source of the problem and to understand how many kits were affected. Once affected batches were identified, the manufacturers issued additional accessory packs with replacement buffer.[79] At the global level, FIND and WHO developed guides for providers on how to identify and handle faulty packs.[80] Based on this experience, WHO changed its guidelines in December 2014 to recommend that single packs should not be used until they are able to preserve buffer in equatorial conditions.[81,82]

[75] Indicator O1.8.
[76] There were obstacles such as procurement delays and challenges in receiving stocks and shipping them to test sites in Nigeria.
[77] Such as clinics, hospitals, pharmacies, etc.
[78] Produced by all three of the manufacturers involved.
[79] Grantees requested that outlets report the number of faulty kits they encountered. Country task forces also led information campaigns so that participating outlets understood the issue.
[80] WHO vetted and approved guides developed by manufacturers to help providers assess whether kits contained sufficient buffer. FIND developed a troubleshooting guide for providers to help them resolve problems on-site.
[81] As a result, in the remaining procurement rounds (by PS Kenya and PSI Madagascar) bulk packs (also known as "hospital packs") were procured instead of the planned single packs. In Nigeria and Uganda, where additional procurement rounds were still planned, there was no shift to hospital packs.
[82] As of March 2016, WHO has prequalified two single-pack mRDTs manufactured by SD.

QUALITY OF mRDT HANDLING AND CARE

Potential risks to public health, which would undermine the longer-term sustainability of market change, were mitigated.

MC required that that implementing consortia provide waste management services at no extra cost to participating outlets. Health ministries and professional associations identified that private outlets were likely to find waste management a challenge. Regular waste disposal services were included in the price paid by providers. By contrast, in PSI's countries, providers handled waste management themselves.

There was less provider supervision than originally planned. Nevertheless, most private outlets targeted demonstrated knowledge of the correct steps for diagnosing malaria with an mRDT.[83] In all countries but Madagascar, support and supervision targets were missed in at least one year.[84,85] Despite lower levels of supervision, programmatic reporting indicates that providers were knowledgeable about the correct process for diagnosing malaria with mRDTs. As a result, a large proportion of patients diagnosed as negative for malaria received appropriate treatment.[86]

The Kenyan project team identified that limited availability of ACTs on the market was a key constraint for the appropriate treatment of malaria cases. Availability was particularly low in the period between the release of donor funding for ACTs and the distribution of stock to first-line buyers. PS Kenya therefore amended project plans to directly procure 30,000 ACTs.[87]

[83] PSI countries used technology to monitor standards of care and target support. Tablet-enabled software was used during the supervision visits at outlets. The software allowed immediate and accurate tracking of outlets. It also enabled trainers and supervisors to target behaviour change communications and supervision towards outlets with the highest patient volumes and/or lowest quality scores. This targeted support may explain why increases in quality of care were achieved despite the fact not all outlets were supervised regularly. There were rapid increases in quality of care as measured by PSI's scorecard in Madagascar and Tanzania (though not in Kenya, where quality of care was higher to begin with).

[84] Indicator O3.2, as presented in Annex 6.

[85] In Kenya, Madagascar and Tanzania, provider monitoring systems were introduced by PSI. These systems promoted quality assurance and continuous improvement, and enabled PSI to focus their attention on providers in greatest need of help.

[86] This was measured as indicator O3.1, as presented in Annex 6. The proportion of clients testing negative for malaria managed according to the recommended treatment algorithm exceeded targets in every year, and increased between 2014 and 2016 in every country but Madagascar (where it declined from 99% to 93%).

[87] In Madagascar, the mRDT project was intended to complement a concurrent project on ACT availability also implemented by PSI. PSI's ACT project was for a private sector co-payment mechanism (PSCM), funded by the Global Fund. PSI teams collaborated on messaging for both training and consumer marketing purposes.

2c. Demand creation (consumers and providers)

The project built some demand among consumers and providers for quality mRDTs. Demand remains very price/margin-sensitive.

CONSUMERS (INCLUDING CAREGIVERS)

There is qualitative and quantitative evidence of consumer demand growth in most countries. According to interviews and sales data, end-user demand grew throughout the project in Madagascar and Tanzania, and towards the end of the project in Kenya and Uganda.

The growth in demand was lower than expected in Kenya, Madagascar, and Nigeria. As illustrated in Figure 2, in Kenya, Madagascar and Nigeria there was an over-stock of mRDTs, suggesting that demand did not reach the expected levels. The picture in Nigeria is less clear, given the flooding of the mRDT market.[88]

Gains in demand may have not been evenly spread and have been greater in wealthier areas. In Kenya, Madagascar, Nigeria and Uganda, interviewees report that increases in demand have been concentrated among wealthier customers.

Consumer marketing efforts such as behaviour change campaigns and the introduction of mRDT branding seem to have contributed to demand growth.

- **In Kenya, Madagascar, Tanzania and Uganda, behaviour change campaigns have built demand.** In Tanzania, demand grew steadily after the introduction of behaviour change communications in late 2014. In Madagascar, demand also grew at a constant but slower pace once the marketing campaign was introduced. In Kenya, the introduction of consumer and provider marketing campaigns in the middle of 2014 coincided with a doubling of monthly sales.[89] In Uganda, monthly sales grew tenfold in the second half of 2015 as compared with the first, when the project scaled from one district to nine and a consumer campaign was begun for the eight new districts. In Nigeria, due to project delays, consumer behaviour change campaigns were not started in earnest and did not result in significant changes in demand. This correlation echoes interviewee's opinions that marketing changed consumers' perceptions of malaria testing and that consumers have begun to demand testing.
- **Consumer education seems to have increased demand for quality-assured mRDTs.** Logos and branding to help consumers identify quality-assured mRDTs and participating outlets were rolled out in all countries but Nigeria.[90,91] Interviewees indicated these logos have increased demand for quality-assured products and for outlets carrying the logo in general. In Uganda, customers have begun to associate the local green logo with high-quality care, further incentivising provider

[88] Given the existing market of lower-cost non-quality assured substitute mRDTs in Nigeria, increases in demand for mRDTs does not necessarily translate to demand for high-quality mRDTs.
[89] Comparison of average monthly sales between the first and second halves of the year 2014. Source: Annual narrative report.
[90] A consumer-facing logo for quality-assured mRDTs was developed and implemented in Madagascar, Tanzania and Uganda in 2014, and in Kenya in 2015.
[91] Logos are registered with the respective ministry of health in each country.

participation. A distributor said of the impact of the logo: "The logo is helpful because before there were lots of low-quality diagnostics. Now, customers want the product with the logo."

Price was a key driver of consumer demand. In most countries adequate pricing was achieved with subsidies. For example, in Kenya, consumer sales tripled in 2015 after the introduction of a subsidy that brought average retail prices down to the recommended level of KES 60.[92] In Uganda, a subsidy of 82% of the target retail price kept prices below target. In Nigeria, where there is greater availability of alternative products, the subsidy of 62% of target price was not able to increase demand.

The price of mRDTs relative to ACTs was crucial. In all countries the recommended retail price for mRDTs was set with reference to the subsidised price of ACTs (as per the AMFm).[93] It is highly likely that mRDTs need to be cheaper than ACTs for long-term market sustainability. As one wholesaler in Kenya explained: "ACTs are subsidised but mRDTs are not. So a [low-income] patient has to choose, do I test or do I treat? So of course they go for treatment. The tests are everywhere. Labels and logos are everywhere; it's in your face. The only problem is, does the patient want to test?"

Demand appears to be sustainable in Kenya, Tanzania and Uganda but less so in Madagascar. As discussed earlier, markets in Kenya, Tanzania and Uganda have reached unsubsidised prices that consumers are willing to pay and that provide sufficient profits to suppliers (approximately USD 1.00, 0.40 and 1.00 respectively). In Madagascar, pricing may not be affordable once subsidies are withdrawn.[94] Moreover, in Tanzania and Uganda consumer awareness of the importance of diagnosis, of mRDTs, and of mRDT providers increased by 20% or more.[95,96]

[92] Recommended price levels according to market research. According to PS Kenya mRDT sales data, quarterly sales to wholesalers tripled from 9,595 to 26,280 following the introduction of the subsidy before the third quarter of 2014.

[93] In all five markets there is some degree of ACT subsidy, although consumer prices vary somewhat.

[94] Nigeria did not reach adequate subsidised prices during project implementation.

[95] Based on baseline and end line surveys carried out as part of the project. Indicators O2.1, O2.2 and O2.3 measuring these three issues were below targets in end line reporting.

[96] However, there was limited change in the percentage of caregiver asking for mRDTs across all countries (indicator O6.2.). In none of the five countries did this exceed 30%; the targets of 60% have been missed by a wide margin.

PROVIDERS

Qualitative insights suggest that demand has been built among providers. Interviewees in all project countries, with the exception of Nigeria, believe that targeted outlets now have an interest in providing mRDTs. Interviewees also suggest that demand is channelled towards larger providers.[97] Moreover, distributors in Kenya, Tanzania and Uganda[98] plan to continue operating in the markets as they have positive expectations for future demand.

Providers participated due to two reasons: profit and appeals to professionalism.

- **Profit was a key driver of provider interest.** In Kenya, grantees report that many additional outlets entered the mRDT market when a subsidy was introduced in 2015 to increase their margin. In Tanzania, outlets' willingness to stock mRDTs increased when recommended prices were increased, increasing their profit margin. In Uganda, retailers that originally relied on the subsidy are now willing to stock unsubsidised mRDTs as they are confident of the volumes they can sell.
- **Grantees also persuaded providers to participate by appealing to their professionalism.** In all countries, outreach was done jointly with national malaria control programmes and professional bodies.[99] These bodies stressed the positive health impact that providers could have and explained that, by participating, providers would be in alignment with national malaria strategies. These arguments persuaded providers that were unsure of the profitability of mRDTs. In Kenya and Uganda, where there was extensive marketing and a high-visibility brand for participating outlets, some consumers also began to associate mRDTs with high-quality care. In Uganda, enrolled outlets reported increased overall sales due to the perception that they were trustworthy providers.

Providers preferred single packs, which they found easier to use. Where both single packs and hospital packs were available (Kenya and Madagascar), providers preferred single packs. The preference was especially strong among smaller outlets that were not used to managing accessories. In Nigeria and Uganda, where only single packs were available from the Unitaid project, providers prefer single packs to bulk packs and appear to have reduced their purchases of mRDTs now that manufacturers are only supplying bulk packs.[100]

Despite engagement, some providers prefer microscopy. In Nigeria, many providers maintained a strong preference for microscopy. This preference was also reported among some providers in Uganda and Kenya. In some countries, however – notably Madagascar – providers' initial preference for microscopy shifted as a result of education and training.

[97] Larger, more expensive clinics offer mRDTs but smaller owner-operated outlets are less likely to do so.
[98] Interviewees we not able to quantify the demand increase. Data on private providers' awareness and trust of mRDTs (indicator O2.4) was not reported in programmatic reporting.
[99] Professional bodies that represented the professions that were targeted to offer mRDTs (e.g., pharmacists).
[100] As of August 2016, WHO recommendations prequalify two single-pack mRDTs manufactured by SD. However, SD has indicated in an interview that it will not supply single-pack mRDTs in African markets in future as they are uneconomical without the Unitaid-funded subsidy.

2D. POLICY AND REGULATORY CHANGE

Temporary regulatory waivers needed for pilot execution were agreed with governments in Uganda and Kenya, and a permanent change in regulation was achieved in Madagascar. There may be future permanent changes in Kenya and Uganda. In all of the five countries, governments have updated policies to include private sector mRDTs in their quality assurance systems and product specifications.

Each country restricted certain private providers such as pharmacies and drug shops from offering diagnosis before the project began. Governments imposed legal or practical restrictions due to several concerns. These include potential public health risks of inadequate waste management or incorrect diagnoses, pressure from stakeholders (particularly lab technicians), and leakages of mRDTs from the public sector to the private sector resulting in public sector stock-outs.

The project did not directly target policy change but aimed to generate evidence to support policy change at a later stage. The project recognised that policy change was important for sustainability. There were no explicit advocacy efforts to permanently change policies. Instead, the project intended to demonstrate that the private sector could safely use mRDTs. Grantees expected that this evidence could be used to justify policy changes. WHO was originally planning to support governments adapt policies and regulations. However, delays in developing the roadmap reduced its ability to engage government audiences.[101]

In four countries, policy waivers were obtained. Temporary waivers were granted for mRDTs in Uganda and geographically-specific waivers were given to project areas in Kenya. In Madagascar and Nigeria, permanent changes were achieved. In Tanzania, the project intended to obtain the waivers needed to operate in a category of small retail outlets approved to provide some essential medicines, known as accredited drug dispending outlets (ADDOs). However, this policy did not change as anticipated. The project therefore operated in private-sector clinics where diagnosis was already authorised (but not at pharmacies or similar outlets).

The project contributed to permanent regulatory changes in Madagascar. In Madagascar, there was no legal basis for private outlets to conduct diagnostic testing. A new regulatory text was developed to allow private providers to offer diagnostic tests, in particular pharmacies and small owner-operated drug shops. A single national quality specification for mRDTs was also established for the public and private sectors.[102] Interviewees from the Madagascar public sector and professional associations cite the involvement of PSI as a catalyst for both changes. PSI's private sector experience informed the government's approach to engaging the sector and its engagement of a broad set of stakeholders ensured buy-in.

The project might contribute to changes in Kenya and Uganda. Government authorities from Kenya and Uganda have made commitments (at the end-of-project meeting and since) which suggest that they aim to extend the temporary waivers. These regulatory changes are not yet guaranteed.

[101] Further detailed in section 3.

[102] The Madagascar project task force, led by the national malaria control programme, the Direction de Lutte Contre le Paludisme, and the Ministry of Public Health led stakeholders in developing this text. These stakeholders also clarified the product standards that applied to the private sector. Thus, they established a single national specification for the public and private sector mRDTs which was based on WHO standards, and they extended public sector provider quality assurance to provider sector providers.

- In Kenya, the National Malaria Control Programme (NMCP) is making the case for a longer-term change. The NMCP is using evidence generated from the Unitaid project to overcome the objections of professional bodies that are opposed to the change.
- In Uganda, the authorisation for pharmacies to diagnose was granted on a temporary basis. The National Drug Authority has indicated that the findings from this project have increased the likelihood that it would grant a permanent authorisation.[103]

Although Nigeria saw policy changes, and Tanzania is likely to do so, these were not directly linked to the project but rather to longer-term engagement with government.

- In Nigeria, owner-operated drug shops[104] were authorised to perform diagnoses in February 2015. Nigeria's National Malaria Eradication Programme reports that this authorisation was already a priority of the government. MC reports that the waiver was the result of concerted advocacy by the sector, of which the Unitaid project was one component.
- In Tanzania, the National Malaria Control Programme is working to secure waivers for ADDOs. A temporary waiver for ADDOs was granted for the period July to December 2016 and might form the basis for a permanent extension. However, this waiver was granted for a different market development project implemented by CHAI and PSI in eight Tanzanian districts.[105] The project will test the applicability of QA systems (such as that used in the Unitaid project) to ADDOs to ensure quality of diagnosis and care.

In all five countries, governments have updated policies to include private sector mRDTs in QA systems and product specifications. All five countries have adopted policies or strategies for QA of private-sector mRDTs.[106] Moreover, all countries have public sector systems in place that can conduct QA for private providers of mRDTs.[107]

The project also contributed to a broader shaping of the policy environment across all five countries. Grantees and their in-country partners engaged in advocacy, gathering and dissemination of relevant evidence and system strengthening. They report that this has shaped debate in each country's health sector and may inform subsequent policy change.

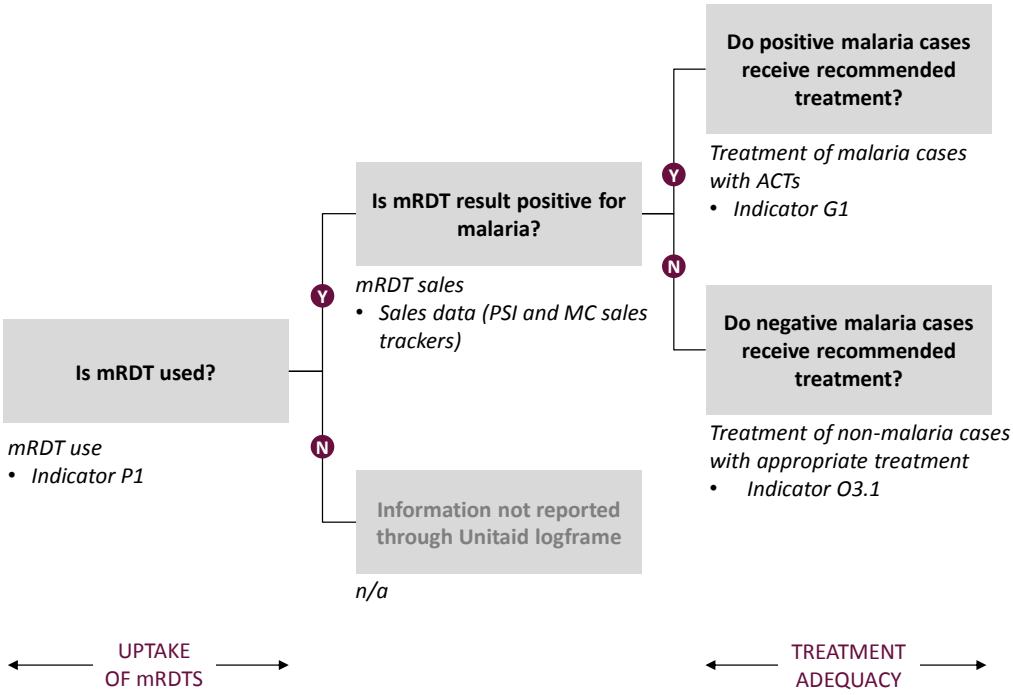
[103] Before a permanent authorisation is possible, legislation has to establish the right of the National Drug Authority to make this decision. The legislation is expected in autumn 2016 and policy change following that.
[104] Known as patent and proprietary medicine vendors (PPMVs).
[105] CHAI is leading implementation in seven districts and PSI in one. This project is based on an earlier CHAI pilot that investigated ways of helping the government to meet its strategic targets of increasing malaria testing capacity by 80%.
[106] Such as product specifications and quality assurance guidelines.
[107] The goals for each of the three indicators that relate to national quality assurance systems have been achieved (indicators O1.7, O1.8 and O6.1).

2E. IMPACT AND OUTCOMES OF THE PROJECT

The project had limited direct impact during implementation as the absolute number of fevers diagnosed with mRDTs and treated with ACTs was likely less than the number of mRDTs procured and than initial targets

The grant aimed to have impact by improving the quality of fever case management. Adequate management included use of mRDTs in diagnosis, and then treatment of both positive and negative malaria cases according to recommendations. The various concepts comprising adequacy of fever case management are outlined below in Figure 3.

Figure 3. *Indicators on the adequacy of fever case management using mRDTs*



In initial versions of the logframe absolute targets were set, these were later dropped. Grantees report that Unitaid agreed to consider only proportional targets and not absolute targets, given the difficulties of recording or modelling the total number of fever cases treated. This decision was not reflected in Unitaid's documentation or in reporting of progress against logframe indicators. Nevertheless, to understand the scale of the impact, the remainder of this section assesses the achievements of targets in absolute as well as proportional terms, recognising the limitations of these absolute targets.[108]

UPTAKE OF mRDTs

The percentage of fever cases diagnosed in the private sector exceeded the end-of-project target (30%) in Kenya, Tanzania and Uganda; however, for all countries, the absolute number of people reached appears to be below the scale intended.

[108] Limitations include (i) the fact that the targets reported in the logframe were not revised to reflect reductions in the number of mRDTs entering the market due to procurement cancellations, (ii) grantees' understanding that absolute targets would not be applied.

- **The percentage of mRDT uptake was above target in Kenya, Tanzania and Uganda but not in Madagascar or Nigeria.** According to survey results, the percentage of people seeking fever treatment at private outlets diagnosed using mRDTs is above the 30% target in Kenya, Tanzania and Uganda. In Madagascar and Nigeria these targets were missed. Attainment increased year-on-year for all countries.[109,110]
- **The absolute number of sales is significantly lower than the absolute targets set in initial project planning.** The project did not track the absolute number of people seeking fever treatment at private facilities who were diagnosed with an mRDT. However, a proxy is the estimated number of mRDTs sold to clients through the project.[111,112] No country achieved its original absolute target for the three years. This can be expected given the compressed scale-up of approximately six months in most countries. By the end of the project, Madagascar, Tanzania and Uganda had surpassed their goals for year one, and a significant portion of their goals for year two. In Tanzania, the total numbers are probably significantly higher than tracked given that additional demand outside project areas was stimulated.[113] By the end of the project, Nigeria and Kenya had not reached their goals for year one.[114]

Demand targets were higher than procurement targets. The project aimed for 10.7 million fever cases to be diagnosed with mRDTs. However, the project only planned to procure 4.9 million mRDTs. Market catalysis during the three years would have been necessary to achieve the impact goals. However, in most countries the monitoring systems (both programmatic reporting through the logframe and sales reporting) did not aim to capture sales of other market actors.[115] Grantees were therefore never in a position to report on the achievement of absolute targets.

[109] Attainment increased year-on-year among people five and over in all countries. In all countries but Tanzania attainment also increased year-on-year for children under five. In Tanzania the proportion of children under five that were diagnosed with an mRDT fell between the second and third survey rounds, while still meeting the end-of-project target.

[110] Variations in mRDT uptake may reflect variations in prior fever case management procedures and use of diagnostics by provider type and by country.

[111] The initial absolute targets for mRDT uptake (combining children under five and people five and over) can be compared to Dalberg's sales estimates reported in section 2b.

[112] As presented in Annex 6.

[113] Data does not capture sales outside of the project.

[114] However, because there was a pre-existing market in Nigeria, it is highly likely that the total numbers are significantly larger for Nigeria, as numbers do not capture sales outside of the project.

[115] Uganda is an exception. MC Uganda conducted a value chain analysis assessing imports of mRDTs to all provider types in the country, and has supported the National Drug Authority's ability to monitor this data on an ongoing basis.

TREATMENT ADEQUACY

The grant also aimed to fund improved quality of treatment for positive and for negative malaria diagnoses.

Survey results provide insufficient and inconclusive data on whether malaria treatment decisions improved as a result of the diagnoses. Only a subset of all survey respondents were positive for malaria and therefore included in this indicator.[116] As a result, it is not clear whether any sample so small (as small as ten survey respondents total in Madagascar) can be sufficiently representative to accurately estimate the public health impact.[117] We are cautious about the ability to draw strong conclusions from these small samples.[118,119]

The percentage of positive malaria cases treated correctly was above targets in all countries. Dalberg modelling based on sales data suggests that the absolute number of fever cases treated correctly was lower than anticipated in the original absolute targets.[120]

- **The percentage of positive fever cases that received effective treatment was broadly above targets.** According to survey results, the percentage of people five and over that tested positive for malaria and received an effective treatment was above the 60% target in all countries but Madagascar.[121] For children under five, this target was met in Kenya, Madagascar and Uganda, narrowly missed in Tanzania and missed in Nigeria.
- **The absolute number of positive fever cases that were treated effectively are likely to be below the scale intended, based on proxies used by Dalberg.** Data on the absolute number of positive fever cases treated was not reported. However, according to Dalberg's modelling, the absolute number of patients that tested positive for malaria and that received effective treatment is likely to be below the initial targets set in all five countries.[122,123,124]

[116] To determine whether there have been improved treatment decisions, the evaluation considers if people (children under five and people five and over) with fever cases testing positive for malaria receiving effective antimalarial treatment.

[117] Although, it is statistically defensible to conclude that targets were met or missed with 95% confidence.

[118] Only those diagnosed using mRDTs could be included in the sample. Where caseloads were small or where uptake of mRDTs was low, the ability to reach an adequate target size was constrained. Use of survey data in project reporting suggests that either the donor and grantees failed to anticipate this possibility, or that researchers engaged by grantees failed to sample accordingly.

[119] To mitigate low samples, PSI also gathered data on these variables through routine reporting but these were not included in the Unitaid logframe.

[120] Details on the methodology for this model and its limitations are outlined in Annex 5 and the results are presented in Annex 6.

[121] In Madagascar, survey results are well below targets but sample sizes are too small to make reliable conclusions.

[122] The evaluation uses estimates of the number of people (children under five and people five and over) with fevers who test positive for malaria that receive effective antimalarial treatment, as a proxy for the number of improved treatment decisions.

[123] Estimates of the number of people (children under five and people five and over) with fevers who test positive for malaria that receive effective antimalarial treatment data are modelled based on (i) the number of mRDT sales modelled above in the supply section, (ii) the proportion of mRDT uses that resulted in positive diagnoses and ACT prescriptions, as indicated in routine sales data (for those sales included in routine data).

