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Title: 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.

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ABSTRACT

Objectives

To describe the state of the public and private malaria diagnostics market shortly after the World Health Organization (WHO) updated its guidelines for testing all suspected malaria cases prior to treatment.

Methods

Ten nationally-representative cross-sectional cluster surveys were conducted in 2011 among public and private health facilities, community health workers, and retail outlets (pharmacies and drug shops) in nine countries (Tanzania-mainland and Zanzibar surveyed separately). Eligible outlets had antimalarials in stock on the day of interview or had stocked antimalarials in the past three months.

Results

3,439 RDT products from 39 manufacturers were audited among 12,197 outlets interviewed. Availability was typically highest in public health facilities, though availability in these facilities varied greatly across countries, from 15% in Nigeria to over 90% in Madagascar and Cambodia. Private for-profit sector availability was 46% in Cambodia, 20% in Zambia, but low in other countries. Median retail prices for RDTs in the private for-profit sector ranged from $0.00 in Madagascar to $3.13 in Zambia. The reported number of RDTs used in the 7 days prior to the survey in public health facilities ranged from 3 (Benin) to 50 (Zambia).

Conclusions

Eighteen months after WHO updated its case management guidelines, RDT availability remained low in the private sector in sub-Saharan Africa. Given the ongoing importance of the private sector as a source of fever treatment, the goal of universal diagnosis will not be achievable under current circumstances. These results constitute national baselines against which progress in scaling-up diagnostic tests can be assessed.

INTRODUCTION

Current World Health Organization (WHO) guidelines recommend prompt parasitological diagnosis with microscopy or rapid diagnostic test (RDT) of all suspected malaria cases prior to treatment (WHO 2010). By 2012, 41 malaria endemic countries in the WHO African Region had adopted the recommendation in their national policies. Public sector scale-up has also seen improvement. Sixty percent of suspected cases in the public sector in Africa were reportedly tested in 2012, up from 20% in 2005 (WHO 2013). While diagnosis has historically been performed by trained laboratory staff using microscopy, the advent of RDTs allows for diagnosis at all levels of the health system, including in the community (WHO 2011a). In 2012, RDTs accounted for 40% of all cases tested in the public sector in Africa (WHO 2013).

To reach the target of universal diagnosis, there is growing attention in finding scalable and sustainable models of RDT access and demand in the private sector (UNITAID 2012; MalariaCare 2013). The WHO estimates that, worldwide, 40% of children with fever seek treatment from some form of private provider, including formal health facilities, pharmacies, drug shops and informal medicine vendors (WHO 2011a).

Few studies have sought to describe the overall retail malaria diagnostics market. Although information on availability in the public sector is captured through routine health information systems, these data are not complete (WHO 2012a). There is less robust evidence on the availability and price of RDTs in the private sector, which is generally limited to small-scale operations research studies on the feasibility of private sector RDT implementation (Mbonye *et al.* 2010; Cohen *et al.* 2012a; Hansen *et al.* 2012). Similarly lacking is information on the quality of RDTs available in the market. Assured product quality is important given the variation in RDT brand performance identified by the work of WHO and the Foundation for Innovative New Diagnostics (FIND) (WHO 2011b). In 2012, Albertini and colleagues presented data on availability, price and quality of RDTs in the private sector in six endemic countries; but the study employed a convenience sample of mostly urban areas and cannot therefore be considered representative (Albertini *et al.* 2012a). One partial exception is in Cambodia, where subsidized RDTs and artemisinin-based combination therapies (ACTs) have been distributed in the private for-profit sector at national scale since 2002. A review of the first 10 years of the program concluded that awareness of the ACT product increased rapidly, but improvements in availability and use of both RDTs and ACTs were slower (Yeung *et al.* 2011).

This paper presents national-level estimates of RDT availability, price and sales volumes from Benin, Cambodia, Ghana, Kenya, Madagascar, Nigeria, Tanzania (mainland and Zanzibar), Uganda and Zambia.