[124] This estimation has several limitations including: (i) potential for low representativeness of the sample of outlets reporting input data, (ii) inability to correct for seasonal and annual changes in rates of RDT use and ACT prescription, and (iii) inaccuracies in the routine sales data. However, the estimations are very far below

The high percentage of adequate treatment, and the falls observed in some countries, may not be a result of the project. At the project outset, the percentage of adequately treated positive malaria cases was already higher than targeted. This percentage might have decreased somewhat over the lifetime of the project in some countries, although this was within the margin of error. Any decrease may reflect issues outside the direct scope of the project – specifically the availability of ACTs following the end of the AMFm – which may have reduced outlets' ability to prescribe the necessary medication.

- **In many countries, the percentage of patients receiving adequate treatment was high to begin with.** In Kenya, Nigeria, Tanzania and Uganda, the percentage of 'people testing positive for malaria that were prescribed ACTs was already at or above the end-of-project target in the first survey round.[125] By contrast, in Madagascar, targets were not met in any year.[126] This suggests that the blanket end-of-project target of 60% across all countries may not have been appropriate.
- **Progress reversed somewhat in Madagascar, and levelled off in Kenya and Tanzania.[127]** In Madagascar, the percentage of fever cases treated fell slightly between the second and third surveys, but this fall was within the margin of error.[128] In Kenya and Tanzania, this figure remained approximately the same and any fall was within the margin of error. The rate of effective treatment dropped in Kenya and Tanzania (where market creation activities were strongest) but increased in Nigeria where market creation was not achieved. This suggests either a weak link between project outputs, outcomes, and overall impact, or unreliable survey results.

The percentage of negative malaria cases treated correctly was high at project outset and increased across all countries. According to surveys, the percentage of negative malaria cases that were treated correctly in 2014 and 2015 was significantly above the original 30% target in all countries.[129] The end-of-project target was therefore increased to 60% at the grantees' request; this target was also exceeded in most countries.[130] Nevertheless, stakeholders in all countries report that a significant proportion of private providers offer malaria treatment without testing. This was identified as a problem particularly in Madagascar, where consumer demand for tests has been slower to build.

It is not possible to discern public health impact in terms of mortality and morbidity due to improved targeting of ACTs due to data gaps. To understand the impact of reduced stock-outs on mortality would require data on malaria mortality and stock-outs that were not collected or

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targets, giving strong reason to believe the actual number of fever cases treated adequately is also likely to be below targets.

[125] According to data on indicator G1.2: children over five years old and adults in project areas testing positive for malaria at targeted private outlets that receive an effective antimalarial treatment.

[126] In Madagascar, targets were not met in any year for indicator G1.1 (on children under five) or G1.2 (on people five and over). The exception is indicator G1.1 (on children under five in the end line survey) when one child was surveyed who was treated. This gave a result of 100% effective antimalarial treatment. This result is not included in this analysis.

[127] Most notably on indicator G1.2 (on effective antimalarial treatment among people five and over).

[128] In Kenya and Madagascar, the proportion of cases treated fell among people five and over between the second and third survey rounds, although in Kenya the fall was small and was smaller than the margin of error of the surveys on which this data is based. In Tanzania, the proportion of cases fell among both age groups.

[129] Indicator O3.1, as presented in Annex 6.

[130] For indicator G1.1, the end-of-project target for children under five was exceeded in Kenya, Madagascar and Nigeria. For indicator G1.2, the end-of-project target for people five and over was exceeded in Kenya, Nigeria, Tanzania and Uganda.

reported. To understand the impact of improved mRDT use on resistance would require epidemiological data that is not available so shortly after project closure.

2F. FUTURE PROSPECTS FOR THE MRDT MARKET

Since the grant finished, in three of the five countries – Kenya, Tanzania and Uganda – there appears to be an emerging private-sector market for mRDTs. In Nigeria and Madagascar there is a risk of reversal. Change in other markets might be catalysed through the roadmap and sharing of learnings.

FUTURE PROSPECTS FOR MARKETS IN SCOPE

We have analysed future prospects by assigning each country to one of three broad scenarios:

- **Reversal:** The mRDT private sector that has been built is not sustainable; the market that has been built to date reduces in size.
- **Continuation:** The mRDT private sector market stabilises, with a potential to grow depending on future changes to the operating environment.
- **Expansion:** The mRDT private sector market continues to grow.

The assessment considers prospects for markets where there are no additional market-shaping activities. In reality, it is highly likely that additional support from other donors will occur, which might lead to more positive scenarios. These are discussed later.

It is probable that if no future market-shaping activities take place, the markets in Kenya, Tanzania and Uganda will remain at their current levels while those in Nigeria and Madagascar will reverse.[131] As seen in previous sections, the projects demonstrated that supply and demand could be built in most countries. Favourable policy change has occurred or is likely to occur in most countries. However, success to date at a limited scale cannot be extrapolated to future success at scale. Future market participants will not enjoy the favourable conditions that attracted pilot participants: the cheap or subsidised stock, free trainings, product marketing, and (in MC countries) free services including waste management. Below we provide a summary of our assessment by country; detailed rationales are in the country profiles.

- **Kenya – Continuation:** In Kenya, three wholesalers and five distributors operate in the market as a result of the Unitaid and DFID projects. mRDTs are affordable for consumers and profitable for suppliers. Initial evidence suggests that prices are affordable for consumers even after retailers' and wholesalers' costs increased after direct distribution was withdrawn. Consumer and provider awareness has increased. However, prospects for future nationwide policy change are unclear.
- **Madagascar – Reversal:** In Madagascar, there is less evidence of a vibrant market. Five wholesalers are operating in the market but they continue to procure stock from PSI. Consumer and provider awareness remains low outside wealthier segments. Ability to pay is low and there is consensus among stakeholders that subsidy will be necessary for the next years to avoid a collapse in demand. The government has made permanent policy changes.
- **Nigeria – Reversal:** In Nigeria, the availability of cheap alternatives to quality-assured mRDTs and free mRDTs provided by the Global Fund have hampered growth of sustainable demand. Premier Medical Proportion no longer supplies the market and it has been difficult to attract new suppliers.

[131] The rationale is explained in more detail in the "future prospects" section of the country profiles in Annex 3.

- **Tanzania – Continuation:** In Tanzania, three wholesalers and ten distributors operate in the market. The supplier market is strong enough that PSI Tanzania was able to stop supplying the market in 2015. Retail prices rose when the effective subsidy ended but demand was sufficient to maintain the market. A permanent policy change has not yet been achieved.
- **Uganda – Continuation:** In Uganda, two of the three distributors will stay in the market, and many outlets report that they intend to continue providing mRDTs. Prices appear not to have risen after the exhaustion of the subsidised stock. While demand has been generated, the bundles that outlets prefer are no longer available.[132] There is therefore a risk that demand has been generated for a different product than what the market can provide for. Temporary policy change was achieved but the prospects of longer-term authorisation are not clear.[133]

Table 2. *Analysis of project achievements and future market prospects by country*

		Kenya	Madagascar	Nigeria	Tanzania	Uganda
Supply	*Availability*	Expansion	Expansion	Continuation	Expansion	Continuation
	Affordability	Expansion	Reversal[134]	Reversal	Expansion	Expansion
	Quality of mRDT	Expansion	Expansion	Reversal	Expansion	Expansion
	Quality of Handling	Continuation	Continuation	Continuation	Continuation	Continuation
Demand	*Consumers*	Continuation	Reversal	Continuation	Expansion	Expansion
	Providers	Expansion	Reversal	Reversal	Expansion	Continuation
Policy change		Expansion	Continuation	Continuation	Continuation	Continuation
Expected future scenario		**Continuation**	**Reversal**	**Reversal**	**Continuation**	**Continuation**

Key

Achievements to date
- *Not achieved*
- *Partially achieved*
- *Achieved*

Expected future change
- **Reversal**
- **Continuation**
- **Expansion**

Taking into account potential work by other actors in developing these markets, future prospects may improve. Relationships have been built and government and private stakeholders have committed to driving change. At the end-of-project event in March 2016, key stakeholders from all five countries and from global organisations gathered to share and discuss their experiences as well

[132] Some outlets continue to provide mRDTs but do not arrange for sanitary waste disposal.
[133] MC reports that the project has contributed to the development and approval of mRDT private sector implementation guidelines at different levels including at the NMCP, and that conversations with senior stakeholders at the Ministry of Health on policy change have advanced.
[134] We expect reversal in affordability because of the end of project subsidies. While availability has increased it has not yet reached the point where unsubsidised mRDTs are affordable (this price point seems to be lower in Madagascar than in other countries).

as to agree on next steps.[135] At the event, national authorities pledged to continue to work on mRDT policies and strategies, to support marketing and behaviour change communications, and to coordinate relevant stakeholders.[136] By improving the environment through policy change or continuation of subsidies, other market shapers may contribute to the increased sustainability of all markets, including those that would otherwise experience reversal.

Moreover, other donors have indicated an interest in taking forward this work. In Madagascar, Nigeria and Tanzania, other donors may engage in market shaping activities. Thus, the Unitaid project might lead to the formation of sustainable markets by supporting and informing the work of others. In Kenya, DFID's parallel project will continue for a year.

- In Madagascar some project activities (elements of provider training and consumer campaigns) will be continued as part of a Global Fund programme.[137] In addition, PSI and the Direction de Lutte Contre le Paludisme have applied for further funding from the Global Fund to cover mRDT subsidies.[138]

- In Nigeria, the Global Fund is funding SFH to implement a project that donates mRDTs in the private sector.[139] An extension to the project is currently being discussed. DFID will support ongoing private sector case management through the Support to the National Malaria Programme initiative (SUNMAP). USAID is investigating opportunities to support states in building private sector malaria markets. While this would not be an extension of the Unitaid project, planning has drawn from the lessons learned by MC and PSI.[140]

- In Tanzania, since July 2016 PSI and CHAI have collaborated on a pilot that tests the feasibility of ADDOs offering mRDTs.[141] Evidence generated may inform nationwide policy change that would allow these outlets to perform diagnoses using mRDTs.

- In Kenya, DFID will continue its support for private-sector mRDT markets in neighbouring project areas for one more year.

[135] Attendees included: PSI, MC, WHO, FIND, Johns Hopkins School of Public Health, USAID, the Global Fund, CHAI, DFID, manufacturers, wholesalers, professional bodies for health professions, and the national malaria control programmes of each of the five target countries.
[136] The five commitments made by each country are detailed in the end-of-project meeting report.
[137] The Global Fund is funding PSI's project on ACT availability through the PSCM until 2017.
[138] PSI will not know whether this additional fund request has been accepted until later in 2016.
[139] The project distributes mRDTs for free in Nigeria, and has been discussed in sections above.
[140] USAID has also investigated working in Tanzania, although Nigeria has been prioritised recently.
[141] These outlets were not included in the Unitaid grant. The CHAI/PSI project is in eight rural districts.

PROSPECTS FOR CATALYSING OTHER MARKETS

The WHO roadmap will provide recommendations to national malaria programs on how to build private sector mRDT markets. There are delays in finalising it.[142] The roadmap will include case studies from each of the five target countries, as well as tools and practical resources. While some of the intermediate steps were completed on time,[143] the roadmap has not yet been finalised due to delays early in the project and during implementation.[144] Much of the content was finalised at the end-of-project meeting and final dissemination is expected in late 2016.[145,146] Some interviewees questioned if the roadmap would provide a concrete and credible guide to other governments, given that the ability to reach scale and sustainability has not yet been proven in the five markets.

A range of other materials were or are being developed. Opportunities to develop and share learning included steering committee meetings, research reports produced and shared during the project, and the end-of-project workshop which included key external audiences including government stakeholders. Grantees report that stakeholders in each country (including national authorities and the private sector) were receptive. In addition, knowledge resources and tools were developed:

- **Grantees developed knowledge resources during the project[147] and are planning several additional pieces.[148]** Since most knowledge resources have not yet been disseminated, it is not possible for Dalberg to assess how influential they will be. However, an interviewee from USAID reported benefitting from project learning that was shared less formally. Data and perspectives shared by PSI and MC have reportedly allowed USAID to make progress in prioritising the Nigerian mRDT market at a speed that would not otherwise have been possible.
- **Grantees built tools to support the mRDT market development interventions.** These tools include knowledge and relevant perspectives for market shapers (donors and governments),

[142] WHO requested a no-cost extension to Unitaid to allow for completion of the roadmap. Source: WHO report to PSI, 'Jan-Dec 2015', 31 March 2016.

[143] These included the reviews of existing national policies, were completed according to schedule, as reported against indicator O4.1 and presented in Annex 6. WHO also produced a set of five papers analysing the regulatory environments in target countries to inform advocacy work throughout the project. These were completed on time, meaning targets against indicator O4.1 were met. However, as country-specific reports they are not intended to influence the development of markets in new countries.

[144] These delays included recruiting consultants to structure, write and advise on the report, and replacing a consultant that left. In addition, opportunities to engage public sector partners were constrained during the project: there were delays in stakeholder mapping in Nigeria and the political situation in Madagascar made identification of relevant stakeholders challenging.

[145] End-of-project report 2013-16.

[146] The central objective of the roadmap are recommendations for public-private engagement in malaria case management. These recommendations have not yet submitted to the WHO Malaria Policy Advisory Committee for endorsement. There is therefore no data for indicator O4.2 on submission of these recommendations.

[147] Knowledge resources developed include (i) the roadmap, (ii) a chapter for the Springer Encyclopaedia on malaria diagnosis in the private sector, (iii) a set of policy papers with an overview of each country, (iv) two qualitative studies on how mRDTs are used in practice in Madagascar and Uganda by the Johns Hopkins School of Public Health team, which may be adapted for publication in a peer reviewed journal, (v) 9 conference presentations on lessons learned, (vi) a manuscript on quality control of mRDT accessories, and (vii) an article drawing on evidence gathered for the project, 'Building a healthy and sustainable market for malaria rapid diagnostic tests'. This article was published in the WHO Bulletin.

[148] Further work is underway, including (i) case studies laying out lessons learned by PSI during the project, (ii) two further conference presentations, and (iii) four peer-reviewed articles.

practical resources for market actors, and new systems to support PSI's own market development work in the future.

- **Grantees have developed tools that market participants can use.** These tools include training materials and job aids, checklists and questionnaires, and FIND's QA kits for actors throughout the supply chain.[149] Peer organisations including CHAI and USAID see them as useful tools for their own work. Additionally, PSI has developed a QA manual and toolkit for private-sector. This was shared at the WHO provider standards meeting in June 2016 and has started to be further disseminated.

Grantees have improved their knowledge gathering and codification systems. PSI reports that the new framework it introduced to document and share project learning is effective. Its systematic process of documenting learning at activity and output stage has now been applied across PSI to other grant areas. PSI has also developed materials on the lessons it has learned about market development generally and quality-assured mRDTs specifically. PSI and MC report that insights derived from this project will inform future work on market creation, and specifically (i) engaging with markets for the poor, (ii) influencing provider networks, and (iii) assuring quality.

[149] The tools were used during the project.

2G. LEARNINGS

The project has generated a wealth of learnings on the possibility and practicality of developing private sector markets for mRDTs. Below we share learnings collected through interviews and research:

Suppliers need sustainable margins, but these have not yet been achieved in every country. Free products, leakages from the public sector, and counterfeit substitutes reduced market prices and suppliers' margins, particularly in Nigeria and somewhat in Tanzania. During the project subsidies were needed to maintain competitiveness. With the expiry of subsidies, suppliers will likely see reductions in their margins.

Training and supervision can increase providers' trust in mRDTs and their capacity to use them, but change is not immediate. Providers (clinicians, private sector doctors, pharmacists, etc.) need to trust the accuracy of mRDT results. Providers have historically relied on microscopy and in some cases they have had experiences with poor quality mRDTs. As a result, providers do not always trust mRDT results. The project has demonstrated that trust can be built through training and supervision, but change is not guaranteed nor immediate.

Behaviour change campaigns help providers and consumers understand that testing is necessary. WHO recommended presumptive treatment of all fevers as malaria in Africa for over a decade. This was translated in to public health messaging across malarial countries.[150] Diagnosing malaria before treatment has therefore not been perceived as necessary. The countries where markets have been built to some extent have seen increased awareness among both providers and consumers due to behaviour change campaigns. However, achievements have varied widely by country and by provider type.

Demand is highly price sensitive and pricing needs to take into account the price of ACTs. Consumers are faced with two options: either paying for an mRDT and potentially for an ACT (if it is malaria) or another treatment (if it is not malaria) or only paying for ACTs. If the consumer does not understand the value in testing, the combined price of ACTs and mRDTs is difficult to justify. As subsidies disappear there is a risk that mRDT prices will rise above ACT prices, and, regardless of ability to pay, consumers may return to presumptive treatment.

The availability of ACTs influences demand for mRDTs and must be factored into planning. Where ACTs are largely affordable – as in most countries covered by the AMFm and the PSCM – the price of mRDTs relative to ACTs is a crucial determinant of demand. In countries where ACTs are less affordable – as they were at times in Kenya – ACT availability will also affect quality of care.[151]

Demand likely differs by provider size and by consumer income and education levels, but more data is needed. Data on these questions was not gathered systematically and should be in the future. Data on consumer profiles would improve understanding of the grant's impact in terms of customer segments reached and the transferability of learnings to new contexts.

[150] 'Time to Move from presumptive malaria treatment to laboratory-confirmed diagnosis and treatment in African children with fever', PLoS Medicine, 2009.

[151] PS Kenya observed that price and availability were erratic due to delays between funds being released by donors and ACT supplies becoming available.

Public health risks can hinder policy change. Policy makers may worry about changing policy because inadequate waste management or misdiagnosis could pose public health risks.[152] Regulators are therefore cautious about further expanding the use of mRDTs in private facilities. Both issues were addressed through training and services during the grant. However, in most countries, less training and fewer services will be offered following the end of the grant. Provider training will only continue at scale in Madagascar through Global Fund funding. In Nigeria and Uganda, private providers had received waste management services at no additional cost but this service has stopped. Suppliers in Uganda have noted a reduction in the use of commercial medical waste management services now that providers must pay for it. The public health risks mitigated during the project may therefore increase following the end of the project, which may reduce the probability of future policy change.

Pressure from opposed interest groups can also hinder policy change. For instance, in Kenya, lab technicians perceived mRDTs as a threat to their jobs and lobbied against the use of mRDTs. In Madagascar, professional organisations representing health professions such as pharmacists objected to non-pharmacist drug shop owners using mRDTs.

Leakage of mRDTs from the public sector to the private sector can be mitigated by working together with the public sector. In Tanzania and Nigeria, the existence of a private sector market had undesired effects on public sector stocks. In both countries there were leakages from public sector stocks to the private sector. This had negative impacts on both the public and private health care: the public sector had unexpected stock-outs, while the private sector suffered from higher volumes flooding the markets and lowering prices. The public sector was an essential partner in addressing these leakages. For instance, in Tanzania, regulators strengthened monitoring and tracking, which reduced leakages.

PSI's gradual step-out of the Tanzanian and Kenyan markets has increased the likelihood of market sustainability. In Tanzania, PSI changed its role from supplier to facilitator mid-through the project. This enabled PSI to continue to support the market, bridge relations between manufacturers and providers, and increase transparency. For instance, PSI Tanzania shared demand forecasts with suppliers to avert significant price increases. PS Kenya took a step in a similar direction and moved from directly supplying retailers, to working through wholesalers.

In contrast, project activities ended more abruptly in other countries, which may jeopardise market development. In Madagascar, there is currently no other market actor that can take on PSI's role. PSI will continue to train provider outlets with funding from the Global Fund. Across the other countries, key market development activities – training of providers and consumer marketing – will stop, as there is no actor to take on these responsibilities. In Uganda and Nigeria, the bundled procurement model appears to have ended with the project.[153] Now that the bundles have been exhausted (in Uganda) or expired (in Nigeria) manufacturers do not intend to continue providing the single packs, and distributors do not plan to provide services such as waste management and training.

The countries where most was achieved are those where national authorities engaged most. In Kenya, Madagascar, Uganda and Tanzania, national malaria control programmes led the engagement of other government arms and championed the project's aims. For instance, Kenya's

[152] Challenges include taking accurate blood volumes.

[153] Procurement from two consortiums of manufacturers and distributors was intended to draw in players who could provide bundles of products and services.

NMCP became an ally in engaging the laboratory regulatory agency. In Nigeria the environment was much more difficult due to the patchwork of relevant authorities at federal and state level, and the difficulties they and external parties faced in coordinating work.

Three years is likely too short to test, create and scale a market. Market development projects are typically carried out over five years or more. They require behaviour change at all stages of the supply chain, from manufacturers and importers to wholesalers and retailers to consumers. Interviewees at PSI, MC and other members of the grantee consortium say that their ability to achieve lasting change within three years was limited.[154] This belief was echoed by external stakeholders.

[154] Timelines were reduced from the three years planned due to procurement delays at the beginning.

3. FINDINGS ON OPERATIONS

The following section follows the program planning and management chain, and discusses key activities in sequence, namely 1) grantee selection, 2) definition of the grant and its overarching objectives, 3) setting of national targets and country operations, 4) project implementation and management, 5) monitoring and reporting.

1. GRANTEE SELECTION

Unitaid did not have tools in place to fully assess grantees' capacity. Unitaid's initial assessment of grantees focused on compliance rather than assessing their implementation capacity. The verification assessed grantees' risk controls through a questionnaire but did not independently assess grantees' management systems or prior performance in similar grants. As a result, it did not identify all the potential challenges the grantee consortium could face when working in the high-uncertainty area of market development. In particular, MC's limited experience in procuring large volumes was not reflected in project plans, and was therefore not addressed through a risk-mitigation plan.

Unitaid has already established new processes to more critically analyse its grantees' capacity. Unitaid has introduced a more detailed grantee capacity assessment, which includes an independent analysis of management structures, and requires enhanced information and risk mitigation where risk is assessed to be higher (for instance, when subcontracting is used or grantees have no prior record with Unitaid).

2. DEFINING THE GRANT AND ITS OVERARCHING OBJECTIVES

There was a degree of tension between the project objectives, particularly between proof of concept and direct market development.[155]

- **Running pilots to prove the concept of interventions in private-sector mRDT markets.** This objective implied learning about the effectiveness of interventions to build private sector mRDT markets, including the safety and effectiveness of the tests in the private sector. Learning that an mRDT market would not be feasible in a country is almost as valuable as learning that it works in another country.
- **Scaling interventions to support the development of sustainable private-sector mRDT markets in target countries.** This objective is to achieve the implementation targets and scale the market. There is a tension with the first objective: failure and learning from failure has an explicit value as per the first objective but is undesirable as part of this second objective. Even within this second objective, there is a trade-off between short-term and long-term targets. Short-term targets focus on reaching supply and demand targets, while long-term targets would imply a greater focus on catalysing lasting policy change,

[155] As discussed in the executive summary, Dalberg perceives that the project had three overarching objectives: (i) to prove the concept of intervening in private-sector mRDT markets, and determining which approaches and interventions are effective; (ii) to support the development of sustainable private-sector mRDT markets in target countries; (iii) to build and disseminate knowledge and tools to inform the development of other mRDT markets.

strengthening the supply chain, and exploring the phase-out of subsidies to ensure the sustainability of the intervention in the long run.[156]

Unitaid and its grantees have different understandings of the weight of each objective. While all interviewees recognise the importance of all three objectives, the relative importance given to each varies between and within organisations.

- Some PSI interviewees report that they understood the primary goal to be proving the safety and effectiveness of mRDTs in the private sector.
- Many PSI and MC interviewees involved in project implementation emphasise the objectives of the grant as building markets in the target countries.
- Some Unitaid interviewees and PSI interviewees describe the ultimate objective as gathering evidence to influence the policy environment in target countries and elsewhere.

Moreover, the logframe was geared towards the shorter-term implementation of pilot and scale up interventions, with a focus on direct impact. The indicators linked to market catalysis or operational research (such as policy change and learning materials developed) measure achievement during the project rather than longer-term influence.

These different understandings were not fully reconciled during project planning and, as a result, design, operations, and reporting were not fully aligned. A meeting between all participating organisations was convened to clarify project goals, but the divergence between documented goals and participants' understandings remained. With staff changes, the shared understanding of the grant started to align more closely with the documented goals and potentially less with the original ambitions. However, as a result of lack of alignment on the implicit objectives of the grant, Unitaid and grantees have different perceptions on whether the goals of the grant have been achieved.

There is an opportunity to improve the processes for developing project objectives and conducting project planning, and to better delineate roles and responsibilities between Unitaid and grantees. By co-developing the project goals, Unitaid created ownership among the grantees, but also diffused the responsibility for this deliverable, which might have contributed to the lingering misalignment. It might have not been understood by all parties who was responsible for articulating the overall objectives, recognising and resolving tensions between objectives, and translating the objectives into lower-level indicators.[157] There is also an inherent tension in developing project objectives and targets after the implementing actors have been selected and the project has started. Both the funder and the grantee have a responsibility for recognising conflicts or tensions between objectives. Unitaid could have been more precise in the project deliverables and objectives, and ideally would have pressure tested for possible tensions and trade-offs. The grantees were, however, responsible for realising, flagging and forcing resolution of tensions and conflicts in the objectives. As noted above, Unitaid reports that it attempted to resolve misalignments with grantees early in the project. By contrast, grantees report that they made attempts to discuss and refine the logframe with Unitaid before and during the project, but that not all of these requests were acted on.

[156] In contrast, subsidies may be a desirable component of the project if the main objective is proof of concept, as it helps to learn about what particular price point is attractive to both consumers and suppliers (even if it might not be sustainable).

[157] The logframe did not reflect the importance of the various goals. Several of the implicit goals understood by PSI and/or MC, such as strengthening the supply chain or developing tools and systems, did not have adequate targets and indicators.

3. SETTING NATIONAL TARGETS AND PLANNING COUNTRY OPERATIONS

The logframes developed by Unitaid with inputs from the grantees were not contextualised and in many cases did not have appropriate targets.

Targets did not take into account national contexts and were not always appropriate. For the majority of indicators, uniform targets were set across all countries and did not take national contexts into account.[158] In many cases, targets were set – and maintained – below the baselines established in first-round reporting.[159,160]

Targets did not always have a realistic timeframe. Given the number of actors involved and the requirement to change a series of ingrained behaviours, the targets may not have been realistic for a three-year project. Examples include the target of tripling caregiver demand for mRDTs,[161] and various objectives not included in the logframe such as strengthening the supply chain. For comparison, Madagascar's national malaria control programme set a five-year timeline for a similar behaviour change programme amongst public sector health care providers.[162]

Grantees' project planning was comprehensive and addressed the full range of relevant issues.

However, there were weaknesses in the evidence gathered by grantees to inform project plans. The landscape studies PSI and MC commissioned did not address all the aspects needed, meaning that project plans did not take account of realities on the ground.[163] The landscape research was in many cases based on secondary research, as opposed to up-to-date primary research. For example, procurement volumes were decided based on epidemiological and demographic data, rather than on market realities that could affect sales volumes in the short term.[164] In future, grantees should prioritise a thorough market landscape analysis that is based on both primary and secondary research. A thorough landscape assessment could have helped the teams develop more realistic and targeted plans. For instance, it might have been unrealistic to expect markets to have been created in three years when considering the time needed to: sign MOUs with governments, change policies, train and incentivise private facilities, change consumer behaviour, etc.

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[158] However, targets referring to a baseline were set for three output indicators: O2.1, O2.2 and O6.2. Targets took the form of improvement against a 2013 baseline. The targeted increase was uniform across all countries.

[159] This includes indicators O1.1, O1.2 and O3.1 for all five countries.

[160] An exception to this is at the goal level, where end-of-project targets were revised up from 30% to 60% at the request of grantees after early surveys indicated that the 30% target had been exceeded in all countries for people five and over and in most countries for children under five.

[161] Indicator O6.2.

[162] Interview, Former head of case management department, Madagascar Direction de Lutte Contre le Paludisme.

[163] In Kenya, the importance of outlets' registration status was not reported, and the number of registered facilities was not recorded. As a result, although the initial project plan included 100 outlets, only 40 were actually included in the first phases of the project. In Tanzania, no formative market landscaping exercise was carried out, meaning that the project was operating on assumptions about the shape of the market. Once such a landscape assessment was carried out, the strategy changed considerably. In Uganda, initial research did not identify the lower than expected number of registered outlets in the pilot region. In Nigeria, the pre-existing market for mRDTs was not identified. As a result, project plans mirrored those for other countries where market creation was the issue, rather than tackling low-quality or leaked alternatives, which was the larger issue in Nigeria. In addition, several stakeholders (including from the government and civil society) explained that the three Nigerian states selected for the project, Anambra, Cross Rivers and Ogun, were challenging environments. With low income levels and low density of private providers, these regions may have been less favourable than more populous states such as Lagos, limiting what could be achieved.

[164] E.g., the number and size of private sector actors, accessibility and regulatory status of outlets, variations in demand by size or sophistication of provider.

As a result, grantees' risk management strategies and ongoing processes for risk mitigation did not recognise and manage the full range of risks faced in market development. In their reflections on the project, grantees identified some problems experienced – in particular, the lack of control over all market actors and the existence of illicit actors – as inherent to market development work. "In my experience there are few health commodities that do not pass through this phase: leakage," said one country manager. Grantees believe that Unitaid did not recognise and act on the risks flagged in routine reporting. By contrast, Unitaid felt that grantees were not proactive in flagging these challenges and making them explicit before they materialised.

As they define project logframes and targets both Unitaid and grantees need to ensure that logframes are responsive to the facts on the ground. Unitaid needs to ensure that the targets it expects are realistic and ambitious, while grantees need to ensure that they commit themselves to achievable goals. Where possible, targets should be derived from baseline data.

Grantees should prioritise a good understanding of the market to enable strong planning. They can ensure thorough market landscape analysis that is based on both primary and secondary research. They can also ensure that each target takes into account baselines and a realistic timeframe, even if some targets might fall outside of the grant timeline.

4. PROJECT MANAGEMENT

Unitaid's decision to retain authority for approving procurement was an important risk management tool, but it slowed down project implementation. Unitaid, as any project funder, had to determine the appropriate delegation of decision-making authority. Unitaid's decision to maintain ownership and accountability over procurement decisions was likely correct, given the challenges with regards to overstocking in the project. However, the inevitable trade-off was that delays caused by this process delayed implementation of other activities (e.g. demand building). Implementation start dates were subsequently between six months (in Kenya, Madagascar and Tanzania) and ten months (in Nigeria) behind original project plans. While grantees conducted some research and policy engagement in the interim, demand building activities did not start until delivery.

Unitaid's approval processes were relatively slow, with decision making criteria that were not always clear to the grantees. Slow approvals affected the project at various points including in developing a common logframe,[165] obtaining procurement approvals,[166] and deciding whether the project would have a no-cost extension.[167]

Unitaid's internal processes and high rotation of staff impacted the grant. The main channel for financial management was ex-post queries to reports submitted. Due to high staff turnover at Unitaid over the course of the grant, grantees report a loss of institutional memory and

[165] There were 12 iterations on the theory of change, and the project was started before all indicators were finalised. As a result, Unitaid and grantees had different perspectives on what had been decided. For instance, grantees reported on performance against percentage targets which they considered conformed with agreements, while Unitaid expected reports on performance against absolute targets.

[166] Procurement approvals were delayed for Nigeria and Uganda by approximately four months, as Unitaid sought to fully understand MC's procurement model. This in turn delayed future activities.

[167] At the end of the project, the decision on the no-cost extension took four to five months. Part of this was due to a lack of clarity around requirements on how to file the proposal for no-cost extension. The document PSI considered to be its formal extension request was considered by UNITAID as incomplete: "with a focus on reallocating project funds without providing concrete justifications and value for money."

understanding of problems raised. Grantees also report receiving limited feedback from Unitaid on the reports submitted.

Unitaid should integrate its decision on delegation and control with the assessment of the capabilities of all potential grantees. As discussed earlier, Unitaid can conduct a more comprehensive risk assessment, to further understand, acknowledge and mitigate potential risks. Using the insights from the due diligence, Unitaid could determine the required amount of oversight and the delegation needed. On the one hand, more oversight will help minimise risk, but will likely result in approval delays. It also requires a significant time commitment from Unitaid. On the other hand, more delegation will minimise delays, require less time commitment from Unitaid, and enhance grantees ownership. However, it exposes Unitaid to higher risks. It is possible that in some cases, Unitaid's perception of the necessary delegation or oversight does not match with grantee's preferences or with Unitaid's own operational model and vision. In such extreme cases, Unitaid might decide not to work with some grantees or fund some projects (if no suitable grantee can be found).

Some grantee country teams successfully made course corrections based on new market information. Some examples of success are due to grantees' deviations from original project plans in response to market realities. For example, Tanzania changed its model from purchasing mRDTs to facilitating the market. Kenya implemented a price subsidy to increase consumer demand and supplier margins based on its market assessment.

As discussed earlier, there were problems with overstocking in Kenya, Madagascar and Nigeria. Overstocking was a result of flawed demand forecasts, incomplete scale-up, and nationally specific challenges. Moreover, PSI's relationship with SFH did not result in project changes in Nigeria once SFH started distributing free mRDTs to private outlets as part of the Global Fund grant.[168] Interviewees identify a range of reasons for the limited information flows and limited influence on Global Fund plans, including: (i) SFH's operational independence from PSI, which reduced PSI's insight into SFH's plans, (ii) siloes between the Global Fund's public-sector division, with which MC and PSI had relationships, and its private-sector divisions, and (iii) the sign-off by the Nigerian government and others actors on the Global Fund plan that included the free distribution of mRDTs, reducing the Fund's ability to change its strategy.

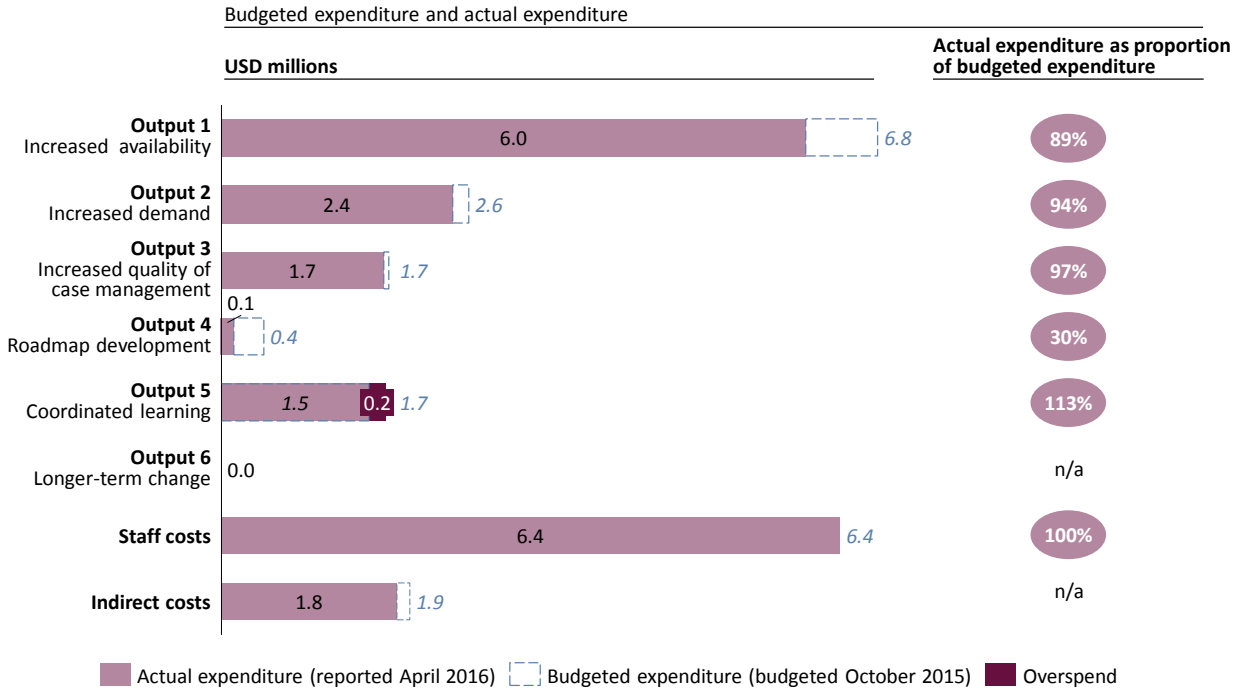
Final expenditure was broadly in line with plans; approximately 94% of the revised budget was spent. Of the final budget of USD 21 million,[169] USD 20 million was actually spent.[170] Expenditure against plans varied by budget item; final expenditures ranged from 113% of the budget for output 5 on coordinated project learning, to 30% of the budget for output 4 on the roadmap**.** This underspending reflects the delays in project execution and lower than anticipated procurement volumes. Expenditure against the original budget is summarised below and illustrated in Figure 4.

- The largest source of the underspend is output 1, which relates to increasing availability of mRDTs, including procurement. USD 0.8 million remained unspent.

[168] SFH and PSI operate fairly independently and have limited visibility over grants they implement. However, going forward PSI and SFH are working towards more clarity and visibility, as well as strategic cooperation.
[169] The original budget was USD 30 million, but this was revised down following the no-cost extension decision and order to scale down activities.
[170] Expenditure was reported against each of the project output areas (these output areas are detailed in Annex 1).

- The largest underspend as a proportion of the target budget was for output 4, which relates to producing the roadmap. Final expenditures by April 2016 were USD 0.1 million, compared to a final, revised budget of 0.4 million (which took into account revised project plans and the delays faced in the work plan for this output). For this output, Unitaid has granted a no-cost extension and released USD 0.4 million to be spent after the scheduled project closure.[171]
- There was an overspend on output 5 on coordinated project learning. Final expenditures were 1.7 million, compared to a revised budget of 1.5 million.
- For the other outputs (output 2 on increasing provider and consumer demand and output 3 on improving the quality of case management) and for cross-cutting staff costs and indirect costs, actual expenditures were closer to budget, deviating from the final revised budget by 10% or less.
- Output 6 (on longer-term change leveraging the systems and evidence generated during the grant) had no separate budget or expenditure lines.

Figure 4. *Planned expenditure and actual expenditure*[172,173]



To improve project management in future, grantees should ensure that market information is comprehensive and up-to-date to ensure optimal decisions and to inform any mid-course corrections. This can in turn improve grantees' ability to execute against plans and to warn donors where this is not possible.

5. MONITORING AND REPORTING

[171] Unitaid approved WHO's separate no-cost extension request specific to output 4.

[172] There was no separate budget line or expenditure reported for Output 6 on longer-term systems change, which was covered through other outputs.

[173] Expenditure data is from June 2016 consolidated expenditure document, which reports expenditure to 11 April 2016. Budget data is from the final consolidated realigned budget as shown in March 2016 award amendment document.

Grantees completed routine monitoring and evaluation, with some challenges. Across all countries, monitoring tools and systems were developed for performance management and learning. Tools and systems included household surveys,[174] interviews with customers, use of mystery shoppers, and analysis of routine data. Research activities were completed according to schedule in Kenya and Uganda.[175] In Madagascar, Nigeria and Tanzania, the limited capacity of local boards led to delays in the ethical approval required for surveys. This constrained data collection, especially at early stages. As a result, some baseline surveys were delayed and in Tanzania no baseline survey was conducted. As discussed above, the surveys resulted in very small sample sizes for some impact indicators, particularly for children under five.

The extensive use of surveys posed practical constraints to grantees. In Madagascar and Tanzania, it was difficult for grantees to manage the external companies that delivered the surveys. These external companies in turn had challenges in conducting the required interviews. The household surveys that were called for in the original monitoring and evaluation plan were not conducted due to practical constraints. PSI suggests investigating the use of routine data rather than survey data in future.

Inventory data was not systematically gathered on a project-wide basis until June 2015. PSI developed a reporting tool for PSI countries and MC countries in June 2015 at Unitaid's request. Previously, PSI and MC had been tracking stock separately since 2014 according to their own requirements. In addition, neither grantee monitored distribution of mRDT kits down to the level of individual sales. In Nigeria and Uganda, the use of barcode technology allowed tracking at the level of individual kits but MC's reporting was dependent on providers' compliance.

Grantees can improve their ability to manage the research process. Grantees should ensure alignment between feasible indicators and the reporting structure they are held to. Some country offices can improve their ability to manage external actors that affect the research process. This may include investigating non-domestic providers to ensure accurate and timely results.

Grantees submitted detailed semi-annual procurement, financial and programmatic reports although there were some inaccuracies. Deadlines for programmatic and financial reports were met. The 2015 annual report had some misallocations, and in 2014 MC was not able to provide documents supporting their statements to auditors, which extended the audit closing period to seven months, in contrast to Unitaid's expectations of two to three months. Moreover, the exact reporting format for some indicators was not agreed upon by Unitaid and grantees, meaning there is some inconsistency in reporting.

Unitaid felt that grantees did not keep Unitaid sufficiently abreast of risks and challenges. Unitaid found that PSI and MC's routine project reporting contained mostly project successes, and did not sufficiently identify risks, emerging problems, or mitigation strategies. As a result, Unitaid perceived that grantees did not signal sufficiently the slow uptake in mRDT sales and the difficult market context in Nigeria. Unitaid did not fully anticipate these challenges and did not appreciate the extent of the difficulties this posed for the project until it conducted joint visits (with PSI) to Uganda, Kenya, and Nigeria in mid-2015. Unitaid and grantees also had different perceptions of the risks that the project posed. In particular, Unitaid considered overstocking as a financial loss to the project, while

[174] Use of household interviews was scaled back in favour of exit interviews, at grantees' request.
[175] Indicator O5.2

MC and PSI did not. MC considered stock to be the property of the distributors, and considered them liable for losses and overstocking, whereas Unitaid considered MC accountable.

Grantees should proactively share information on risks and challenges, and the implications this may have for the project. Unitaid may want to enhance or modify its formal processes. For example, if challenges are foreseeable, short update reports focusing on risks, challenges and mitigation plans might be required every three months. Unitaid may also want to emphasise less formal interactions to engage in constructive and frank collaboration. Grantees can also improve the accuracy and timeliness of their operational reporting. This includes greater standardisation of operational data across grantees that is not included in logframe requirements.

4. CONSIDERATIONS ON THE NO-COST EXTENSION

Unitaid decided not to accept grantees' request to extend operations by six months.[176] Unitaid assessed this request based on its perceptions of: project implementation to date; results obtained, especially in terms of mRDT distribution; and feasibility of delivering the activities described in the extension application

Unitaid's denied grantees' no-cost extension request for three reasons. First, grantees' progress in distributing mRDTs was slower than anticipated, which decreased the likelihood of achieving the objectives set out in the extension application. Second, Nigeria was included in the no-cost extension application despite all the challenges in the country.[177] Third, Unitaid judged that grantees had not been sufficiently frank about emerging challenges and that risk mitigation plans were insufficient.

Not extending the timeline may have reduced grantees' ability to achieve some of the project's goals. As noted in section 3 on operations, the project had three implicit objectives. Below we describe the status of each goal by the end of the project and discuss if the no-cost extension could have further enhanced its achievement.

i. Prove the concept of interventions in private-sector mRDT markets

The project proved the concept of catalysing private-sector mRDT markets. The pilots were intended to prove if and how a set of interventions could build mRDT demand and supply, and what interventions were effective in which contexts (and which were not). Despite challenges, overall proof of concept was established and a range of learnings on the challenges and success factors were documented, including those highlighted in section 2g. Moreover, the pilots generated insights into the effectiveness of two different models (bundles and simple commodity distribution). In some countries, the pilot phase generated evidence that interventions could successfully shape market conditions, and (potentially equally valuably) the pilot also showed that in other contexts and countries intervention is more challenging, and potentially requires customised approaches. Granting the no-cost extension would not have fundamentally changed the outcomes under this objective, although might have enriched the learnings with further details and insights.

ii. Support the development of sustainable private-sector mRDT markets in target countries

The implementation of pilots was partially on track in most countries and some pilot targets had been achieved. As discussed in the "findings on programmes" section, grantees delivered a range of outputs during the pilot phase, including quality assurance of kits, training of providers, and consumer marketing. Performance against targets was mixed at the pilot stage. Most countries met certain targets – in supply (including the number of private outlets enrolled[178]), demand (including

[176] As discussed in the introduction section, the first implementation start date was April 2014 (in Kenya and Madagascar) and the last September 2014 (in Nigeria), compared to original plans for approximately October 2013. Given the delays at the outset of the project, the time available for implementation was shorter than originally planned. As a result, in April 2015 PSI made a request to Unitaid to extend the duration of the project by six months (the "no-cost extension request"). The no-cost extension would have allowed a scale-up phase of approximately one year in four countries. As PSI and MC waited for Unitaid's decision, teams in Madagascar, Nigeria, Tanzania and Uganda began to scale up.

[177] Grantees report that they included Nigeria in the application because Unitaid had indicated that it would consider applications on a country-by-country basis.

[178] In all countries but Nigeria, the target for the number of private outlets enrolled was met during the pilot phase

consumer awareness) and quality (including establishment of QA processes). Other targets – such as consumer demand[179] were missed in all countries. Sales of mRDTs were also a significant problem, as discussed earlier. Granting the no-cost extension would, however, not have improved performance in pilot implementation as it was not intended for pilot but for scale-up.

The scale-up was only partially implemented and most scale-up targets were not achieved. The decision not to grant the extension resulted in a scale-up phase of six months compared to the original 18 months. Towards the end of the project, grantees had scaled up market-building operations in four countries.[180] As discussed in the "findings on programmes" section, however, grantees did not reach the intended scale and did not reach most scale-up targets. In most countries, indicators of demand (including consumer awareness) and supply (including the number of outlets enrolled) were below targets, although quality of treatment remained high.

Despite limited scale up, some markets grew and appear to be sustainable at local scale, the no cost extension could have increased the scale further. As discussed in the future prospect section, sustainable local markets were developed to different extents in Kenya, Tanzania and Uganda. It is possible that a longer intervention could have increased the eventual market size.

- In Tanzania, a range of suppliers were serving the private sector market independently before project closure. However, PSI was still building consumer demand and recruiting new providers. An extension would likely have increased the size of the market for these actors (and potentially others).
- In Uganda, an extended scaled-up phase could have recruited additional suppliers. An extension would also have allowed for increased building of consumer and provider demand, increasing the size of the market developed.
- In Kenya, where scale-up was not planned, the additional six months were less likely to be transformative. These six months would have funded the continuation of activities in the same county. However, as in Tanzania and Uganda, the size of the market could have been built further by continued demand building and provider training.

In Madagascar and Nigeria, the proof-of-concept phase did not establish the longer-term commercial feasibility of the intervention for different reasons. Scaling up would therefore not have contributed to the development of sustainable mRDT markets.

- In Madagascar, an extension was unlikely to have changed the ongoing need for subsidies nor contributed to the development of a sustainable market. However, extending the project for an additional six months might have generated more evidence on operating at scale. In turn, this may have provided the evidence needed for another funder to continue to fund the model.
- In Nigeria, the ability of the planned interventions to build consumer and provider demand was not proven.

iii. Build and disseminate knowledge and tools to inform the development of other mRDT markets

The project resulted in knowledge and tools that could be used by other actors, including the roadmap. During the project, grantees generated, codified and disseminated evidence and

[179] Measured as indicator O2.2 as the proportion of consumers seeking fever treatment at private outlets who told the exit survey they asked for an mRDT.
[180] No scale-up was planned for Kenya. Nigeria began to scale up until it was ordered to scale down by Unitaid.

knowledge. As discussed in the future prospect section, multiple outputs have been produced or will be produced. The major tool for sharing this research was the WHO roadmap. WHO received a separate extension to finalise the tool.

However, the richness of content could have been further enhanced. As discussed above, the project generated evidence and learnings from the pilot phase. However, the project generated limited insights on how to scale up the markets to national level (crucial for the roadmap, which is intended to support other governments in their market development). The no-cost extension would have enabled grantees to document more insights on how to scale a local market.[181]

It is too early to know if the knowledge and tools will inform the development of other mRDT markets. The identification and sharing of lessons learned were intended to support development of private-sector mRDT markets elsewhere. It is too soon for new mRDT markets to have been launched or developed. However, anecdotal insights suggest that actors in the space see value in the knowledge and tools that were developed and have used some of these to inform decision making.

[181] The project has not yet been able to generate insights on the sustainability of markets; as sufficient time has not yet passed. The no-cost extension has no influence on such information.

5. VALUE FOR MONEY

The grant has created and will likely continue to create value. As discussed earlier, the project had three implicit objectives. The project has already achieved valuable outcomes for each objective. Additional value may result later from the momentum generated during the project. Finally, in time, other actors may increase the project's impact by using the tools and evidence generated to implement private-sector distribution models in other health commodity markets.

The three combined goals should result in the project's intended impact: increasing access to affordable high quality mRDTs to improve health. Increased access to and use of affordable, high-quality mRDTs can be expected to improve health by avoiding unnecessary use of ACTs, thus reducing the risk of ACT stock-outs and of resistance from overuse of ACTs. It should be noted that our assessment of project value is largely based on outcome data (such as the number of mRDTs distributed) rather than health impact data. The calculation of public health impact would require additional datasets (e.g. stock-out data) that were not available at the time of the evaluation and additional epidemiological modelling.

The next section discusses: (1) the value and impact achieved to date, (2) the value and impact that is likely to materialise in the medium term due to the momentum built, and (3) the value and impact that might materialise in the long term.