METHODS

Data collection

This analysis uses data collected from ten surveys in nine countries between October 2011 and January 2012. Six of the countries were part of the Population Services International (PSI) ACTwatch project (Benin, Cambodia, Madagascar, Nigeria, Uganda and Zambia); and for three additional countries data were collected as part of the Independent Evaluation of the Affordable Medicines Facility – malaria (AMFm), which drew on ACTwatch methods (Ghana, Kenya and Tanzania; data from Tanzania-mainland and Zanzibar are presented separately). Survey methods have been described in detail previously (O'Connell *et al.* 2011; Shewchuk *et al.* 2011; Tougher *et al. 2012;* AMFm Independent Evaluation Team 2012). Briefly, nationally representative cluster surveys of outlets with the potential to stock antimalarials were conducted in each country. Clusters were administrative areas with a typical population in the range of 10,000 to 15,000, and were sampled with probability proportional to size. In Ghana, Kenya, Madagascar, Nigeria, Tanzania-mainland, Uganda and Zambia, clusters were stratified into urban and rural domains. Clusters in Cambodia were stratified according to artemisinin resistance containment zones. No stratification was applied in Benin, and a full census of outlets was conducted in Zanzibar given its small population size. Within each cluster a full census of health facilities, community health workers (CHWs) and retail outlets with the potential to stock antimalarials was conducted. Given their relatively low numbers, public health facilities and pharmacies were oversampled, most commonly by drawing additional outlets from a larger geographical area.

Eligibility criteria for the studies were any outlet with antimalarials in stock on the day of the survey or reporting having stocked antimalarials during the previous three months. Providers in eligible outlets who had given informed consent to participate were administered a questionnaire that included an audit of RDTs in stock. Audit sheets were used to collect information on RDT brand names and manufacturers, the reported retail price to consumers and number of tests sold or used in the past seven days.

Data analysis

Data were analyzed using Stata v11.2 (StataCorp College Station, TX). Point estimates were weighted using survey weights, and 95% confidence intervals for availability were calculated accounting for clustering and stratification. Indicators are presented for the following outlet types: public health facilities, CHWs, private not-for-profit health facilities, private for-profit health facilities, pharmacies and drug shops. General retailers such as shops and market stalls were sampled for the original surveys but excluded from this analysis due to their negligible availability of diagnostics. Pharmacies and drug shops are presented separately to reflect the different licensing and regulations they officially follow. In theory, pharmacies licensed by the national drug or pharmacy authority must count a qualified pharmacist among the staff, and are generally permitted to sell all classes of medicines. While they are often licensed, drug shops are typically staffed by lower cadres of health or retail workers, and sales are restricted to over-the-counter medicine. Together, public health facilities, CHWs and private not-for-profit health facilities constitute the public/not-for-profit sector; while for-profit health facilities, pharmacies and drug shops together make up the private-for-profit sector.

In total 16,697 outlets from the specified categories were approached to participate in the ten surveys (Table 1). Of these, 12,197 outlets were eligible for inclusion and consented to be interviewed: 4,071 in the public/not-for-profit sector and 8,126 in the private for-profit sector. In total, 3,439 RDTs were audited in these eligible outlets (2,516 in the public/not-for-profit sector, and 923 in the private for-profit sector).

Availability

Availability of any diagnostic test was calculated as the proportion of outlets offering microscopy or offering/selling RDTs among all eligible outlets. Availability of microscopy was defined by provider self-report and was not assessed by the interviewer. Availability of any RDT was calculated as the proportion of outlets with at least one RDT audited. There is interest in assessing availability of RDTs meeting specified quality standards. However, quality results are specific to the parasite species, antigen(s), and type of test (cassette, card, dipstick, etc) (WHO 2011b). As these details were not collected during the outlet survey, a proxy measure was used of whether the manufacturer had submitted any RDT to Rounds 1-3 (2008-2011) of WHO/FIND RDT product testing (WHO 2011b), as an indicator that the manufacturer had a demonstrable interest in product quality. Manufacturer names recorded on the RDT audit sheets were compared against those who submitted at least one RDT product for testing. Outlets with incomplete manufacturer information for any RDTs audited were excluded from this analysis.

Price

6

Median retail selling price per test was calculated from provider reports of the price for one test. Retail prices did not include consultation or registration fees which may be charged by certain types of outlet. Prices were converted to US dollars using the average interbank exchange rate for 2011 (*www.oanda.com/historic*), but not adjusted for differences in purchasing power between countries.

Ethics approval was obtained from the national ethics committee in each country. For the AMFm pilot countries, additional approval was obtained from the Institutional Review Boards of ICF International and the London School of Hygiene and Tropical Medicine.