1. VALUE AND IMPACT ACHIEVED TO DATE

The project has proven the concept, resulted in some sustainable markets at sub-national scale, and generated learnings and materials that are starting to be used. Across the five countries, 2,872 outlets have been signed up and an estimated 1.3 to 1.6 million mRDTs have been distributed. Market actors are continuing to supply the private-sector mRDT market in three countries. Actors believe that the private sector can safely handle mRDTs (given the right conditions) and some governments are considering further regulatory changes. Moreover, significant learnings on what works and does not work have been generated (see section 2g on learnings). Moreover, WHO is developing a guide for governments that brings together lessons learned, and an additional 14 knowledge outputs have been developed.[182]

In terms of impact, the project funded the distribution of mRDTs to private-sector customers who might not otherwise have had access to diagnostics. Approximately 1.3 million to 1.6 million mRDTs were sold to consumers.[183] This compares with an initial project plan of 4.9 million mRDTs to be distributed to private outlets.[184]

The distribution of these mRDTs has likely contributed to public health gains in project areas. The majority of fever cases diagnosed with mRDTs were negative for malaria, according to project

[182] In addition to the roadmap, knowledge resources developed include (i) a chapter for the Springer Encyclopaedia on malaria diagnosis in the private sector, (ii) a set of policy papers with an overview of each of the case study countries, (iii) two qualitative studies on how mRDTs are used in practice in Madagascar and Uganda by the Johns Hopkins School of Public Health team, which may be adapted for publication in a peer reviewed journal, (iv) 9 conference presentations on lessons learned, (v) a manuscript on quality control of mRDT accessories, and (vi) an article drawing on evidence gathered for the project, 'Building a healthy and sustainable market for malaria rapid diagnostic tests'. This article was published in the WHO Bulletin.

[183] This is quantified above in our estimations of reach and the value of stock distributed.

[184] End-of-project target for indicator P1 for all five countries and all years.

reporting.[185] Given that an estimated 1.3 to 1.6 million mRDTs were distributed, the project likely averted hundreds of thousands of cases where non-malarial fevers would have been treated with antimalarials.[186,187] As a result, unnecessary use of ACTs was reduced in project areas. This is likely to lead to reduced stock-outs of ACTs and therefore to improved health outcomes for malaria patients who would otherwise not have had access to ACTs.[188]

The cost of achieving this impact is approximately USD 11 to 14 per mRDT distributed. Expenditures relevant to this stage were USD 18.0 million.[189,190] This implies total expenditures of USD 6.10 per mRDT distributed to suppliers or retailers, or USD 11.40–13.80 per mRDT sold to a consumer during the project.[191,192] This figure varies greatly by country, as illustrated in Figure 5. This cost of USD 11.40–13.80 compares with an implied cost of USD 6.79 per mRDT sold based on the originally planned procurement volumes and budget.[193,194]

[185] The proportion of fever cases diagnosed using mRDTs that were negative for malaria was 81% in Madagascar, 58% in Kenya and 69% in Tanzania, according to PSI caseload data

[186] Comparing the proportion of fever cases diagnosed using mRDTs that were negative (footnote 176) to the estimated mRDT sales suggests 260,000 – 330,000 averted ACT treatments in Kenya, 210,000 – 420,000 Madagascar, and approximately 150,000 in Tanzania. A minimum estimate for the number of ACT uses in negative cases averted is therefore 620,000. Data on negative mRDT results were not available for Nigeria and Uganda.

[187] This assumes that no fever cases diagnosed with mRDTs would otherwise have been diagnosed. In fact, mRDTs displaced microscopic diagnosis to some extent.

[188] Project reporting did not include data that would allow the proportion of malaria patients affected by stock-outs to be estimated.

[189] Cost is equal to expenditure against outputs 1-3 (on building demand, building supply and increasing quality), output 5 on codification and dissemination of learning from the proof of concept) and staff expenditure (which is not available by output and therefore includes the cost of staff working on activities not relevant to supporting mRDT distribution). Combined, these expenditures equal USD 18.0 million.

[190] This expenditure figure is net of approximately USD 97,482 of project income from sales. This income funded additional programme activity.

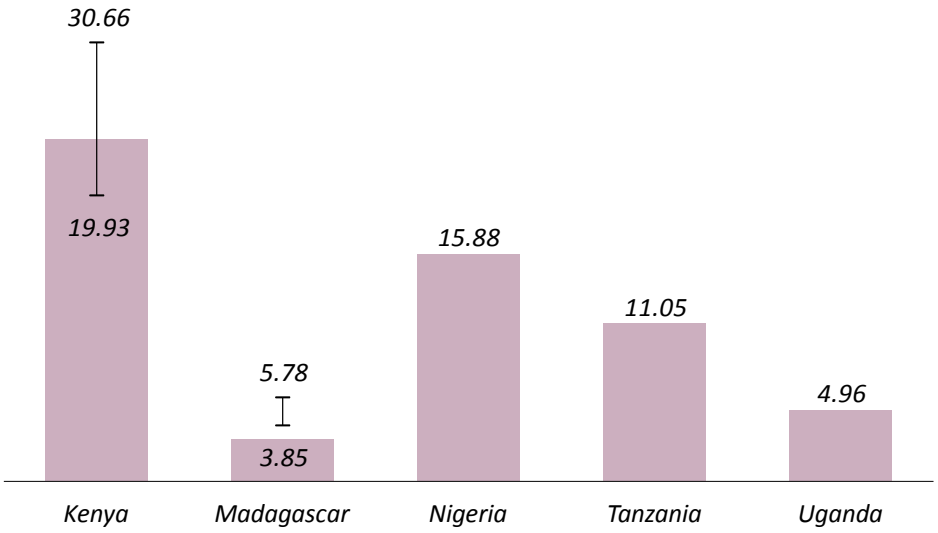
[191] According to project data on correct management of negative malaria cases, not all mRDT diagnoses resulted in a correct treatment decision. Hence the number is slightly higher per mRDT that led to improved treatment.

[192] The unit used in this analysis, mRDTs sold, is the basis for the proxy used to assess mRDT uptake in section 2e above. It is not possible to model value for money in terms of uptake of ACTs. This is because data on the percentage of mRDT sales that lead to malaria diagnoses and ACT treatment is not consistently available across the five countries or across time.

[193] This is based on the original budget of USD 33.4 million for outputs 1-3 and 5 and staff costs, and the 4.925 million mRDTs in original procurement plans.

[194] This assumes that all mRDTs procured were intended to be sold during the project, which was never an explicit expectation.

Figure 5. *Project expenditure per mRDT sold, project period,* ***USD***



NB: Kenya and Madagascar rely on modelled estimates of sales data. Ranges rather than precise estimates are therefore shown.

VALUE AND IMPACT IN THE MEDIUM TERM

The project has also built momentum which will extend the value generated across all three goals. For example, the proof of concept has triggered an interest in mRDTs among other donors, as described in section 2f on future market prospects. The markets created might continue at current level or even increase (with support from additional actors).[195] In Tanzania, PSI's mid-term market research established that there was a landscape of mRDT suppliers that could operate independently. It appears that independent supply also had been built before project closure in Kenya and Uganda. Moreover, the project has strengthened systems that will allow the market to be maintained, including professional oversight systems. In time, additional material, including the roadmap, will be developed and shared. It is likely that other actors will continue to use knowledge materials and tools developed to inform decision making.

In terms of impact, if recent sales volumes are maintained in Kenya, Tanzania and Uganda, future sales of mRDTs in the private-sector market could increase, ensuring longer-term availability of mRDTs to consumers.[196] Assuming that monthly sales of mRDTs continue at the same rate as during the last six months of the project, the volume of annual sales in Kenya, Uganda and Tanzania could be approximately 1.8 million.[197] At this rate, the within-project goal of 10.7 million mRDT uses could

[195] The grant attracted new suppliers and outlets to the market, built demand, and changed the policy environment to allow new groups of private facilities to operate. New suppliers attracted include three wholesalers and five distributors in Kenya, three wholesalers and ten distributors in Tanzania, and two distributors in Uganda.

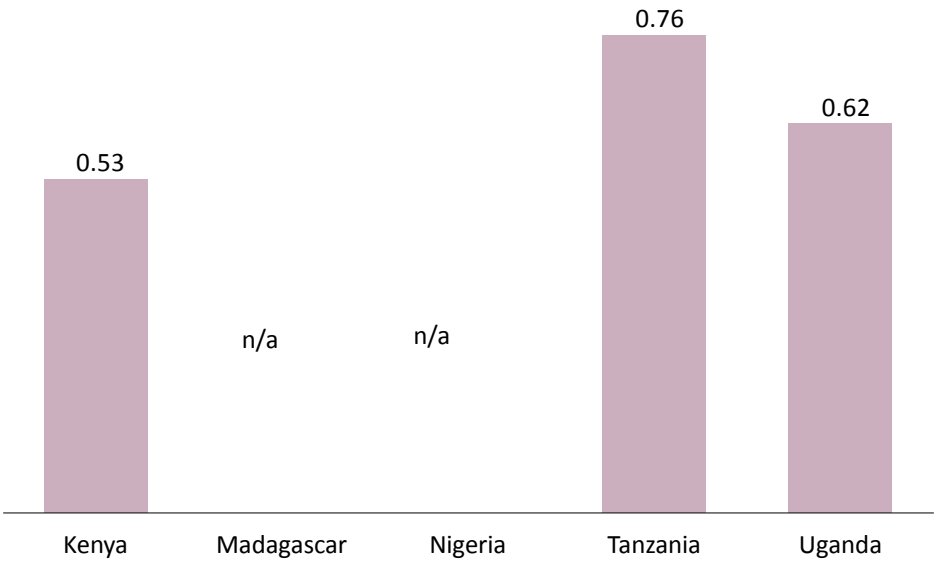
[196] Average monthly sales over the last six months were approximately 35,000 mRDTs in Kenya, 48,000 in Tanzania and 70,000 in Uganda according to sales data.

[197] For the last six months of the project, monthly sales totalled 35,000 in Kenya, 48,000 in Tanzania and 70,000 in Uganda – according to sales data. This would imply annual sales of 420,000 in Kenya, 576,000 in Tanzania and 840,000 in Uganda.

be reached in approximately six years. These sales would also bring public health gains by averting ACT stock-outs and resistance.[198]

Over the coming five years, expenditures per mRDT distributed would fall as the number of sales to consumers in Kenya, Tanzania and Uganda increases. Including these additional sales in the definition of mRDTs distributed due to the project would reduce the cost of the project per mRDT sold. Nigeria and Madagascar are not included due to the assessment that grant activities have not generated sustainable markets there. In these countries, we assume that costs per mRDT would remain the same as costs to date (Figure 5) given the probability of reversal if no other market shaping initiative occurs.[199]

Figure 6. *Project expenditure per mRDT sold, project period and subsequent five years,* ***USD***[200]



VALUE AND IMPACT IN THE LONG TERM

In time, the project may also inform the development of private-sector mRDT markets in other countries. The project was designed to make significant contributions to the sector's understanding of private-sector mRDT markets. The most fundamental addition to the knowledge base is likely to be the body of evidence on how to generate market interest in and engagement with mRDTs. The evidence generated has also increased regulators' and donors' confidence in private providers' capabilities to use mRDTs in the project countries.[201] The other forms of evidence generated may be

[198] The contribution of mRDT sales to these dimensions cannot be calculated due to the absence of data on negative malaria diagnoses in Uganda (in addition to the gap on epidemiological data for all countries).
[199] They have not been included because of the assessment that the project did not foster sustainable markets in those countries but require additional donor support. It is therefore not possible to extrapolate future sales and attribute them to the project.
[200] Cost is equal to total project expenditure per country against outputs 1-3 (on building demand, building supply and increasing quality), output 5 on codification and dissemination of learning from the proof of concept) and staff expenditure (which is not available by output and therefore includes the cost of staff working on activities not relevant to supporting mRDT distribution).
[201] Specifically confirmed for Uganda and Madagascar (possible also for other countries). In addition, CHAI and USAID note that this this project has had a role in proving the private-sector mRDT market, including providers' ability to administer diagnostics safely.

less impactful than envisaged in supporting market actors and shapers, such as governments and suppliers, to engage in market development. The WHO roadmap was intended to draw together the evidence generated through the project to guide governments in building private sector mRDT markets. However, some interviewees were sceptical about the extent to which the limited evidence on scale-up will meet the needs of the roadmap's audience. Additional research materials have been planned but not yet disseminated. Interviewees were therefore not able to assess how the evidence base built might contribute to future market building.

The research has also generated knowledge and processes that will improve the effectiveness of grantees, Unitaid, and potentially the sector. As mentioned above, PSI has introduced new knowledge codification systems that it expects will improve its ability to learn and improve during other projects. MC has gained and shared learnings on market shaping through "bundling".

Finally, the project may generate interest to experiment with and potentially expand private sector distribution in other health-commodity markets, building on the tools and concepts developed for mRDTs.

6. CONCLUDING THOUGHTS

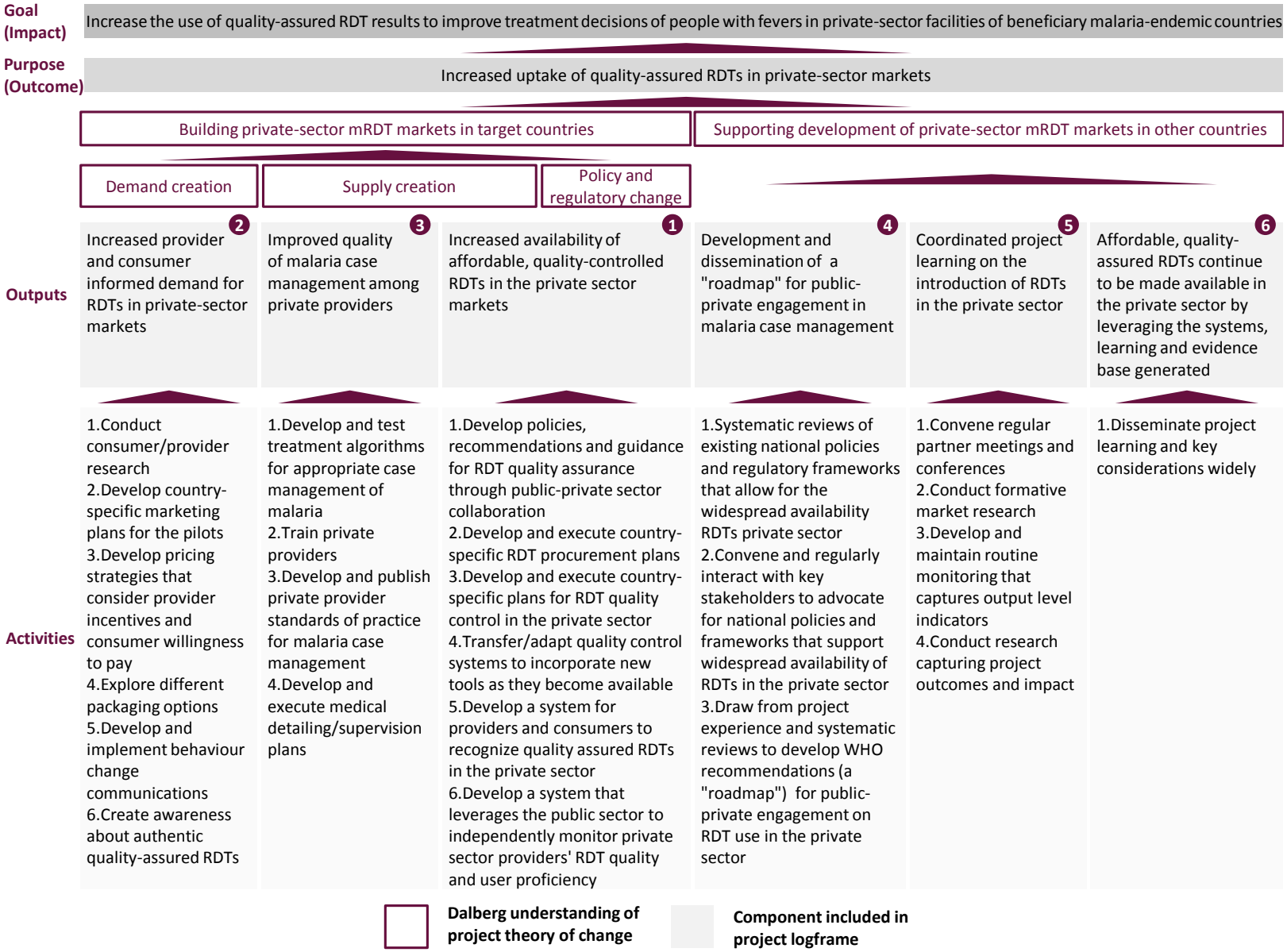
This project was a bold and forward-leaning attempt to tackle a public health challenge by reshaping private-sector markets. The lack of appropriate malaria diagnosis in the private sector is a major issue plaguing the global fight against malaria, and new and innovative approaches to tackle this problem were and are needed. Unitaid and its grantees should be lauded for their commitment to explore and experiment, their ambition to tackle five complex and diverse markets, their willingness to look at novel and innovative approaches, and their willingness to take risks.

System intervention is a cycle of trial, error and adjustment. The project achieved several, but not all, of its stated goals and targets. In some instances, these challenges may have been preventable by better planning and foresight; in others, this was not possible. We believe that, especially when intervening in complex systems, it is a fundamental skill to manage feedback loops (observe-interpret-decide-act) in a timely manner. We hope that the project outcomes, the reflections shared by Unitaid and its grantees, and the observations in this evaluation will help to further increase the speed and accuracy of these loops in future projects.

Experimentation and innovation includes learning about what works and about what does not work. One of the implicit objectives of the project was to understand whether and where the private sector distribution of mRDT might be successful, and which interventions and approaches work (or do not work) in different contexts. Given the diverse and complex contexts in which the project was implemented, certain interventions are inevitably less successful than others. The learnings on what does not work are in our opinion a valuable outcome of the project, and should be analysed and shared. Moreover, the project generated a wealth of lessons and insights on the managerial and organisational requirements on how funders and implementers should plan, collaborate and manage on these types of innovative projects.

The value of this project will be further augmented by disseminating the lessons learned. We believe that the analysis of this innovative project, and the sharing of the lessons learned, will be of great value to many stakeholders in the global health community. We hope that this evaluation makes a small contribution to that wider goal.

ANNEX 1. **THEORY OF CHANGE**



ANNEX 2. **ASSESSMENT OF LOGFRAME**

We have assessed the logframe along six dimensions: relevance, attainability, logic, comprehensiveness, measurability and timeliness. Overall, our assessment is that the logframe included clear and specific indicators for most variables, time-bound targets, and measurable indicators as well as a clear strategy for monitoring and evaluating achievement of each target. The logframe could have been improved by: ensuring that indicators were relevant to the objectives of the grant and of Unitaid, including additional relevant factors to increase comprehensiveness, articulating more clearly the logic between outputs and expected outcomes, considering attainability of targets, and developing specific targets for every indicator. Below we detail each point further.

- **Relevance: The KPIs collected did not fully align with overall grant goals.** At the goal level, there was no KPI for market catalysis such as number of wholesalers purchasing mRDTs for distribution in-country. The impact indicator on quality of fever treatments did not address all dimensions of fever treatment; it did not include the proportion of total fever cases receiving ACTs as part of treatment, whether mRDTs were quality assured, or information on how negative cases were treated.

- **Attainability: Targets did not take account of large variances across countries.** Targets at the goal level and at the output level were mostly identical across all countries. Goal and outcome targets were not grounded in the baseline results and were not updated to reflect them. For instance, the baseline results for indicator G1.2 met or exceeded the end-of-project targets in all countries but Madagascar. Target levels were not adjusted to reflect the specific circumstances in each country, such as the prior relationships with distributors in Madagascar and Tanzania, or the more challenging market context in Nigeria**.**

- **Logic: The linkages between project activities and outputs and behaviour changes among other actors were not all clear.** In particular, output 6 was designed to measure impact achieved through changing systems, and developing learning and evidence that could be used by the broader sector. Because this output tracks change that depends on planned project outputs and the choices of other actors, it could have been considered as an outcome. Indicators under output 6 relate to other work streams and could easily have been included under other outputs. For example, indicator O6.2 on caregivers requesting febrile kits measures demand and could therefore have been included under output 2. Indicator O6.3 on research dissemination could have been included under output 5 on learning. This reflects the great difficulty of designing a logical framework for assessing catalytic impact.

- **Comprehensiveness: The theory of change addressed a wide range of activities and outputs relevant to a markets for the poor (M4P) approach but did not prioritise specific activities and neglected some factors that are important to ensure quality of care.**

  The theory of change was ambitious in scope and addressed a range of market failures. In each country, objectives included building demand, improving supply, and influencing the policy environment. Activities included marketing to consumers and providers, procurement and managing distribution chains, QA activities, engaging with regulators, and ongoing research and learning.

  The reporting framework did not include some important factors such as the availability of ACTs. A key assumption in the theory of change was that improved management of negative fever cases would improve ACT availability. There was no KPI on ACT availability. Nevertheless,

project plans were amended mid-term to procure ACTs to ensure availability in Kenya and Madagascar.

- **Timeliness: Three years may not have been a realistic timeline for the ambitious objectives and activities planned.** Market development is a long-term process and, as noted above, three years may not have been long enough to meaningfully engage with these markets. In addition, this short timeframe increased the effects of project delays. Delays early on significantly reduced the project timeline and the feasibility of the targets.

- **Measurability: Targets were measurable, and each had its own measurement strategy, but not all targets were in fact measured and reported as planned.** At goal and outcome level, achievement of percentage targets was measured using a variety of pre-agreed methods such as population surveys and client exit interviews. This ensured a degree of objectivity and comparability between counties and over time. However, many absolute targets were not measured or modelled. From the outset, grantees did not report against these absolute targets due to practical difficulties. This suggests low feasibility of measuring absolute targets. At output level, the agreed measurement strategy for most indicators was also objective and comparable. The challenges in gathering data and evidence are covered in section 3 on operations.

In future, Unitaid and grantees can also ensure logframes include indicators that provide more insight on system-level change during implementation. The indicators measured focused on grantees' activities rather than on system-level change. A stronger logframe could provide a better understanding of the broader system by assessing dynamics between consumers, providers and suppliers. Such insights would require an element of market research similar to the landscape assessment PSI Tanzania completed, which assessed players in the market and the role PSI could take to complement them. As in Tanzania, such analysis would help guide decisions on when and how to participate in the market and on other mid-course corrections. In the table at the end of this section we provide some suggestions of additional indicators that would improve Unitaid's and grantees' ability to understand impact and make mid-course corrections.

Similarly, in the future, Unitaid can also support measurement of longer-term, catalytic change through promoting post-project evaluation. Unitaid could set up structures that allow it to monitor and evaluate its catalytic effect after the project has finished. Some relevant market data is already being collected through the Unitaid-funded ACTWatch programme (such as the proportion of outlets stocking mRDTs). Additional data could be gathered through a one-off landscape review after project closure. In future grants, Unitaid can ensure that key grantees and actors along the supply chain have contractual obligations to share the necessary information (on sales volumes at aggregate level, for instance).

Table 3. *Illustrative market development indicators*

Topic	Indicators	Source
Players active at each stage	○ *Number of manufacturers, importers, distributors and wholesalers in the supply market*[202] • Number of outlets providing mRDTs ○ *Qualitative insights on their future intentions/prospects*	Interviews with manufacturers, importers, wholesalers
Commercial relationships between players	• Sales volumes between suppliers and providers • Number mRDTs sold to consumers	Aggregate data shared by manufacturers, importers, wholesalers, and/or sample retailers (as possible)
Quality assured mRDTs	○ *Prevalence of quality-assured mRDTs vs non-quality-assured mRDTs in the market*	Data shared by wholesalers and by sample retailers
Consumer satisfaction	○ *Qualitative accounts of satisfaction/ dissatisfaction of using mRDTs*	Interviews with retailers and consumers
How mRDTs are handled	• How training is provided and scaled, how waste is managed (could be qualitative)	Interviews with retailers and wholesalers
Other market shaping interventions	• *Qualitative insights on additional interventions funded by donors/ governments, USD invested, mRDTs moved through these interventions, etc.*	Interviews with key donors in country
Policy	• Status of policy change	Interviews with government
Price	• Price evolution	Interviews with actors along the supply chain / data shared by wholesalers and by sample retailers

Key

- Indicators from project logframe
- ○ *Suggestions for new indicators*

[202] This information was collected by implementing partners, but not as part of the logframe.

ANNEX 3. **COUNTRY PROFILES**

3A. KENYA

The Unitaid-funded project was implemented in coastal Kwale county. DFID funded a similar market intervention in two neighbouring counties (Mombasa and Kilifi) and the two projects shared some resources, including two QA officers. Unlike all other countries, no scale-up phase was planned. The original plan for the Unitaid-funded project included a target of reaching 100 social franchises and private pharmacies. However, initial landscaping did not identify that 60 of the 100 outlets identified were not officially registered. The National Malaria Control Programme only permitted 40 of the outlets to participate.

In order to allow private outlets to provide diagnostics, a waiver was granted by the Kenyan Medical Laboratory Technologists and Technicians' Board to allow pharmacists to provide diagnostics tests.

PS Kenya procured 250,000 mRDTs from AccessBio and imported them into Kenya. There was initially no direct mRDT subsidy, but PSI procured the mRDTs at advantageous wholesale prices pre-negotiated by CHAI. In addition, rather than working through wholesalers, PSI handled distribution directly. This acted as an effective subsidy of 100% of distribution costs.

This system was set up based on information on the margins needed by retailers in other market development projects. A landscape study in 2015 identified that price was a significant constraint on growth of the mRDT market. Retailers were charging approximately USD 1.00 per mRDT – above the recommended price – but earning low margins. A direct subsidy was introduced, reducing the retail price to USD 0.60. Quarterly sales to wholesalers tripled from 9,595 to 26,280 following the introduction of the subsidy.

Over time, PS Kenya moved away from direct distribution and towards working through existing market players. PS Kenya also changed its strategy over time to improve availability of ACTs. ACTs were less easily available in the country between the wind-down of the Affordable Medicines Facility for malaria and the implementation of DFID and Global Fund subsidies for ACTs. PS Kenya identified that that this low affordability was a barrier to best-practice malaria case management, and procured an additional 30,000 ACTs. The original plans to include 500,000 mRDTs were changed when the slow movement of stock was recognised; only the first of two consignments of 250,000 mRDTs was approved. In order to avoid the expiry of 132,000 mRDTs, Kenya supplied 117,000 kits to the NMCP, which in turn distributed the kits to private outlets; the cost of these donations was not recovered.

To date, 52 outlets have been trained.

Future prospects

Due to PS Kenya's DFID-funded work in contiguous Mombasa and Kilifi counties, some of the market infrastructure developed in the region is also attributable to DFID funding.

Supply. Quality-assured mRDT kits are now available to retailers on the private market in the coastal area; three wholesalers and five distributors are currently operating in the market. Distributors expect further growth and intend to continue supplying mRDTs to providers. Outlets report that the tests are easily available from suppliers. As of the end of the project, retail prices had fallen to a level that is affordable to consumers (approximately USD 1.00). It is not clear to what extent suppliers will

remain in the market. However, a wholesaler reports that mRDT sales are increasing, resulting in lower margins being offset by higher volumes.

Demand. A range of stakeholders (including government authorities and wholesalers) report an increased use of mRDTs. Wholesalers expect the market to continue to grow and intend to stay in the market. Among consumers, demand has been built to some extent. There is evidence of consumer awareness and, anecdotally, some consumers have started asking for mRDTs. However, stakeholders report that consumer demand has not been built as much as it could have been. "There are gaps. We can do better," one interviewee from the NMCP said. Supply and price of ACTs remain erratic, affecting the value proposition of mRDTs relative to presumptive treatment.

Policy change. Prospects for the policy environment are uncertain. As part of a revision of the national malaria strategy, the government has extended its QA remit to private sector care providers. The temporary waiver is still in operation. However, there has been no national policy change. In addition, the NMCP reports that regulatory issues more broadly, including product specifications, have not yet been addressed. A positive relationship with the NMCP has been built, which may increase the likelihood of future regulatory changes.

3B. MADAGASCAR

Project summary

PSI Madagascar began a pilot phase in the city of Tamatave in April 2014. PSI procured an initial consignment of 60,000 single-pack mRDTs from Standard Diagnostics. These were then distributed to wholesalers, including partners from previous PSI work. Later in 2014 an additional consignment of one million hospital packs was ordered, although Unitaid approved delivery of only 716,675 due to concerns about overstocking following slow progress in demand building. Having already paid for the 283,325 cancelled mRDTs, PSI Madagascar sold these to PSI Angola to recoup the cost.

In 2014, the Ministry of Health introduced a new policy to allow private sector pharmacies to offer malaria diagnosis, which allowed training of private providers to begin. PSI worked to stimulate demand from providers through training, and from consumers through behaviour change campaigns.

A direct subsidy by PSI was used to ensure that mRDT kits were affordable to consumers. The level of subsidy was approximately half the recommended retail price, with small variations to ensure one recommended retail price across single and hospital packs (USD 0.47, set with reference to the highly subsidised price of ACTs). Interviewees across the Malagasy health system reported that this price is affordable to consumers but that unsubsidised prices would not be.

Nationwide scale-up started in November 2015, around the same time that Unitaid decided not to grant a no-cost extension. Training and behaviour change therefore happened on a nationwide basis for approximately six months before the project ended in April 2016. The project has so far enrolled approximately 450 private outlets. However, sales volumes are lower than anticipated due to low demand. Up to half of the mRDTs procured may not have been pushed out to retailers.

Future prospects

Supply. Five wholesalers are operational but they have all secured their stock from PSI rather than from importers or manufacturers. Approximately half of the subsidised stock made available by PSI

remains with wholesalers. This subsidised stock will continue to be available to private outlets for over a year as it will not expire until 2018. PSI and the Direction de Lutte Contre le Paludisme have applied for further funding from the Global Fund to finance further mRDT subsidies; the outcome of this application is outstanding.

Demand. Despite increases in supply, demand remains low. Providers are aware of mRDTs but provider use of mRDTs is not yet systematic. Most consumers – especially those with lower incomes – do not demand mRDTs. PSI's ACT project, funded by the PSCM, will take on some demand building activities including provider training and consumer behaviour change in the future. Ability to pay remains low for most of the population. The consensus across stakeholders is that, without subsidy, consumer demand would collapse. Subsidy will be necessary for the medium term. Subsidised ACTs will remain available in the market through the PSCM and, without subsidised mRDTs, treatment without diagnosis is likely to remain attractive to consumers – and therefore to providers.

Policy change. Permanent policy changes made during the project are likely to support gains in availability of mRDTs and quality of kits and of treatment. These include (i) a regulatory text authorising diagnosis by private providers, (ii) incorporation of the private sector in public sector systems for assuring quality of provider care, and (iii) a common set of product specifications for mRDTs in the public and private sectors.

3C. NIGERIA

Project summary

MC's model in Nigeria gave most responsibility for distribution to the manufacturer. MC procured 2,200,000 "bundles" of single packs of mRDTs and various services required down the supply chain: stock management, demand creation, provider training, medical detailing, supervision and waste disposal. MC subsidised the cost of these services by providing a subsidy equal to the difference between the average cost of the mandated service and its target unit cost. This unit cost was set to satisfy two targets: (i) a retail price lower than over-the-counter ACTs, and (ii) the margins expected by players at each step of the supply chain. Single packs were chosen to appeal to operators of small shops who find it hard to manage the components of the diagnostic (such as swabs, lancets and alcohol) separately.

There were some favourable policy developments during the project due to the federal government's support. Notably, PPMVs were authorised to perform mRDTs, opening up a large segment of the private provider market.

Procurement was delayed from initial project plans as it took longer than expected to secure Unitaid's approval for the new bundled model. Delivery took place in August 2014. There were also challenges within the MC team due to staff turnover.

Over the course of the project, it became apparent that Nigeria was a more challenging market environment than initial market research suggested. Significant challenges were: (i) provider resistance to replacing microscopy with mRDTs, (ii) opposition of professional associations including lab technicians to allow new facilities to diagnose, (iii) the selection of less economically developed states, with smaller supplier bases, and (iv) flooding of the local market. This flooding included mRDTs illicitly taken from the public sector and sold on and a large stock donated to private providers for free in the three project states by the Global Fund through SFH.

The market price for mRDTs remained far lower than the target retail price of USD 1.00, due to the availability of substitutes. As a result, it was very difficult to build demand. Far fewer outlets than targeted are operative in the market (868 at project closure, against plans for 3,000). Overstocking was considerable. Unitaid cancelled delivery of 999,875 mRDTs not yet delivered to Nigeria by one manufacturer, Premier Medical Corporation).[203] This resulted in losses for PMC and a reduction of total planned stock for Nigeria to 1.2 million. When Unitaid denied the extension in 2015, it ordered that Nigerian operations further scale down by 85%, effectively ending the project.

Some of the overstock was dealt with by distribution through SUNMAP, an MC project providing support to some Nigerian states in executing their malaria strategies. 13,450 mRDT kits that were not distributed in this way or sold have been destroyed.

Future prospects

Supply. The impact of the project on the availability of mRDTs to private-sector suppliers was limited. PPMVs, a large segment of the private health market, are able to offer mRDTs. The market is flooded with cheap or free mRDTs and low-quality diagnostic kits. It has been difficult to attract new wholesalers and distributors to the market for quality-assured mRDTs because of the low margins as compared to lower-quality substitutes. However, the distributors involved in the MC project – Codix and SHI – are still supplying mRDTs. The share of quality-assured mRDTs in the market remains low, according to civil society interviewees.

Demand. It has been challenging to build both consumer and provider demand. The considerable subsidy did not translate into mRDTs competitive pricing for outlets. This was due to availability of lower quality diagnostics and free tests given away by the Global Fund. Where demand exists, this is concentrated in higher income areas, as it was before the project. Provider demand for quality-assured mRDTs as compared to lower-quality alternatives remains low. Due to the scale-down, the opportunities to further build demand among consumers or providers are low.

Policy change. The 2015 waiver allowing PPMVs to perform malaria diagnostic tests is still in force. However, progress in regulation and QA of mRDTs for the private sector remains slow, according to a Nigerian health NGO.

3D. TANZANIA

Project summary

The start date of the Tanzanian project was pushed back eight-months due to the time needed to sign a memorandum of understanding with the Ministry of Health. The 215,000 hospital pack mRDTs PSI procured were delivered in May 2014, compared to a planned start in September 2013.

PSI did not subsidise prices but negotiated a favourable wholesale price by buying in bulk and passing along savings.

In contrast to other countries where temporary approvals were won, in Tanzania the project was operational only among formal health care providers in the private sector such as hospitals and clinics. While the project was initially expected to include accredited drug dispensing outlets

[203] Unitaid clarified that these mRDTs had not been approved by Unitaid.

(ADDOs), a major segment of the private health care market, authorisation for this segment to conduct diagnostic testing was not given. This reduced the reach of the project.

During the pilot, PSI implemented provider trainings, behaviour change campaigns and support to regulators including supervisions of participating facilities. PSI worked with suppliers and facilities with whom it had prior relationships. PSI Tanzania further built trust and guaranteed demand by sharing market data and its stock data with suppliers to prove that the market was viable.

No market landscape was conducted at the outset of the project; PSI instead drew on a recent landscaping conducted by CHAI. The initial PSI landscaping was instead conducted midterm, in April 2015. This market assessment found that suppliers of mRDTs had entered the market and established relationships with importers and facilities. By 2015, there were additional sources of quality-assured mRDTs besides PSI. PSI judged that the market could operate independently, stopped procuring and shifted to a facilitative role where it supported others' commercial relationships.

A key challenge identified during the project was illicit sales of mRDTs from the public sector to the private sector market. Collaboration with government authorities, which ran an employee education campaign in the public sector and increased monitoring, addressed the problem.

Tanzania began its scale-up to forty districts as Unitaid announced its decision on scale-down. By the end of the project, PSI had trained 546 private facilities.

Future prospects

Supply. Players operating in the market include three importers and an estimated ten regional distributors. Distributors report that they perceive market growth and intend to continue supplying mRDTs to providers.

Demand. Prices rose after directly procured stocks were exhausted. However, the existence of a broader supply-base has ensured that prices did not rise beyond consumer's ability to pay. As noted above, due to regulatory restrictions, the market is currently limited to formal health care facilities and does not include pharmacies, drug shops or ADDOs.

Policy change. There have not been enduring policy changes in Tanzania as a result of this project. A separate project currently being executed with CHAI is piloting diagnosis in ADDOs, which may increase the private provider market in Tanzania.

3E. UGANDA

Project summary

MC used the same model in Uganda as in Nigeria. MC procured 600,000 mRDTs each from two providers (1.2 million total). PMC and Standard Diagnostics, the same manufacturers as in Nigeria, supplied the commodities and worked with local importers: Medilink and BDH. These importers in turn contracted distributors – UHMG, Quality Chemicals and Karuri – to organise the services mandated by MC: stock management, demand creation, provider training, medical detailing, supervision and waste disposal. MC retained responsibility for designing the e-learning course used to train providers and for organising mass marketing.

As in Nigeria, procurement approval took longer than anticipated, and approval was given in July 2014.

The project originally operated in Wakiso district outside Kampala. For the project, a waiver was introduced to allow private providers such as drug stores to conduct diagnostic tests.

A similar model of direct payments to suppliers of mRDT bundles was used as in Nigeria. The level of subsidy was 82% of recommended retail price. As a result, average retail price remained around the recommended price of USD 1.00, which consumers were willing to bear and which was less than the price of ACTs.

MC did not assume control or responsibility for building relationships between distribution partners. Instead, the manufacturers (and the distributors the manufacturers contracted) built demand as they chose, using different approaches. This led to a variety of models. Standard Diagnostics paid for services such as waste management in advance, while PMC paid these in arrears following the final sale of each commodity to a consumer. PMC's model appears to have inhibited demand by adding short-term costs for wholesalers and retailers.

As a result of this overstocking and challenges in building supply, in 2015 Unitaid cancelled the order of 500,000 mRDTs that PMC had not yet delivered, resulting in revenue losses for PMC and a reduction of the total stock to 700,000.[204]

The project scaled up in late 2015, before the no-cost extension was denied. Since that time, the project has operated in an additional eight districts. The majority of the 700,000 mRDTs procured have been sold. (13,700 mRDTs that expired before they were sold have been destroyed.) 1,502 outlets were trained and are operating in the market.

Future prospects

Supply. Two of the three distributors have stayed in the market and continue to supply mRDTs to the private sector: UHMG and Kariuri. A third distributor involved in the project, Quality Chemicals, has left the mRDT market. In addition to the two multinational manufacturers, SD and PMC, a Ugandan manufacturer of mRDTs, Astel Pharma, has begun to market to the Ugandan private sector, selling approximately five percent of its stock directly to private providers. Many outlets intend to continue to offer mRDTs, and to do so at a price affordable to consumers (despite subsidies ending). According to supervision data, quality of kits and of handling is high and the National Drug Authority (NDA) has been satisfied with quality.

Demand. Consumer awareness has been built, and many perceive outlets that offer malaria testing as of higher quality than those that do not. Retail prices have stayed the same since the end of the subsidised stock. While demand has been created for the mRDT "bundles" of single packs and services, these bundles are no longer available on the market. Suppliers report that there has been a sharp drop-off in demand while providers wait for these to be reintroduced. However, SD does not plan to manufacture single packs in future as they are insufficiently profitable. Other manufacturers are also unlikely to start manufacturing them as WHO guidelines currently recommend against use of single packs. There is therefore a risk that demand has been generated for a different product than the market can provide for. "They want to wait until we have single packs again. We've taught them to drive a car and now we're giving them bikes," said a distributor. The distributor also notes

[204] Unitaid clarified that these mRDTs had not been approved by Unitaid.

that some providers who were used to getting services such as waste management provided for free by distributors are dropping out of the market rather than organising these services themselves.

Policy change. Temporary policy change was achieved but the prospects of longer-term authorisation of private providers to carry out malaria diagnosis are not clear. MC and its in-country partners are confident that change will occur. Before a permanent authorisation is possible, however, legislation has to establish the right of the National Drug Authority to make this decision. The legislation is expected in autumn 2016 and policy change following that.

ANNEX 4. **EVALUATION METHODOLOGY**

The evaluation combined desk research using documents provided by Unitaid and members of the grantee consortium, interviews with 49 stakeholders, and visits to Madagascar and Uganda.

Dalberg assessed (i) progress against the explicit objectives spelled out in documentation including project planning and the logframe, (ii) additional objectives understood by project participants and implicit in project planning – and progress against these, and (iii) explanations for successes and challenges against each.

Research was undertaken as follows:

- **Desk review of documents shared by Unitaid, PSI and MC with Dalberg.** The evaluation team relied on counterparts at grantee organisations to provide:
  - Implementation plans.
  - Routine documentation, including semi-annual reporting, approvals notices, procurement reporting, budget sheets, and documents produced as part of the monitoring and evaluation process.
  - Additional important sources, including records of communications between grantees and Unitaid.
  - Learning documentation, codifying the lessons learned and summarising project achievements.
- **Additional desk review.** The evaluation team also consulted additional materials, including the World Malaria Report and policy literature on market development in global health.
- **49 stakeholder interviews.** Interviewees were suggested by Unitaid, PSI and MC and spanned members of the grantee consortium, national authorities and malaria control programmes, private sector suppliers, private outlets participating in the project, and civil society. Country teams identified a shortlist of interviewees for each country. For Kenya, Nigeria and Tanzania, Dalberg conducted three to five phone interviews per country. For Madagascar and Uganda, Dalberg conducted eight interviews in each country. These in-person interviews included on-site interviews with wholesalers and private health providers, which offered a first-hand insight into market conditions. The interviewees are listed in Table 4.

In addition to interviews and document submission, country teams, Unitaid, and PSI and MC steering committee members provided information ad hoc in response to Dalberg's questions.

As with any evaluation exercise, there were practical constraints. Due to time limitations, the number of interviews possible in each country was limited and not all interview targets were available to speak.

Table 4. *Interviewee list*

Interviewee	Country	Organisation	Title or position
Annet Brenda Mushabe	Uganda	Allied Health Professionals Council	Quality Assurance Officer
Dr Raharivelo Vololomanitra	Madagascar	Top Riseau	Doctor
Alex Ogwal	Uganda	CHAI	Programme Manager
Theodoor Visser	Global	CHAI	Global Malaria Diagnostics Manage
Christian Nsanzabana & Sandra Incardona	Global	FIND	Malaria Group
Wellington Oyibo	Nigeria	College of Medicine, University of Lagos	Professor
Steve Harvey	Global	Johns Hopkins	Assistant Professor
Nina Martin	Global	Johns Hopkins	Researcher
Naomi Woods	Global	Malaria Consortium	Regional Programme Manager
Elizabeth Streat	Global	Malaria Consortium	Senior Public Health Specialist
Edward Idenu	Nigeria	Malaria Consortium	Country Programme Manager
Maxwell Kolawole	Nigeria	Malaria Consortium	Country Director
Godfrey Magumba & Robert Mugerwa	Uganda	Malaria Consortium	Country Director & Uganda Project Manager
Dr Ebenenzer Baba	Global	Malaria Consortium	Technical Advisor
Dr Hortense Rakotoniriny	Madagascar	Direction de Lutte Contre le Paludisme	Head of Malaria Case Management Department
Dr Lalanirina Ravony	Madagascar	Direction de Lutte Contre le Paludisme	Head of Malaria Case Management Department (former)
Dr Kate Kikule	Uganda	National Drug Authority	Head, Inspectorate Department
Dr Dorothy Naisiae (Memusi)	Kenya	National Malaria Control Programme	Head
Mgohamwende Fidelis	Tanzania	National Malaria Control Programme	Focal Person Laboratory
Dr Godwin Ntadom	Nigeria	National Malaria Eradication Programme	Director, Case Management
Dr Tiana Ravelonarivo	Madagascar	Ordre National des Pharmaciens	Advisor
Dr Samwel Onditi	Kenya	PATH	Programme Coordinator, Malaria Care
Dr Mbolatiana Raharison	Madagascar	Somaphar	Pharmacist
Nikki Charman	Global	PSI	Project Director
Andrea Cutherell	Global	PSI	QA Technical Advisor
Ann Musuva	Kenya	PSI	Director, Malaria and Child Survival
Desmond Chavasse	Global	PSI	Senior Vice President, Malaria and Child Survival
Stephanie Dolan	Global	PSI	Deputy Project Director
Stephen Poyer	Global	PSI	Research Advisor, Malaria and Child Survival
Gaston Shayo	Tanzania	PSI	-
Edgar Lusaya	Tanzania	PSI	Head, Health Services
Brenda Raphael Mshiu	Tanzania	PSI	Programme Manager Malaria and Child Survival
Dr Rova Ratsimandisa	Madagascar	PSI	Project Coordinator
Dr Mikael Randriamanjaka	Madagascar	PSI	Project Coordinator

Ruth Ashibende	Kenya	Royal Run Clinic	Proprietor
Bhavesh Kotecha	Kenya	Sai Pharmaceuticals	Director
Jane Rose Waiswa	Uganda	St Maama Thereza Pharmacy	Proprietor
Chad Kim and Steve D	Uganda	Standard Diagnostics	Regional Managers
David Katabaire	Uganda	UHMG	Project Assistant
Lorenzo Witherspoon	Global	Unitaid	Procurement Specialist
Ombeni Mwerinde	Global	Unitaid	Monitoring and Evaluation Officer
Ambachew Yohannes	Global	Unitaid	Technical Officer
Ross Leach	Global	Unitaid	Manager, Value for Money
Dr Alexandra Cameron	Global	Unitaid	Manager, Strategy
Matthieu Vittot	Global	Unitaid	Grant Finance Officer
John Cutler	Global	Unitaid	Technical Director (former)
Amy Lin	Global	USAID	Senior Market Access Advisor
Jane Cunningham	Global	WHO	Medical Officer, Quality Assurance
Dr Henintsoa Rabarijaona	Madagascar	WHO	Malaria Control Programme Focal Point

ANNEX 5. **MODEL METHODOLOGIES**

5A. MODEL OF STOCK FLOWS

Stock management data was collected and reported in a variety of formats, reflecting the diversity of models. In order to put stock flows in perspective and to allow aggregation across countries, Dalberg has had to make assumptions based on the available data. The sources for stock data are reported below. Where this is derived from other sources or is estimated, the methodology used is also outlined below.

Procured. Stock procured is taken from annual procurement reports and semi-annual project narratives. This includes stock that was procured by partners and subsequently cancelled by Unitaid (in Madagascar, Nigeria and Uganda).

Cancelled. This is inferred from the difference between stock procured and stock delivered, and checked against cancellations noted in semi-annual project narratives. Cancellations were due to Unitaid denying permission for delivery of stock procured.

Delivered. Stock delivered is taken from semi-annual project narratives.

Remaining with PSI or MC. This is inferred from the difference between (i) stock delivered and (ii) stock sold to distributors, wholesalers or retailers and stock donated.

Donated. This is taken from data supplied by the PS Kenya country team (where 117,000 mRDTs were donated to the Kenyan NMCP) and UHMG, a distributor in Uganda (which donated 4,000 mRDTs to NGOs). If donations were not reported as such by grantees, they would be counted under stock remaining with PSI or MC, as they were not sold to wholesalers, distributors or retailers.

Sold to wholesalers, distributors or retailers. This data was supplied by PSI's integrated case management team and M&E advisor, who also manage data for MC on this grant. Suppliers are grouped together rather than showing flows between wholesalers and retailers due to the variations in the models used. In Madagascar and Tanzania, data was collected on sales to wholesalers. In Nigeria and Uganda data was collected on sales to retailers. In Kenya, where the model changed, data was collected first on sales to retailers since PSI acted as a distributor and sold directly to retailers, and then later to wholesalers.

Remaining with wholesalers, distributors or retailers. This is inferred from the difference between sales to consumers and sales to wholesalers, distributors or retailers.

Used for other uses e.g. training. This was taken from data supplied by country teams and includes kits given away for reasons such as training, promotion and invalidity.

Sold to consumers. This was modelled by Dalberg, since this data was not reported through routine project processes. Reflecting the differences in models and data availability by country, a different approach was taken for each country. In Kenya and Madagascar, a range is estimated to reflect the uncertainty and imprecision of estimates. In the other three countries, where this estimate is inferred from other stock data, one central estimate is generated,

- For **Kenya** the estimate of consumer sales is modelled based on PSI's data on case management at participating outlets. From routine reporting on the number of cases tested with mRDTs per month and the number of outlets reporting, the number of cases tested using mRDTs per outlet per month was derived. Three values for cases per outlet per month were used to reflect the

uncertainty that comes from using a subset of outlets (e.g. seasonal fluctuations, and whether average number sales per outlet reporting is representative of all outlets). A minimum estimate, central estimate, and maximum estimate were calculated based on the interquartile range of the monthly average. These values were multiplied by the number of participating outlets (which was larger than the number of outlets reporting) to give an estimated range of the total number of mRDTs sold.

- For **Madagascar**, the estimate is based on the PSI Madagascar team's own assessment that approximately half of the 770,000 stock has been sold and half remain with wholesalers. This was corroborated by interviews with wholesalers. Reflecting the imprecise nature of these qualitative estimates and the range of responses from market players, the estimate uses an upper limit of two thirds of stock sold to consumers, and a lower limit of one third. (Estimates generated from replicating the methodology for Kenya did not match the PSI Madagascar team's own estimates.)
- For **Nigeria**, the estimate is derived from the difference between the stock sent to wholesalers and the overstock reported in correspondence between Unitaid, PSI and MC on this subject.
- For **Tanzania**, the estimate assumes that, given market developments and the interest of wholesalers and retailers in continuing to supply the market, 0% of stock remains with retailers or wholesalers.
- For **Uganda**, the estimate is derived from the difference between the stock sold to wholesalers and data supplied by MC on stocks remaining with wholesalers. This assumes that no stock remains with retailers, which is unlikely, but is likely to be approximately correct given the interest of wholesalers and retailers in continuing to supply the market.