RESULTS

Availability of any RDT

Availability of any RDT varied substantially both among countries and among outlet categories within each country (Figure 1, Supplementary Table 1). Availability of any RDT in public health facilities varied from less than one-in-five in Nigeria (15%) and Kenya (19%) to over 90% in Cambodia (94%) and Madagascar (92%). RDTs were stocked by CHWs in three countries: Cambodia (97%), Madagascar (54%) and Uganda (70%). Relatively few private not-for-profit health facilities were interviewed in the surveys, making it hard to draw inferences on RDT availability; of 64 facilities interviewed in Benin, 22% stocked RDTs. Availability in the public/not-for-profit sector was higher than in the private for-profit sector in all countries except Benin, where 11% of outlets in both sectors stocked RDTs, with relatively low RDT availability in the public/not-for-profit sector reflecting the absence of RDTs among CHWs.

Availability in the private for-profit sector ranged from 1% in Ghana and Tanzania-mainland to 46% in Cambodia. Of all private for-profit outlet types, availability was typically highest for health facilities and lowest among drug shops. Only three counties had any private for-profit outlet types with RDT availability of at least 20% (all categories in Cambodia, and health facilities and pharmacies in Uganda and Zambia). Conversely, availability of any RDT was less than 10% in all for-profit outlet types in Kenya, Madagascar, Nigeria and Tanzania-mainland, and at most 12% in Benin and Ghana.

Availability of any diagnostic test

Among public health facilities, availability of any test (microscopy or RDT) ranged from 26% in Nigeria to 97% in Zanzibar (Supplementary Figure 1). In addition to Nigeria, less than half of facilities had any test available in Benin (40%), Ghana (41%) and Tanzania-mainland (48%). Availability in the private

7

for-profit sector ranged from less than 10% in Ghana (4%), Madagascar (4%), Nigeria (4%) and Tanzania-mainland (6%), to 61% in Cambodia. Approximately one-in-three private for-profit outlets stocked any test in Benin (28%), Zambia (32%) and Zanzibar (31%).

Availability of RDTs by manufacturer

RDTs from 39 manufacturers were recorded in the 10 surveys, with the number of manufacturers found in each survey ranging from 2 in Tanzania-mainland to 23 in Uganda (Table 2). Across study countries *SD Bioline* products from *Standard Diagnostics* and *Paracheck* products from *Orchid Biomedical Systems* were most commonly present, each being audited in 8 countries. *CareStart* products from *Access Bio, Inc* were audited in 7 countries. Diversity in brand availability between public/not-for-profit and private-for-profit sectors was greatest in Uganda, where nine unique manufacturers were identified in the public/not-for-profit sector and 13 additional manufacturers were recorded among for-profit outlets.

Twenty manufacturers had submitted at least one product to WHO/FIND testing during Rounds 1-3. All RDTs indentified in Cambodia, Ghana, Tanzania-mainland, Zambia and Zanzibar were from manufacturers participating in WHO/FIND product testing. In countries where RDTs from non-submitting manufacturers were present, availability of non-submitted product across outlet types ranged from less than 1% to 19% (Supplementary Tables 2 and 3). Availability of RDTs from non-submitting manufacturers was highest in Nigeria and Uganda. Seven percent of public health facilities in Nigeria stocked at least one RDT from a non-submitting manufacturer.

Price

Median price of RDT varied by country and type of outlet (Table 3). Rapid diagnostic tests were free (median price was $0.00) in public health facilities in all countries except Nigeria, where the median price was $1.24 (IQR: $0.00-$1.24). In Cambodia, Madagascar and Uganda – the 3 countries in which CHWs had RDTs available – the median price among CHWs was $0.00. In most countries RDTs had a zero median price where they were stocked by private not-for-profit health facilities, the exceptions being Kenya ($0.58) and Nigeria ($1.85).

Median RDT prices in private for-profit health facilities ranged from $0.00 among three RDTs audited in Ghana and 13 audited in Madagascar, to $4.18 in Zambia. The median price in Cambodia was $0.51 (IQR: $0.51-$0.76), less than half the median price in Uganda ($1.20, IQR: $0.80-$1.60). No pharmacies

provided RDTs for free, with median prices ranging from $0.51 in Cambodia to $3.67 in Madagascar, although the number of pharmacies stocking RDTs in Madagascar was small. In Zambia, where 39 RDTs were audited in pharmacies, the median price was $3.13 (IQR: $2.09-$5.43). With the exception of Uganda, Zambia and Cambodia, median RDT prices were higher in pharmacies than in for-profit health facilities. Median prices in drug shops (where available) were often lower than those in health facilities and pharmacies.