5B. MODEL OF STOCK VALUE

The estimations of the value of the stock at each stage apply a unit cost to each of the units estimated in the above analysis.

For Kenya, Madagascar and Tanzania, unit costs are taken from the unit cost paid for mRDT commodities procured, as reported in annual procurement reports. For Nigeria and Uganda, unit costs are the price paid to the importer by the wholesaler assumed in MC's pricing strategy. The unit cost in the procurement report applies to the whole "bundle" including services, and is not comparable to other countries.

At procurement, cancellation and delivery, unit cost is reported per consignment. For subsequent stages, an average unit cost per country is derived from the unit cost of the consignments delivered and the number of stock per consignment.

5C. CALCULATION OF CONFIDENCE INTERVALS FOR SURVEY DATA AT GOAL AND PURPOSE LEVEL

Confidence intervals are the Wilson binomial confidence interval. This method was selected to recognise that the sample sizes are small – especially for goal-level indicators – that the population size is unknown, and that the survey questions are binomial (yes or no).

5D. MODEL OF NUMBER OF MALARIA CASES DIAGNOSED WITH MRDTS AND TREATED WITH ACTS

As outlined in the report, absolute data on the number of malaria diagnoses was not reported during the project. As a result, section 2e above uses Dalberg's estimates of mRDT sales as a proxy for achievement of the purpose-level indicator on mRDT uptake in absolute terms. As mRDT sales are

not available by year, it is not possible to apply the annual proportional data from programmatic reporting to estimate achievement in absolute terms of the goal-level indicator on patients diagnosed with malaria and treated with ACTs.

Dalberg estimates this using data derived from PSI's routine case management data. It is therefore only available for Kenya, Madagascar and Tanzania. For each country, the total number of mRDTs used is the denominator and the total number of ACTs given to patients who have tested positive using an mRDT is the numerator. From this, the proportion of mRDT uses that result in a positive malaria diagnosis and prescription of ACTs is derived.

This proportion is then multiplied by modelled sales data to produce an estimate of total number of malaria sales that result in positive malaria diagnoses and prescription of ACTs.

This analysis is very approximate. The ability to extrapolate from the subset of outlets reporting is limited. Deriving the number of treatments using ACTs based on the whole set of mRDT uses introduces the possibility of error if the rate of positive fever diagnosis is different in the sample reporting than in the whole population. There are also drawbacks in assuming that one mRDT sale is equal to one mRDT use in a fever case. This estimate is therefore considered only as an indication of the order of magnitude of absolute achievements.

ANNEX 6. **PERFORMANCE AGAINST LOGFRAME INDICATORS**

The graphs below chart targets and actual results against the indicators specified in the project logframe. The source is the end of project programmatic report table. The logframe divides these indicators into three levels: goal, purpose, and six outputs.

These indicators are shown in table 5 and performance against each is illustrated on the following pages.

Table 5. *Indicators by logframe component*

Goal (Impact): Increase the use of quality-assured RDT results to improve treatment decisions of people with fevers in private sector facilities of beneficiary malaria endemic countries.	
Indicator G1.1	Number and % of children under 5 years in project areas testing positive for malaria[205] at registered private sector outlets that receive an effective antimalarial treatment by target country
Indicator G1.2	Number and % of children (5 years and over) and adults in project areas testing positive for malaria[206] at registered private sector outlets that receive an effective antimalarial treatment by target country
Purpose (Outcome): Increased uptake of quality-assured RDTs in private sector markets	
Indicator P1.1	% of Children under 5 seeking fever treatment through private sector outlets received an RDT in the project area of each target country.
Indicator P1.2	% of Children over 5 and adults seeking fever treatment through private sector outlets received an RDT in the project area of each target country.
Output 1: Increased availability of affordable, quality-controlled RDTs in the private sector markets	
Indicator O1.1	Number & % of registered private sector outlets in project areas with quality assured RDT brands in stock by target country
Indicator O1.2	Number and % of registered private sector outlets in project areas with no reported stock out of quality assured RDTs lasting more than one week at any time during the past three months by target country
Indicator O1.3	Retail RDT price in project areas by target country
Indicator O1.4	Value (USD) and % (of retail price) of RDT subsidy by target country
Indicator O1.5	Value (USD) of RDTs procured by target country (broken down by type of product, by manufacturer)
Indicator O1.6	Number and % of RDTs procured in line with country-specific procurement plan timeline
Indicator O1.7	Number of countries with adopted recommendations, policies and/or strategic plans for RDT quality assurance spanning public and private sectors
Indicator O1.8	Number of countries using malaria RDT QA systems in the private sector
Output 2: Increased provider and consumer informed demand for RDTs in private sector markets	
Indicator O2.1	Number and % of caregivers in project areas who can cite a private provider source of RDTs by target country
Indicator O2.2	Number and % of people surveyed who seek treatment for a fever at a registered private sector outlet ask for an RDT by target country

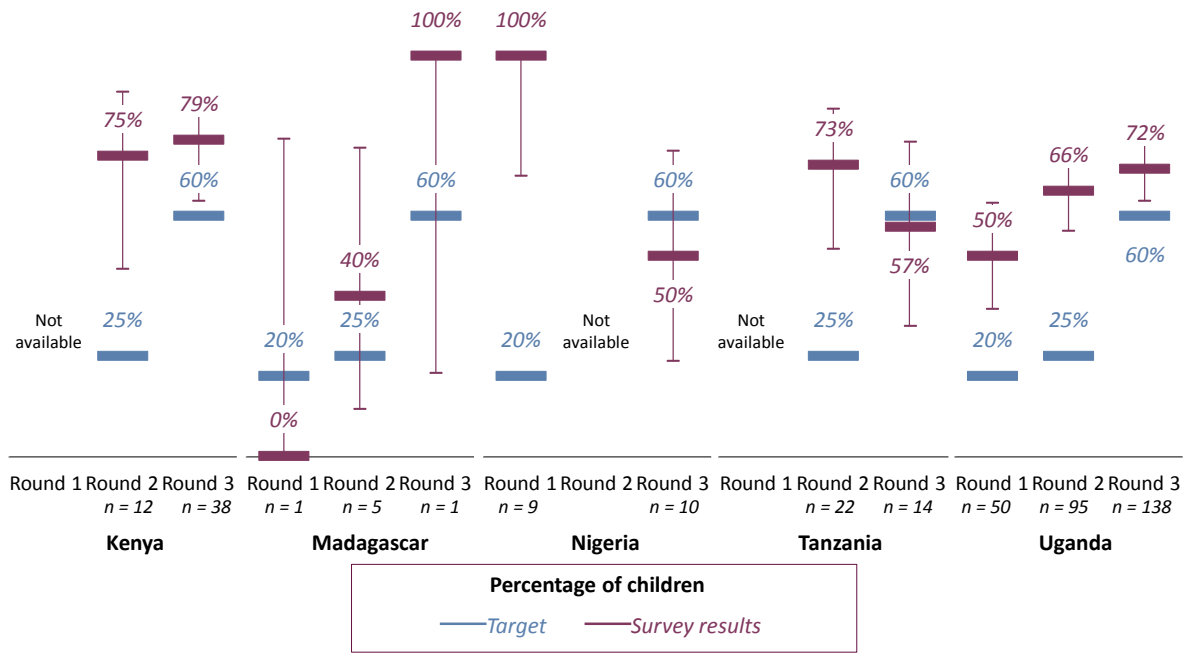
[205] Only people who were tested with an mRDT were included.
[206] Only people who were tested with an mRDT were included.

Indicator O2.3	Number and % of caregivers in project areas that can recall messages about seeking fever diagnosis in the private sector by target country
Indicator O2.4	Number and % of private providers in project areas that believe that RDTs are a trustworthy diagnostic tool by target country
Output 3: Improved quality of malaria case management among private providers	
Indicator O3.1	Number and % of clients in project areas testing negative for malaria at registered private sector outlets managed according to the government recommended treatment algorithm by target country
Indicator O3.2	Number and % of trained/certified providers supervised at least once every six months by target country
Indicator O3.3	% of clients testing positive for malaria managed in private sector facilities in project areas according to the recommended treatment algorithm relative to the frequency of facility supervisory visits by target country
Output 4: Development and dissemination of a "road map" for public-private engagement in malaria case management	
Indicator O4.1	Published review of existing national policies and/or regulations and evidence on RDT use in the public and private sector of target countries and relevant additional examples.
Indicator O4.2	Set of recommendations for public-private engagement in malaria case management submitted to the WHO Malaria Policy Advisory Committee (MPAC) for endorsement
Output 5: Coordinated project learning on the introduction of RDTs in the private sector	
Indicator O5.1	% of research activities that are completed compared to the research & monitoring plan
Indicator O5.2	# of survey reports disseminated
Output 6: Affordable, quality-assured RDTs continue to be made available in the private sector by leveraging the systems, learning and evidence-base generated through this project.	
Indicator O6.1	Number of target countries with public sector mechanisms in place to conduct QA in the private sector
Indicator O6.2	Number and % of caregivers in project areas that request an RDT for febrile cases by target country
Indicator O6.3	Consolidated project learning & key considerations for RDTs in the private sector is disseminated to key stakeholders in each target country

Goal

Figure 7. *Indicator G1.1*

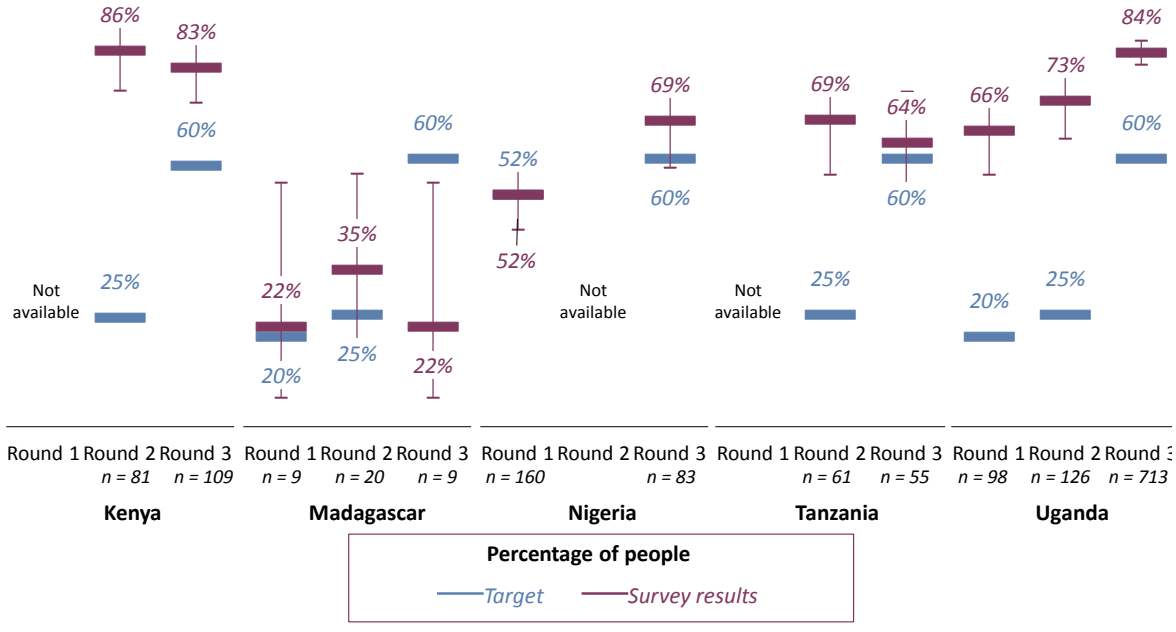
Children under five years old in project areas testing positive for malaria* at targeted private sector outlets that receive an effective antimalarial treatment



* Only people who were tested with an mRDT were included

Figure 8. *Indicator G1.2*

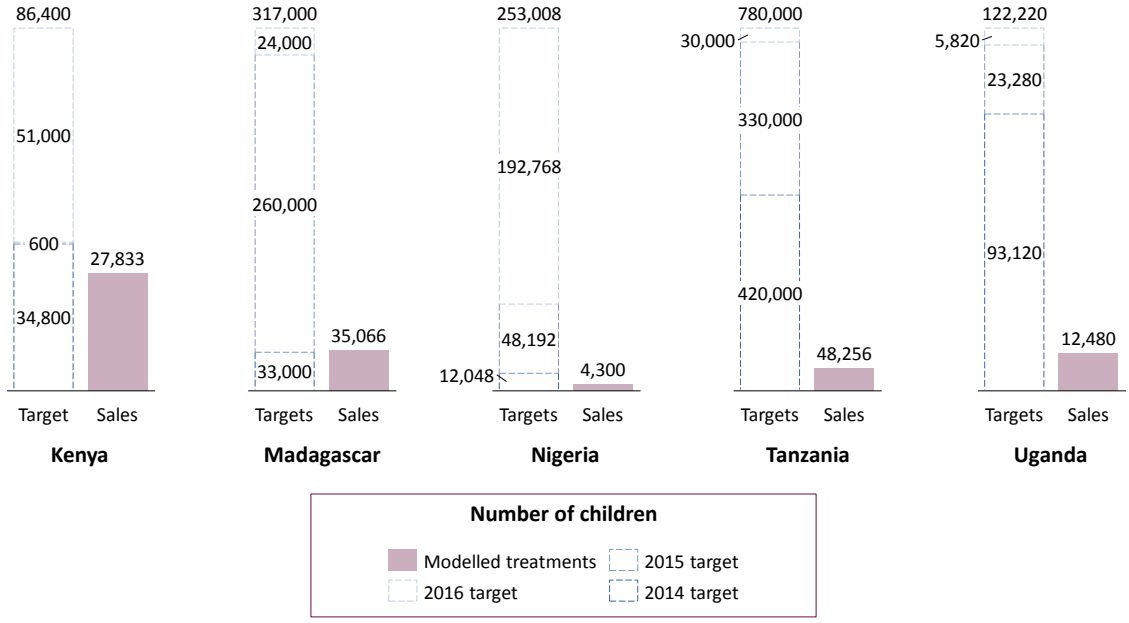
Children over five years old and adults in project areas testing positive for malaria* at targeted private sector outlets that receive an effective antimalarial treatment



* Only people who were tested with an mRDT were included

Figure 9. *Indicator G1*
Modelled by Dalberg, per methodology in Annex 5

People in project areas testing positive for malaria* at targeted private sector outlets that receive an effective antimalarial treatment



* Only people who were tested with an mRDT were included

Purpose

Figure 10. *Indicator P1.1*

Children under five years old seeking fever treatment through targeted private sector outlets that received an RDT in the project area of each target country

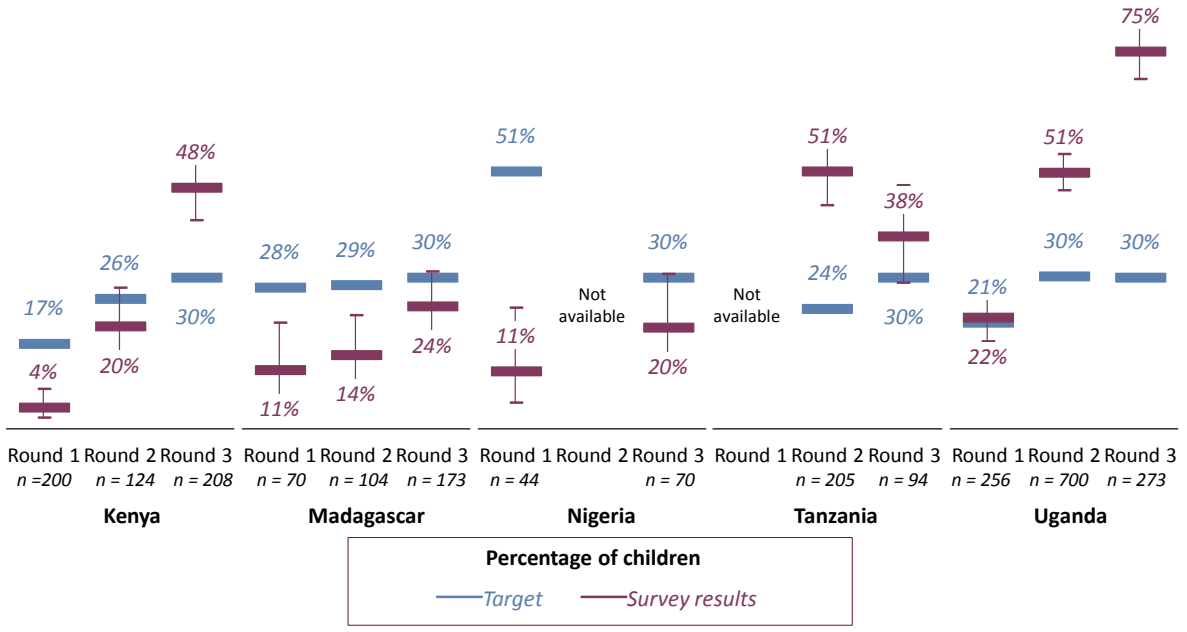


Figure 11. *Indicator P1.2*

Children over five years old and adults seeking fever treatment through targeted private sector outlets that received an RDT in the project area of each target country

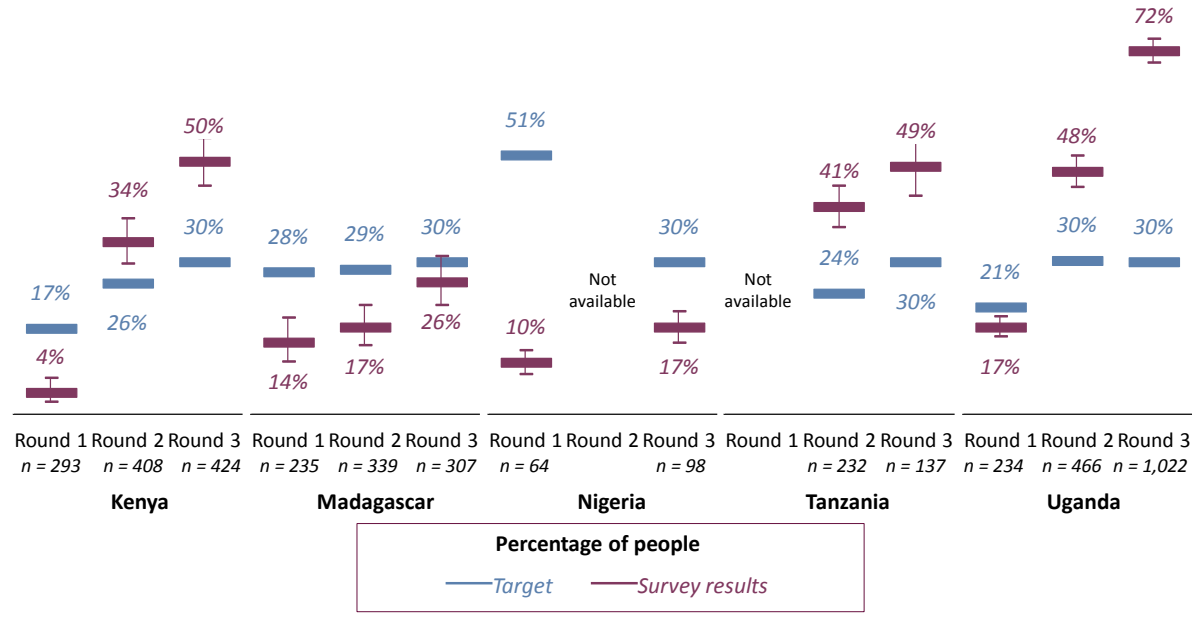
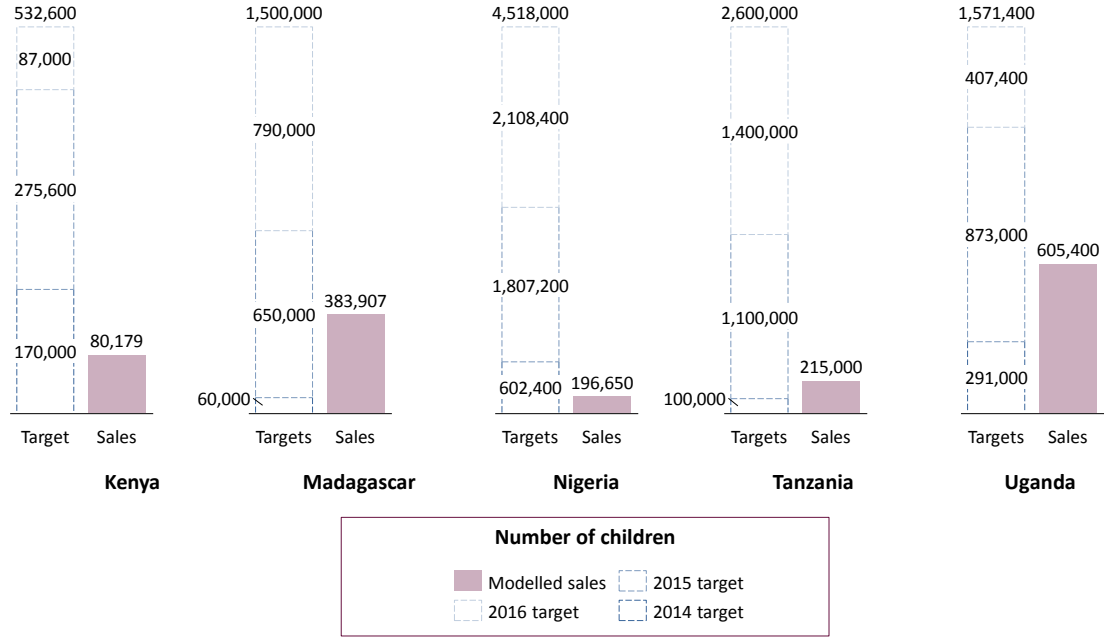


Figure 12. *Indicator P1 versus modelled mRDT sales*

Fever cases seeking treatment through targeted private sector outlets that received an RDT in the project area of each target country



Output 1

Figure 13. *Indicator O1.1*

Targeted private sector outlets in project areas with quality assured RDT brands in stock

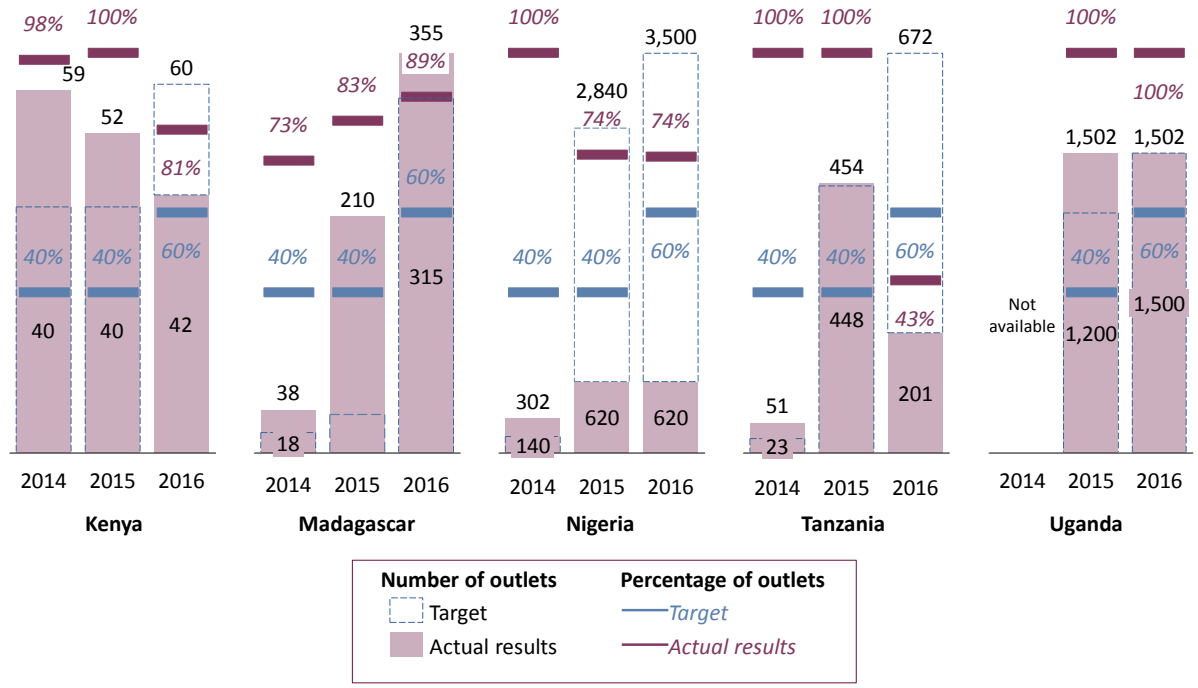


Figure 14. *Indicator O1.2*

Private sector outlets in project areas with no reported stockout of quality assured RDTs lasting more than one week at any time during the past three months

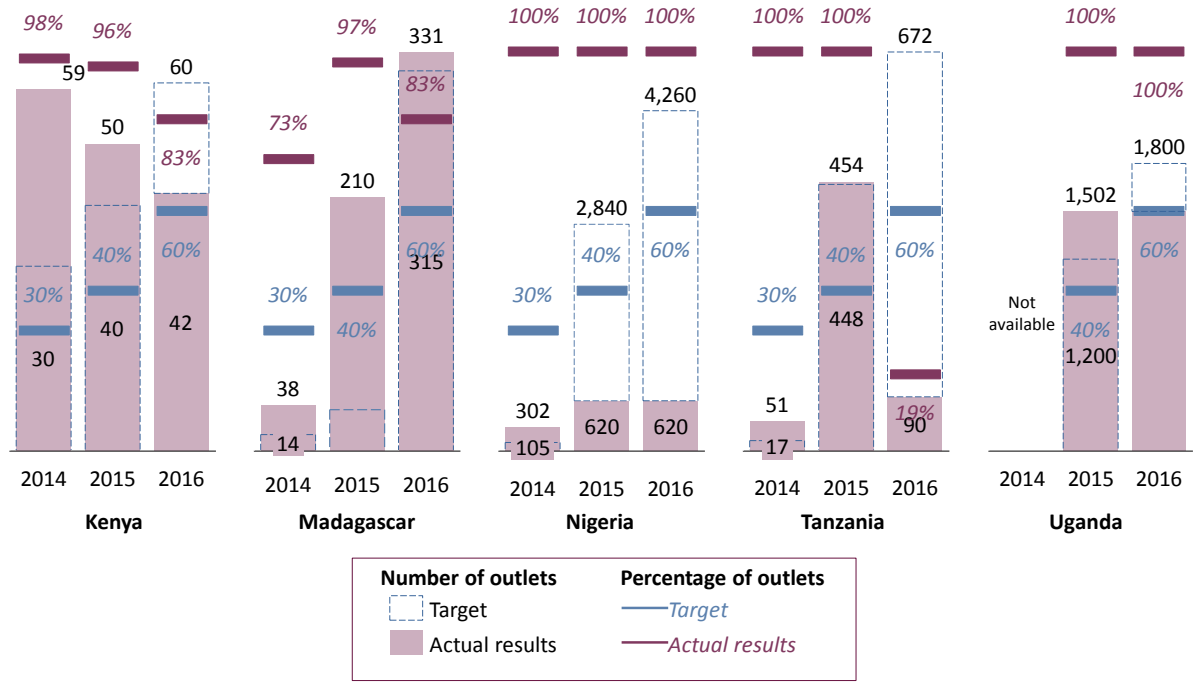
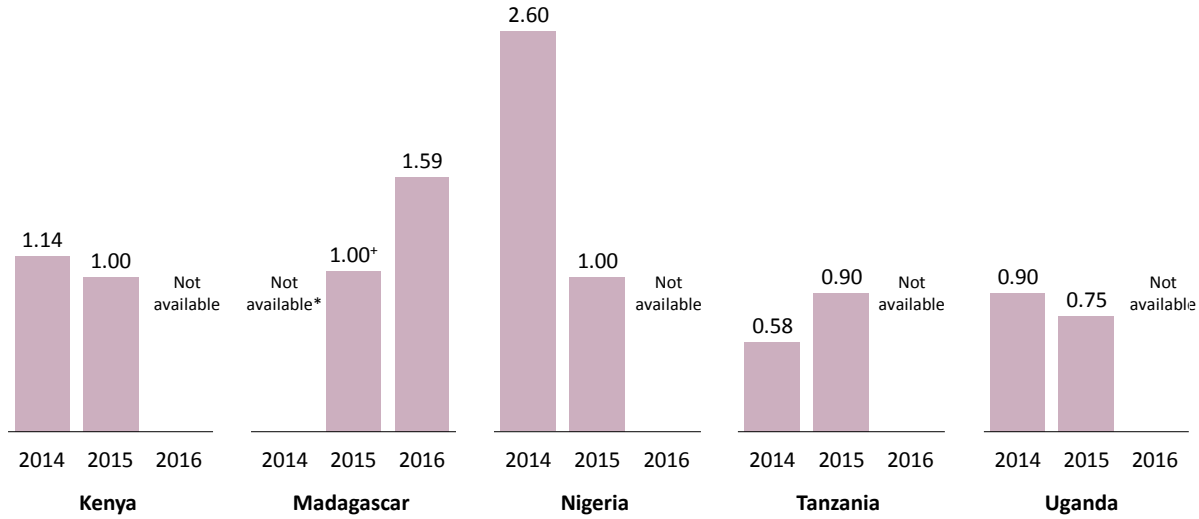


Figure 15. *Indicator O1.3*

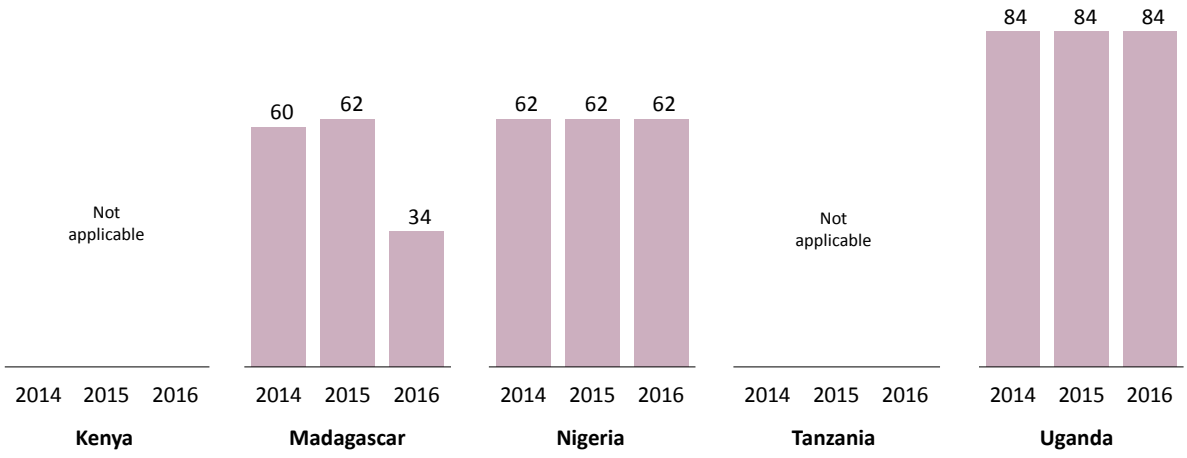
Median (IQR) retail RDT price in project areas
USD



* Reported as USD 0.00 – 1.00 in project logframe reporting
\+ Reported in surveys as USD 0.00 at PSI franchises and USD 0.42 in other outlets, but not reported in project logframe

Figure 16. *Indicator O1.4*

RDT subsidy
Percentage of recommended retail price



Indicator O1.5

No data reported

Figure 17. *Indicator O1.6*

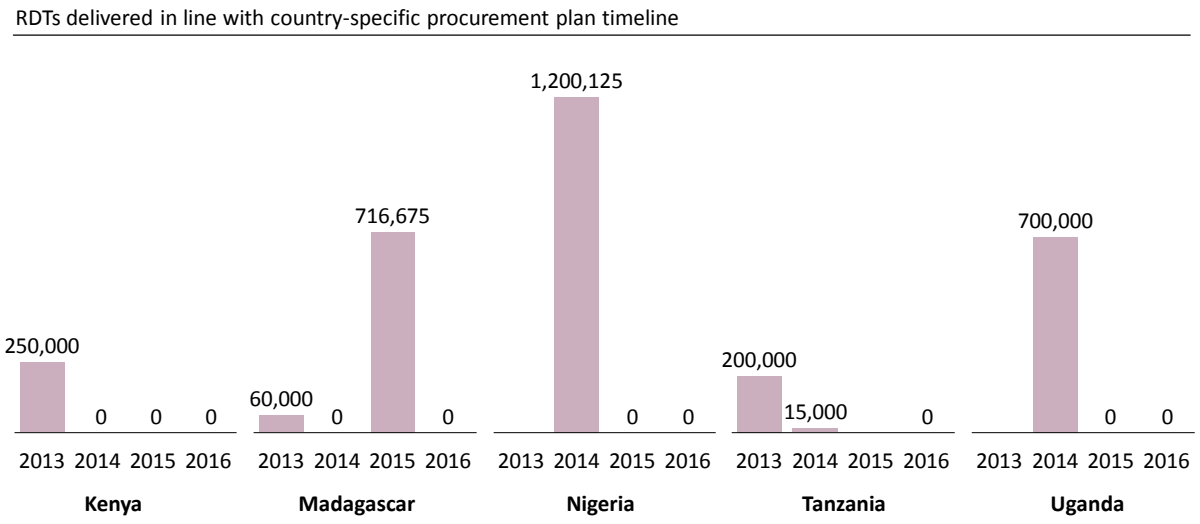


Figure 18. *Indicator O1.7*

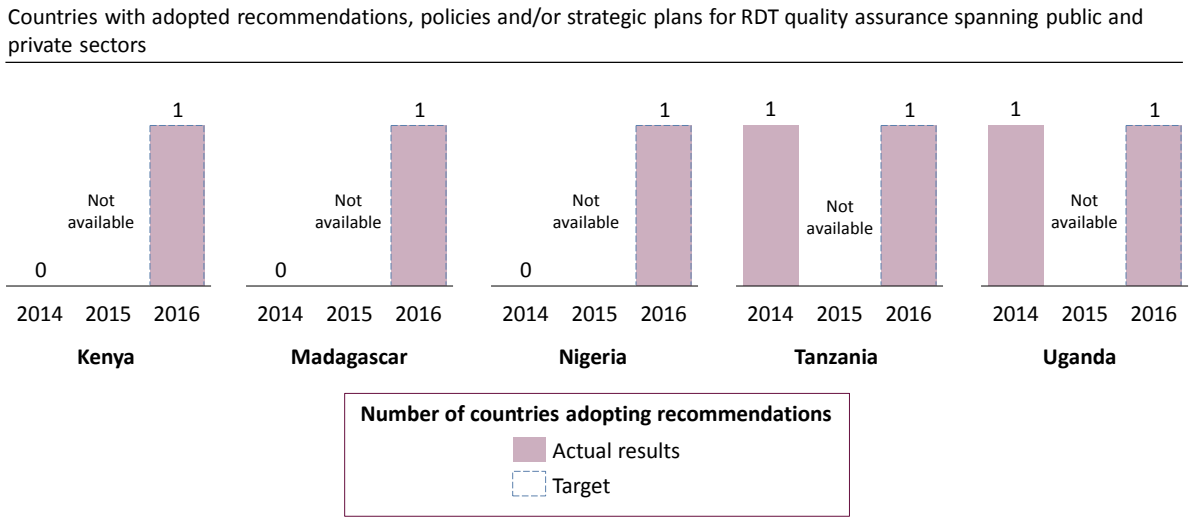


Figure 19. *Indicator O1.8*

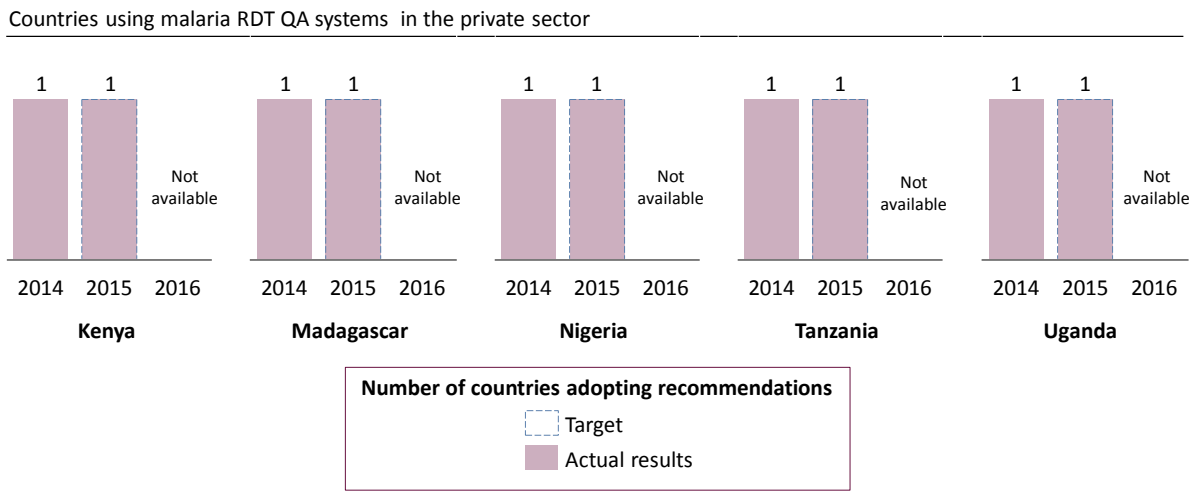
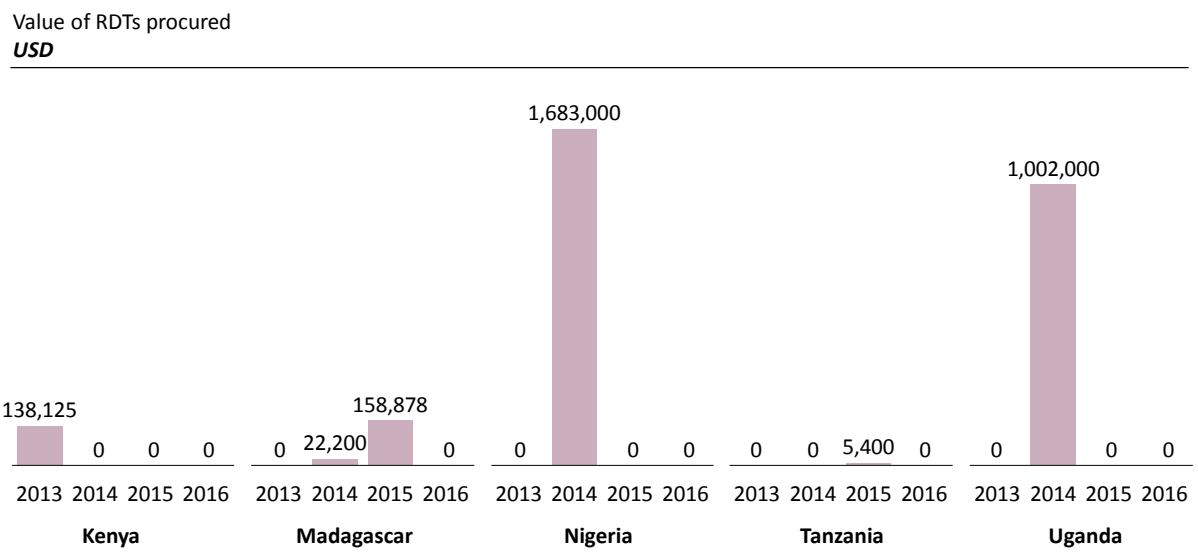
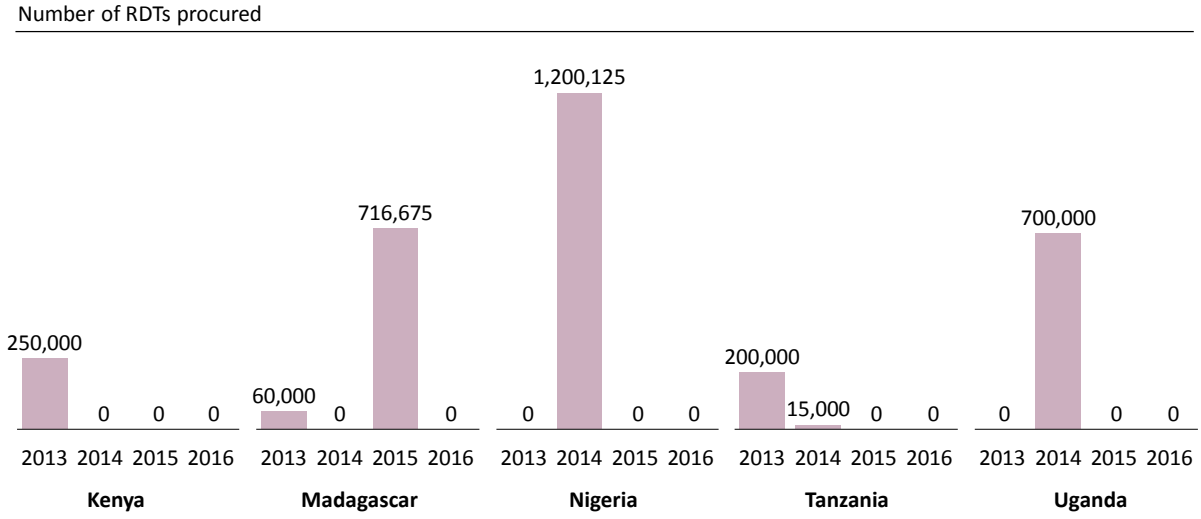


Figure 20. *Indicator O1.9*



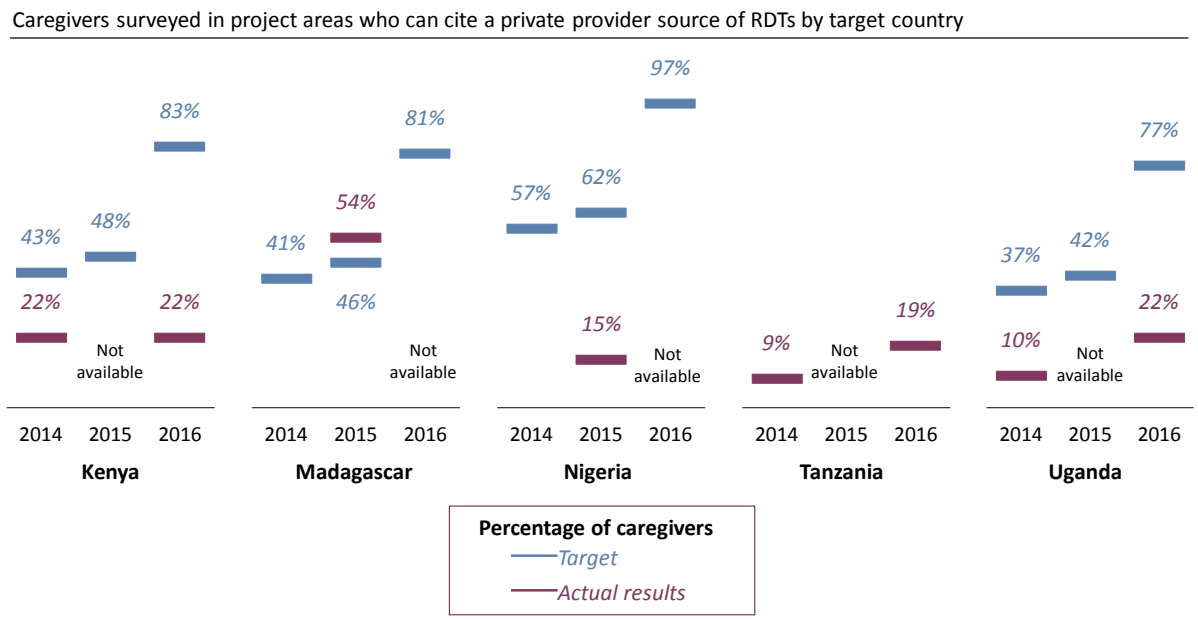
NB: Tanzania data as reported in project logframe.

Figure 21. *Indicator O1.10*



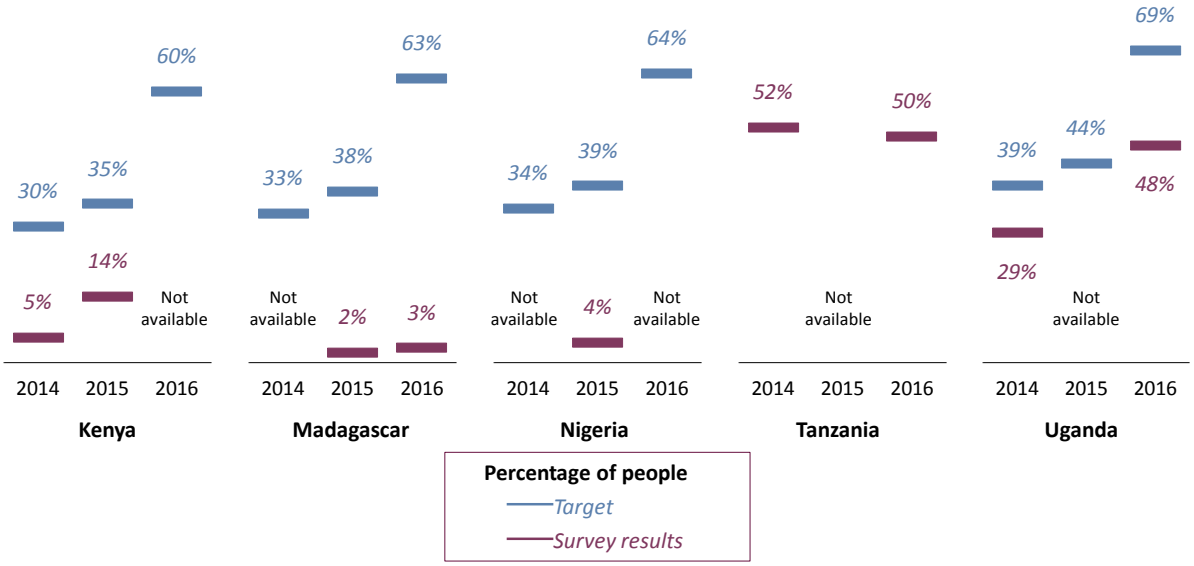
Output 2

Figure 22. *Indicator O2.1*



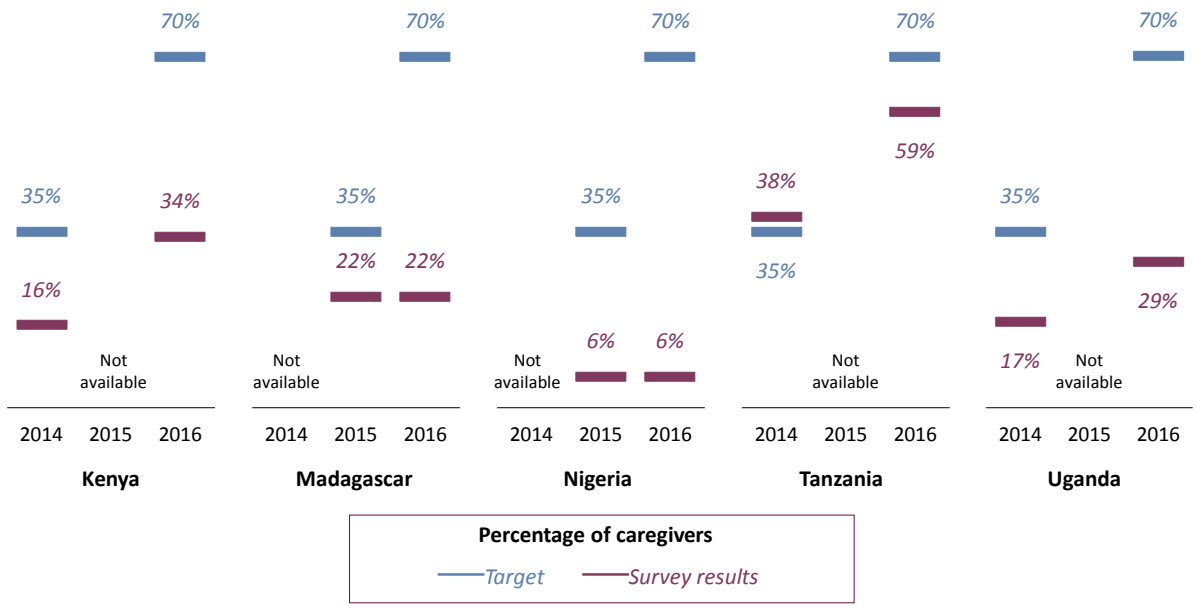
NB: Targets were set relative to baselines (30% above baseline for 2014, 35% above baseline for 2015, 70% above baseline for 2016). No baseline took place in Tanzania.

Figure 23. *Indicator O2.2*



NB: Targets were set relative to baselines (30% above baseline for 2014, 35% above baseline for Tanzania for 2016 and 60% for all other countries for 2016). No baseline took place in Tanzania.