Number of RDTs sold or used (*sales*)

Within each country, the median reported number of units sold in the past seven days was typically highest for products audited in public health facilities, where it ranged from three in Benin and Cambodia to 50 in Zambia (Table 4). The exceptions were Ghana (35 units sold on average when stocked in private for-profit health facilities compared to 10 in public health facilities) and Tanzania-mainland (25 units sold on average in registered pharmacies compared to 15 in public health facilities). These cases aside, sales over the last seven days were overall low in private for-profit outlets, with no more than 7 units on average being sold when stocked.

DISCUSSION

The availability of diagnostic testing documented in the public and private sectors in this study indicates clearly that the goal of universal parasitological diagnosis (WHO 2010) is far from being achieved. Although availability of any diagnostic test was higher in public health facilities than in the private sector, it was less than 60% in public health facilities in five countries. However, in Cambodia, Madagascar and Zambia, RDT availability was very high in public health facilities, reflecting early adoption and scale-up of RDTs by governments in these countries. RDT scale-up in the public sector occurred in 1999 in Cambodia and in 2008 in Madagascar and Zambia (MOH 2001; RBM 2011; RBM 2013). In 2010, approximately 1.5 million and 2 million RDTs were distributed to public providers in Madagascar and Zambia, respectively (RBM 2011; RBM 2013).

RDT availability in the private sector was 10% or less in seven of the ten surveys. For the nine sub-Saharan African settings, private sector RDT availability was typically less than 15% for all private for-profit outlet types, and availability among pharmacies and drug shops was less than 10% in seven countries. These findings are of concern given the important role that the private sector plays in fever case management generally (Colvin *et al*. 2013), and specifically given the targeting of pharmacies and drug shops for interventions such as training and ACT subsidies to improve malaria case management

(Smith *et al.* 2009; Sabot *et al.* 2009; Yeung *et al*. 2011). An outlier, both geographically and in terms of availability, is Cambodia, where availability in for-profit health facilities (66%) and drug shops (44%) was the highest for these outlet types across the ten settings. Cambodia is unique among the study countries in having a private sector RDT intervention operating at national scale (Yeung *et al.* 2011). Since 2003 PSI has socially marketed RDTs (and ACTs) through private sector providers in Cambodia, and in 2010 PSI distributed over 800,000 test kits nationwide (PSI 2011). The results in Cambodia suggest that such an RDT intervention may be one approach to increase access at scale, though improvements in RDT availability and uptake were relatively slow, particularly in more remote areas (Yeung *et al*. 2011).

Substantial increases in availability of effective antimalarials have resulted from other large-scale private sector interventions, though these have not targeted RDT availability. Results from the AMFm show national-level ACT subsidies can lead to large increases in ACT availability in private health facilities and retail outlets, in some settings (Tougher *et al.* 2012). The AMFm pilot intervention was hosted by the Global Fund and comprised negotiated manufacturer price reductions, a co-payment to manufacturers that acted as a consumer subsidy, and support for demand creation activities. Increased consumer availability and access through ACT subsidies have also been shown in Senegal, where the government began subsidizing ACTs through private pharmacies in 2006 (Kone 2007, cited in Schaferhoff *et al.* 2011).

The results presented here imply that presumptive treatment of febrile illness is currently very common. Several potential consequences of this include: inefficient resource allocation by governments and donors, unnecessary out-of-pockets expenses for households, increased risk of drug resistance through overtreatment with ACTs (Perkins *et al.* 2008), and increased morbidity and mortality when the true source of illness is left untreated. The question of what role the private sector should play with regards to diagnosis is characterized by a lack of empirical evidence and strong opinions. Important arguments put forward in favor of private sector RDT scale-up include the potential for improved case management of fever cases and a reduction in drug wastage (Odaga et al. 2014) and thus cost savings. However, achieving these benefits is likely to require a complementary training and supervision package, including Integrated Case Management of fevers in order to assure correct management of malaria-negative cases. Whether countries could coordinate such an approach and whether the additional costs can be justified are unanswered questions. One possible solution is to draw on the resources of private sector manufacturers to fund and oversee training and supervision of retail providers (Malaria Consortium 2013). It may also be possible to build on other initiatives to improve private sector quality of care, such as clinician and provider training (Rao et al.