Figure 24. *Indicator O2.3*



Indicator O2.4

No data reported

Output 3

Figure 25. *Indicator 3.1*

Clients testing negative for malaria at targeted private sector outlets managed according to the government recommended treatment algorithm by target country

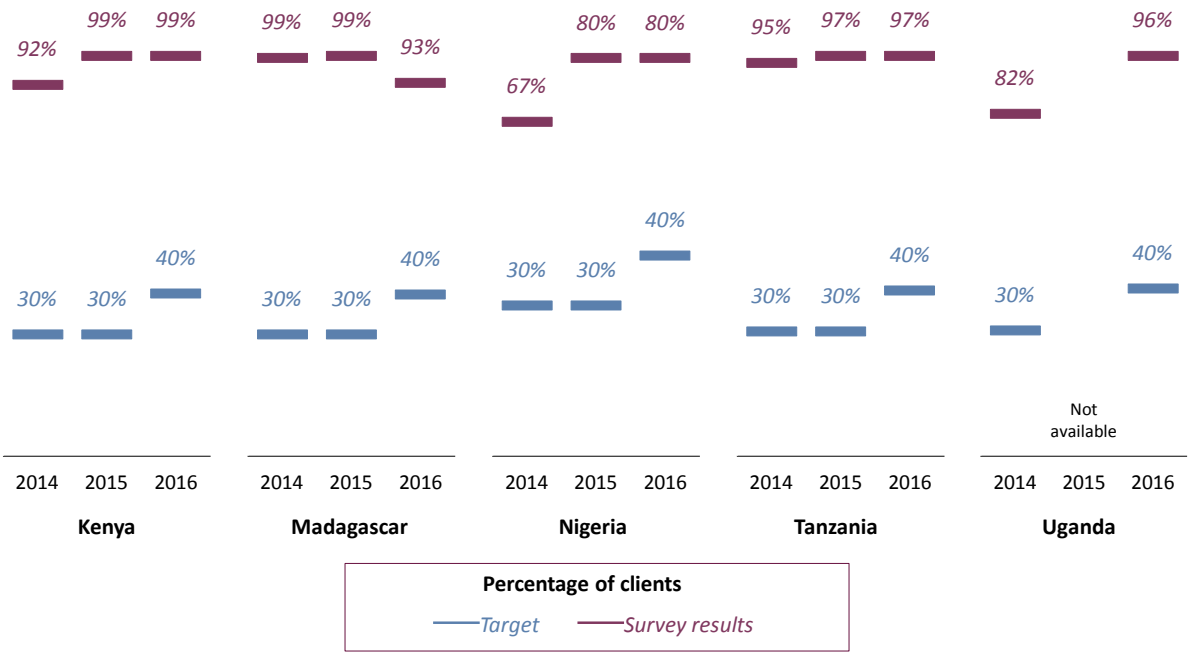


Figure 26. *Indicator 3.2*

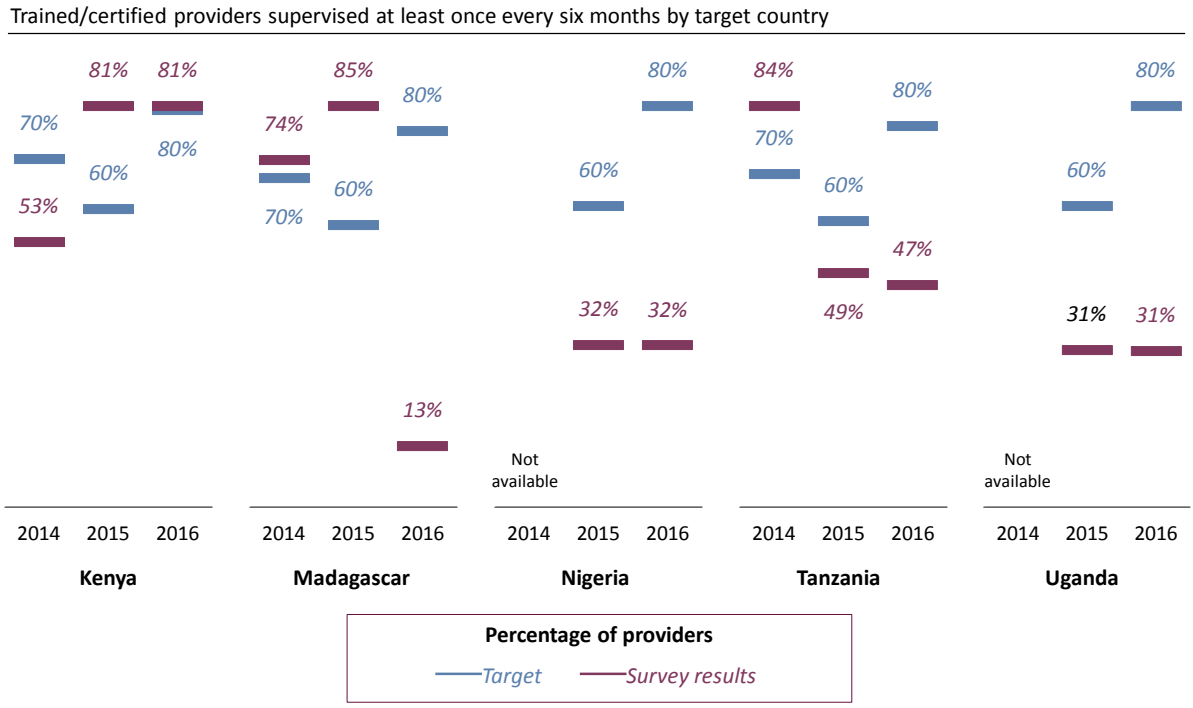
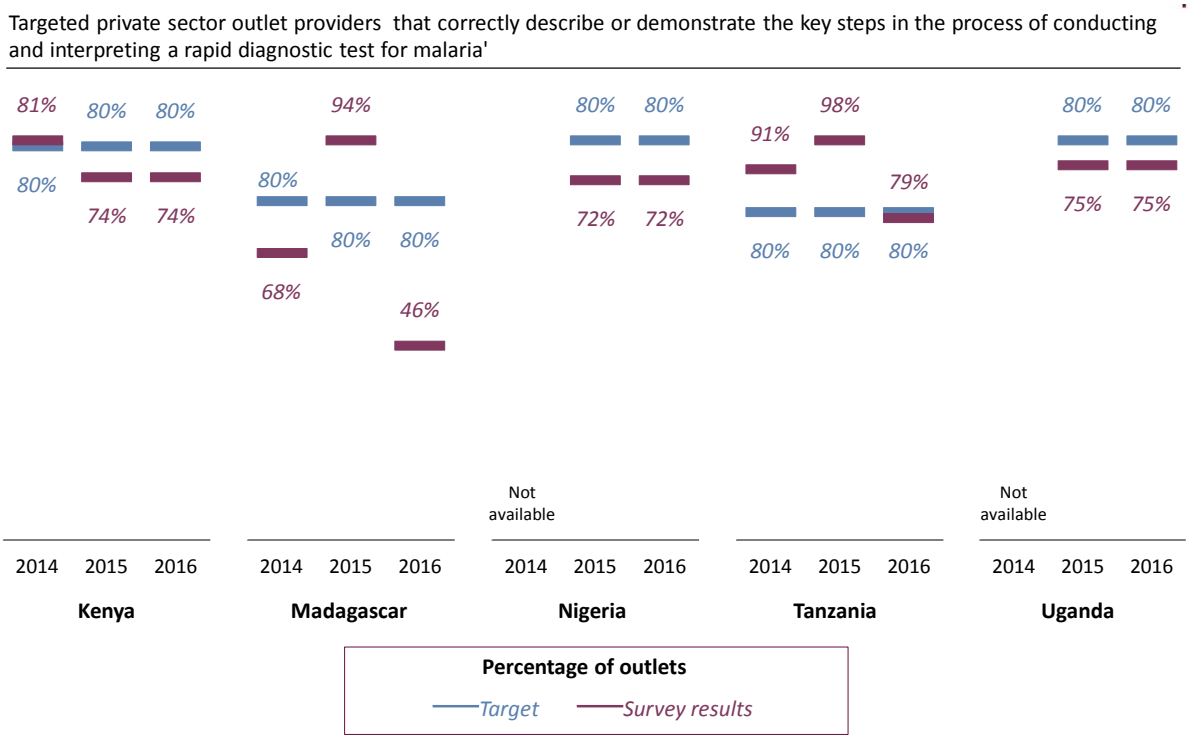
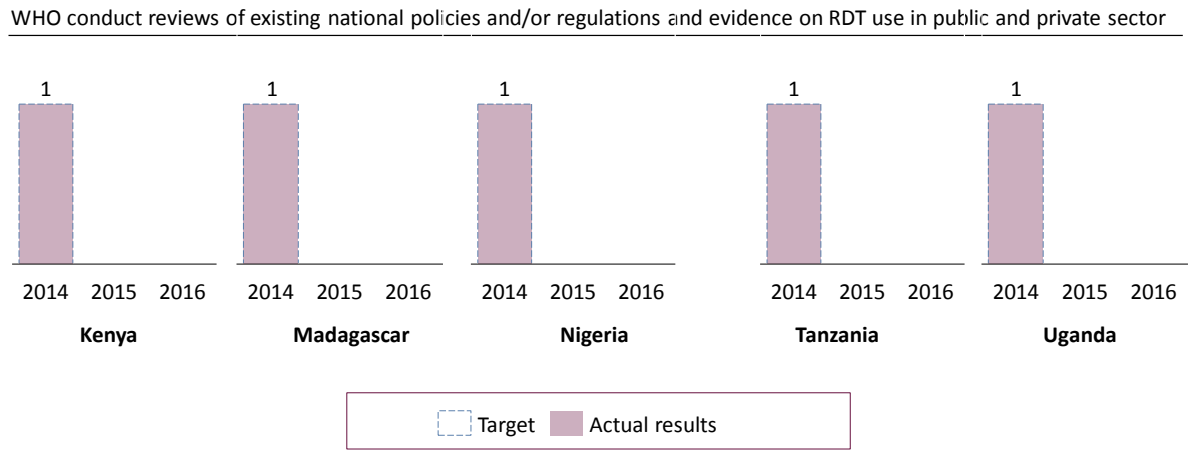


Figure 27. *Indicator 3.3*



Output 4

Figure 28. *Indicator O4.1*



Indicator O4.2

No data reported (recommendations not yet made).

Output 5

Figure 29. *Indicator O5.1*

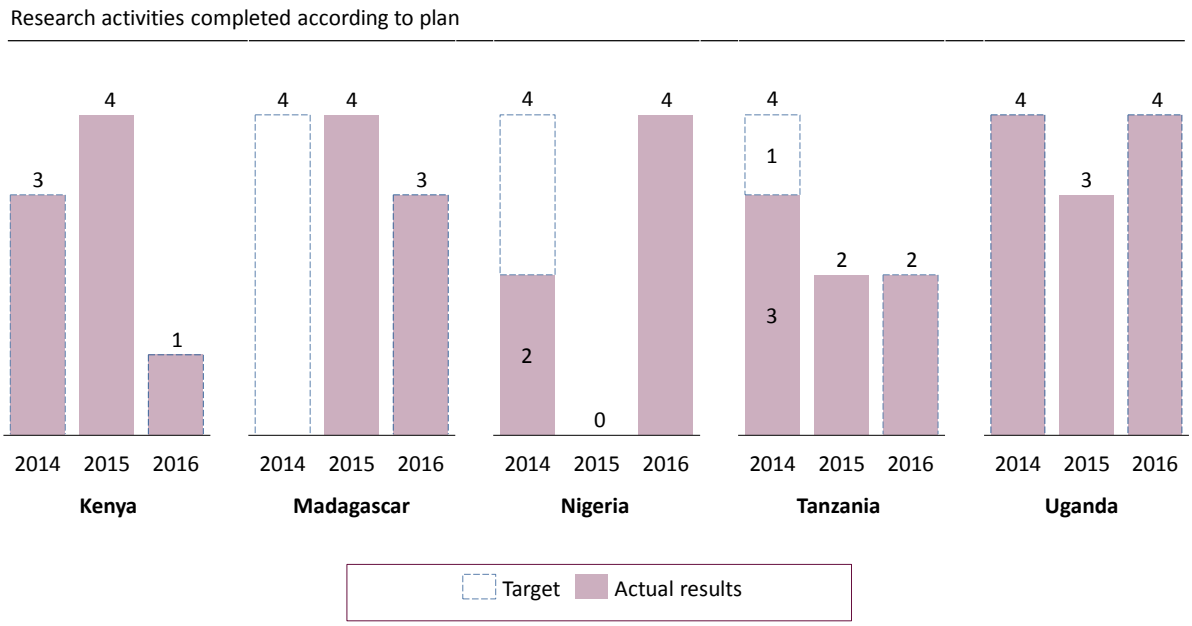
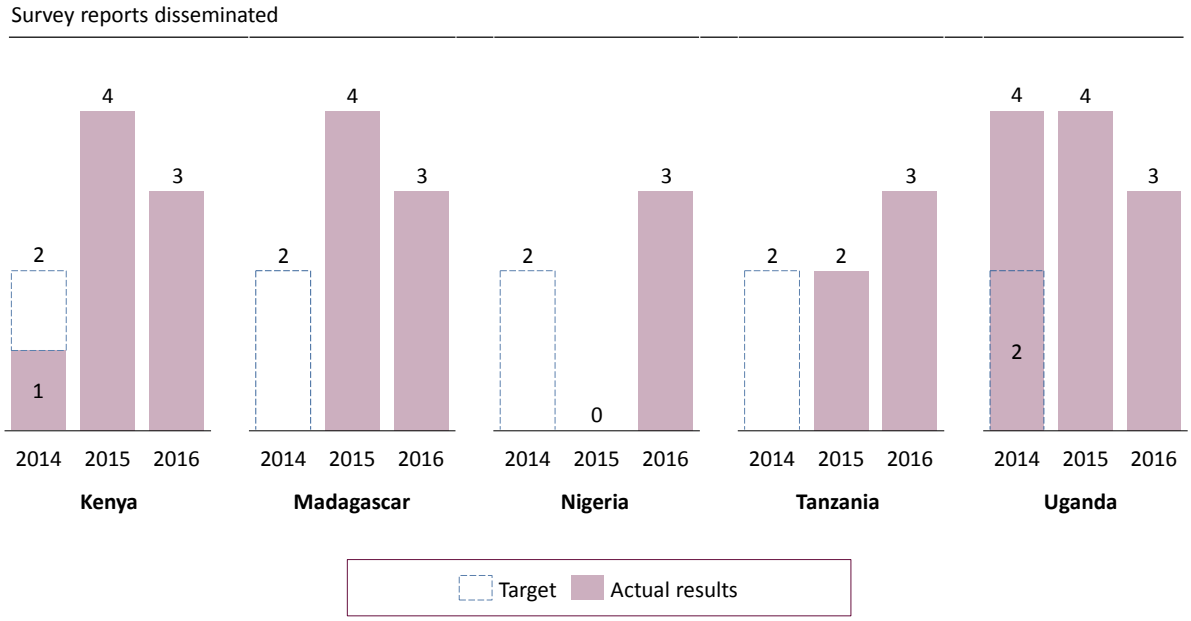


Figure 30. *Indicator O5.2*



Output 6

Figure 31. *Indicator O6.1*

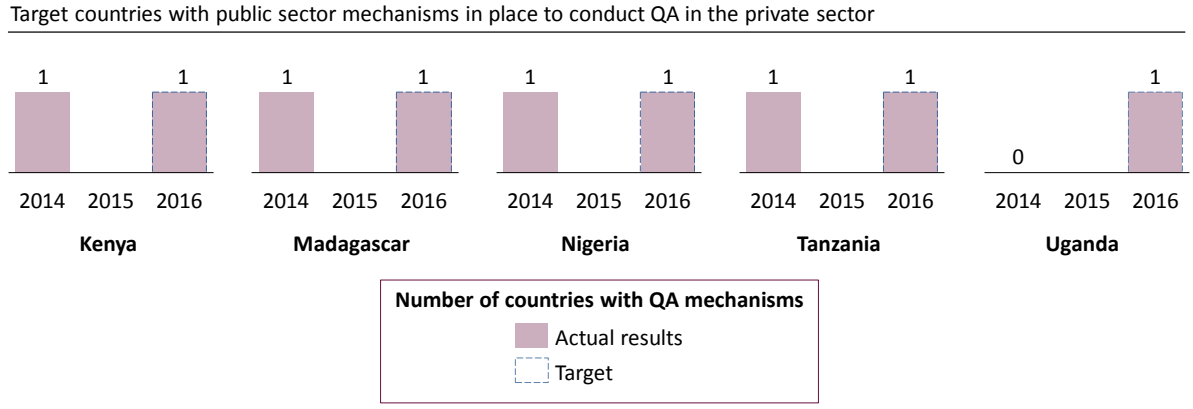
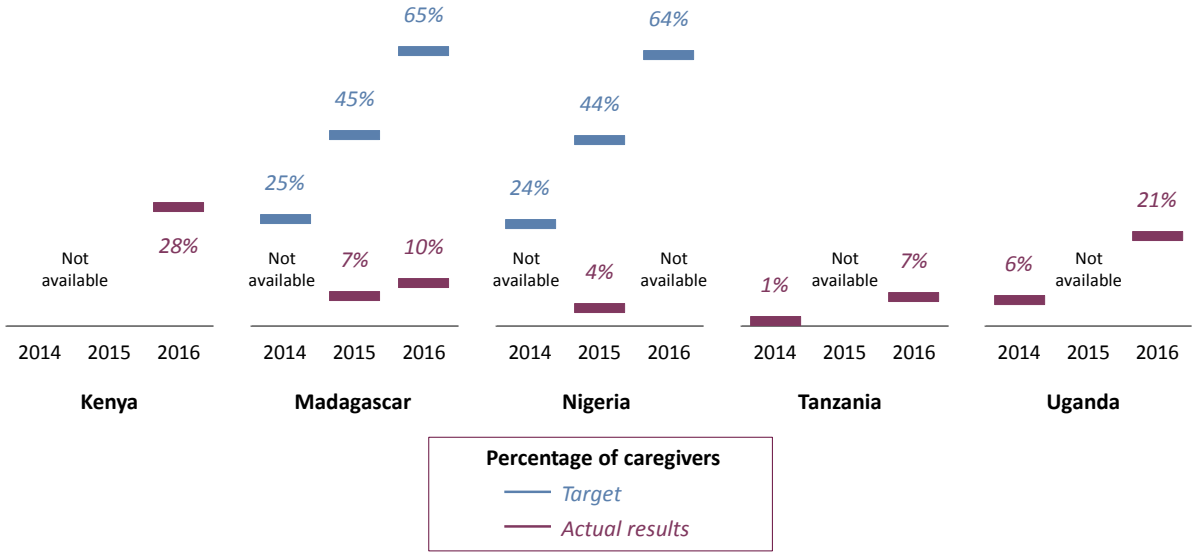


Figure 32. *Indicator O6.2*

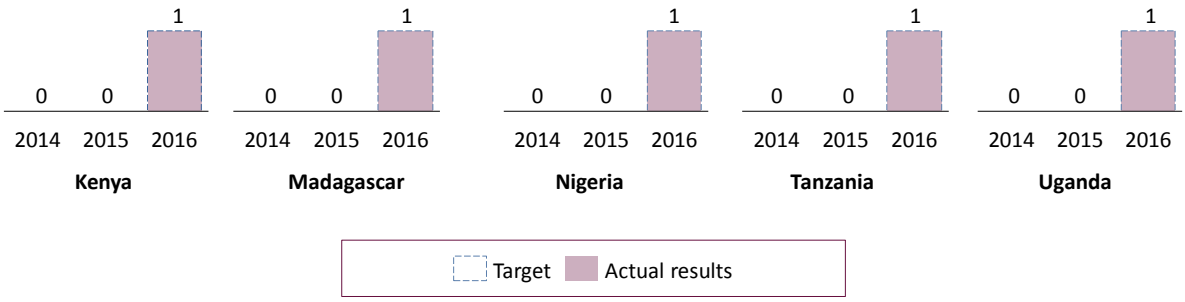
Caregivers in project areas that request an RDT for febrile cases by target country



NB: Targets were set relative to baselines (20% above baseline for 2014, 40% above baseline for 2015, 60% above baseline for 2016). No baseline took place in Kenya, Tanzania or Uganda.

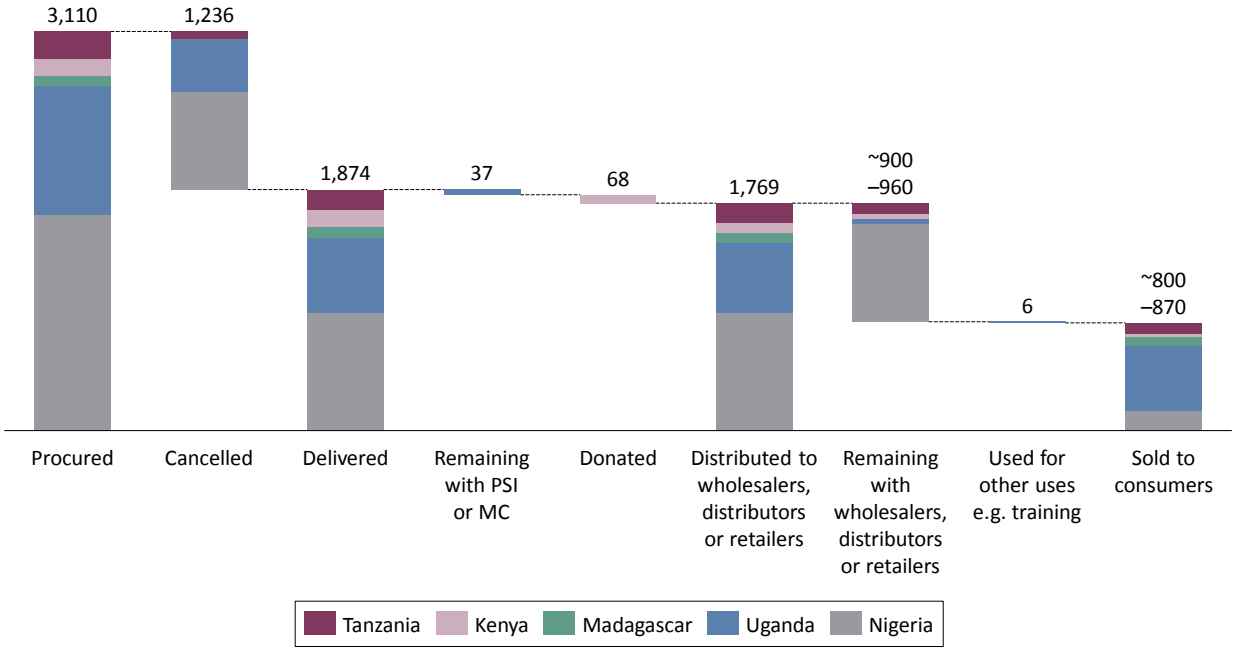
Figure 33. *Indicator O6.3*

Countries in which project learning and key considerations for RDTs in the private sector have been disseminated to key national stakeholders



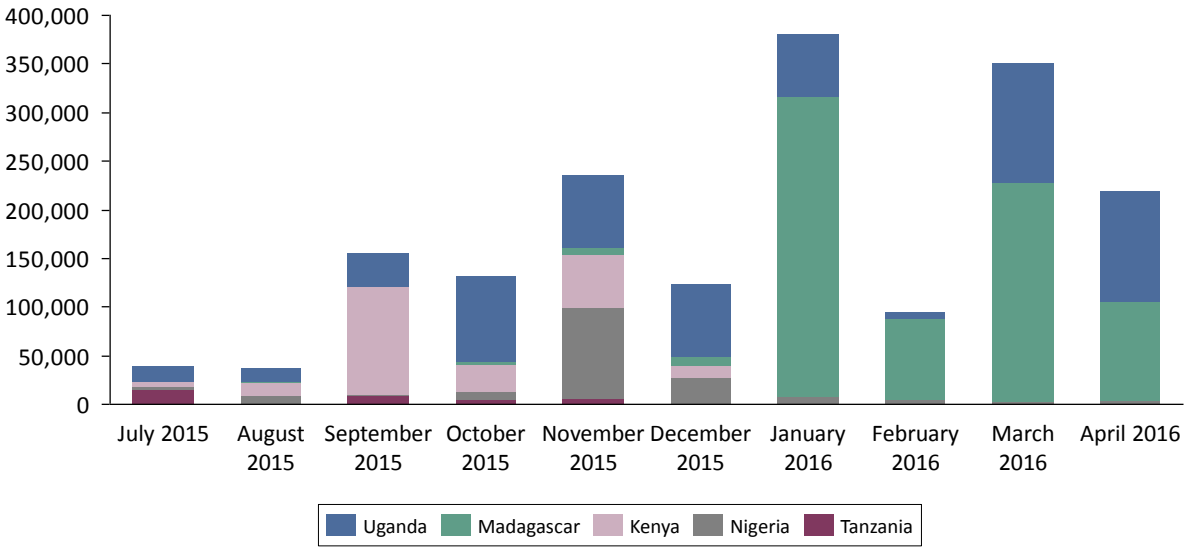
ANNEX 7. **ESTIMATIONS OF STOCK FLOWS**

Figure 34. *Estimated stock flows by value,* ***USD***



Source: Dalberg analysis (per methodology specified in Annex 5)

Figure 35. *Sales of centrally-procured mRDTs, 2015-16,* ***Units sold per month***



Source: PSI stock management tracker