2013; ACT Consortium 2014; Chandler et al. 2014; Mbacham et al. 2014) and accreditation programs for retail outlets (Centre for Pharmaceutical Management 2008; Rutta et al. 2009). Despite some positive trial results, major challenges remain in ensuring effective supervision and regulation for both accredited and non-accredited retailers.

As this debate continues, it is clear that increasing access to RDTs in the private sector will be more challenging than achieving scale-up of ACT described earlier. One important barrier in most countries is the existing regulatory framework, which frequently prohibits retail providers from performing consultations and offering an RDT service or selling RDTs. Consistent with this, the lack of existing referral systems from private retail outlets to public facilities poses an important challenge when addressing an intervention that is a health service as opposed to the provision of a commodity. These and other challenges are being explored through a number of small-scale operational research projects to evaluate the feasibility of incorporating RDTs into the private retail sector. Recent projects have been conducted among patent medicine vendors in Nigeria, drug shops in Uganda, chemical sellers in Ghana and accredited drug dispensing outlets in Tanzania, and results of many projects are forthcoming (Chandler *et al*. 2013). A review of progress held in London in 2013 drew together common findings, including a willingness by retail providers to incorporate RDTs into their business, and an acceptance by clients of testing before treatment (Chandler *et al*. 2013). Published results lend weight to these early findings. A project on RDTs in the retail sector in Uganda showed that subsidized RDTs can be distributed through existing retail supply chains (Cohen *et al.* 2012a); and an RDT voucher program in Kenya increased the proportion of illness episodes that were tested for malaria by 22 percentage points across all subsidy levels (Cohen *et al.* 2012b). A systematic review of rapid diagnostic test performance by CHWs reported a high overall quality of care was achieved, though highlighted low referral completion and sometimes poor adherence to negative test results (Ruizendaal *et al*. 2014). Building on the lessons learned from earlier pilot studies, in 2012 UNITAID committed $34 million to invest in creating a private sector market for RDTs in five countries (UNITAID 2012). Contingent on successful pilot phases, this will be the first program in Sub-Saharan Africa to implement diagnostic testing at scale with RDTs in the private sector.

RDTs in all sectors need to be of high quality. This means having adequate panel detection scores from the WHO/FIND product testing rounds, and being able to withstand the heat and humidity inherent in tropical supply chains (Albertini *et al.* 2012b). This study used submission to WHO/FIND product testing as a proxy for potential RDT quality. Typically, outlets that stocked RDTs stocked products from a manufacturer that had submitted at least one product for testing. The clearest exception was among registered pharmacies in Uganda, 19% of which stocked RDTs from manufacturers who had not

submitted a product for testing. In total, products from 22 named manufacturers were recorded in Uganda, nine of whom do not appear in Rounds 1-3 of product testing. Taken together, these results suggest a relatively mature market of potentially variable quality. Continued assessment and guidance will be required to assist public procurement services, private importers and sector regulators to take quality into account when making purchasing and regulatory decisions.

This study also reports on the median purchase price to patients for an RDT. Comparable private sector RDT price information from other studies is limited, likely due to the low penetration of RDTs in most markets. However, findings from this research suggest that rapid RDT scale up in the private sector is unlikely without substantial reductions in retail prices. In their 2011 study, Hansen et al. (2012) found that the mean willingness to pay for an RDT among drug shop customers in Uganda was $0.53. By comparison this study found the median retail price for an RDT in drug shops in Uganda was $0.80 in 2011.

This study has several limitations. First, the ACTwatch and AMFm Independent Evaluation surveys did not include diagnosis-only service providers, reflecting the focus of the original studies on antimalarial provision. Diagnostic laboratories may be an important subset of private sector outlets in some countries: Albertini's 2012 study included 25 private laboratories in Lagos sampled purposefully based on proximity to the collaborating institution. The likely effect of excluding laboratories from this study is to bias private sector RDT availability downward in some contexts.

Second, the operational definitions of two indicators are limited by the available data. In order to define RDT quality, either recorded brand characteristics such as parasite species must be compared against lists such as the WHO selection criteria for RDT procurement (WHO 2012b) or the Global Fund Quality Assurance Policy (Global Fund 2014), or RDT samples must be purchased in the field and tested. The latter was considered beyond the scope of this study. In addition, the data collected did not include details of parasite species or lot numbers for RDT products. We thus defined *quality* on the basis of manufacturer submission for WHO/FIND testing, rather than on product-specific test results. Study results do not therefore directly provide information on quality-assured RDTs as defined by WHO or the Global Fund. Expiry information was not recorded as data collection was tailored towards determining availability and pricing, and interviewers did not examine all batches of products held in stock. RDT retail price information was captured through provider reports of the retail selling price for one test (question wording: *how much do you charge for one test?*), and as such may be liable to under-estimation due to social desirability bias. Furthermore, additional aspects of pricing such as any consultation fees and service or laboratory fees were not captured. The likely effect is that the presented prices underestimate the total out-of-pocket cost for an RDT, particularly in private health

facilities where the testing service is often part of a broader consultation. Future studies should seek to capture a finer level of detail on RDT brands and their quality, including lot and catalogue numbers if examples cannot be purchased in the field for testing. Investigators should also seek to capture total out-of-pocket costs and provide more clarity on retail price in relation to consultation and other fees.

Third, some outlet types are scarce and lead to estimates being calculated from only a small sample of outlets, with a resulting large error associated with the estimate. This is particularly a problem for private not-for-profit health facilities, but also affects private for-profit health facility estimates in some countries. Although the number of such outlets is sometimes small, indicators are presented at this level of disaggregation to reflect the differing incentives and operating methods of each outlet type. In particular, health facilities (whether non-profit or for-profit) may be more likely to provide a full RDT testing service than a pharmacy or retail drug store. This distinction could be important when selecting outlets for an RDT scale-up intervention as the means and methods of intervention will differ depending on whether providers view themselves as offering a service or (just) selling a commodity.

The results presented here can be used as baseline indicators in countries that are beginning to scale up RDT availability in the private sector. The ACTwatch outlet survey approach more generally can be used to monitor RDT and ACT interventions in the future. Data such as these are critical for target setting and for monitoring service readiness towards the goal of universal diagnostic testing of febrile illness. However, there are obvious limits of such descriptive studies, and further research is needed to understand how RDTs are being used by providers and patients, particularly in the private sector; where and why bottlenecks in supply occur; whether results are respected by providers and patients; and what steps are being taken to ensure appropriate storage and quality assurance of RDTs and safe disposal of RDTs and sharps.

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Table 1. **Sample description – total number of outlets visited and screened, number of eligible[1] outlets interviewed, and number of RDT products audited**

	Public / private not-for-profit sector (public health facilities, community health workers and private not-for-profit health facilities)					Private for-profit sector (private for-profit health facilities, pharmacies and drug shops)				
	Outlets visited	Outlets screened	Eligible outlets	Outlets interviewed	Number of RDT products audited	Outlets visited	Outlets screened	Eligible outlets	Outlets interviewed	Number of RDT products audited
Benin	351	330	315	308	79	376	352	341	328	17
Cambodia	818	873	739	739	701	1,440	1,356	580	569	295
Ghana	341	321	316	316	99	740	670	652	646	17
Kenya	854	837	477	477	74	1,225	1,074	1,046	1,033	70
Madagascar	1,607	1,482	773	771	698	632	554	517	509	24
Nigeria	161	134	122	122	22	1,574	1,338	1,326	1,322	22
Tanzania-mainland	71	68	65	65	24	772	713	710	710	16
Uganda	1,787	1,756	832	830	481	2,662	2,476	2,429	2,373	362
Zambia	307	297	296	296	198	495	448	425	416	80
Zanzibar	169	164	147	147	140	315	271	220	220	20
Total	**6,466**	**6,262**	**4,082**	**4,071**	**2,516**	**10,231**	**9,252**	**8,246**	**8,126**	**923**

RDT: rapid diagnostic test.

[1] An eligible outlet either had antimalarials in stock on the day of interview or had stocked antimalarials in the past three months. Not all visited outlets were screened; reasons include outlets that had closed down permanently, outlets that were closed on each visit, and outlets with no eligible respondents available at the time of interviews.

Figure 1. **Availability of any RDT in outlets that have stocked antimalarials in the past 3 months, including the day of interview, among (a) public/not-for-profit sector outlets, and (b) private for-profit sector outlets (2011)**
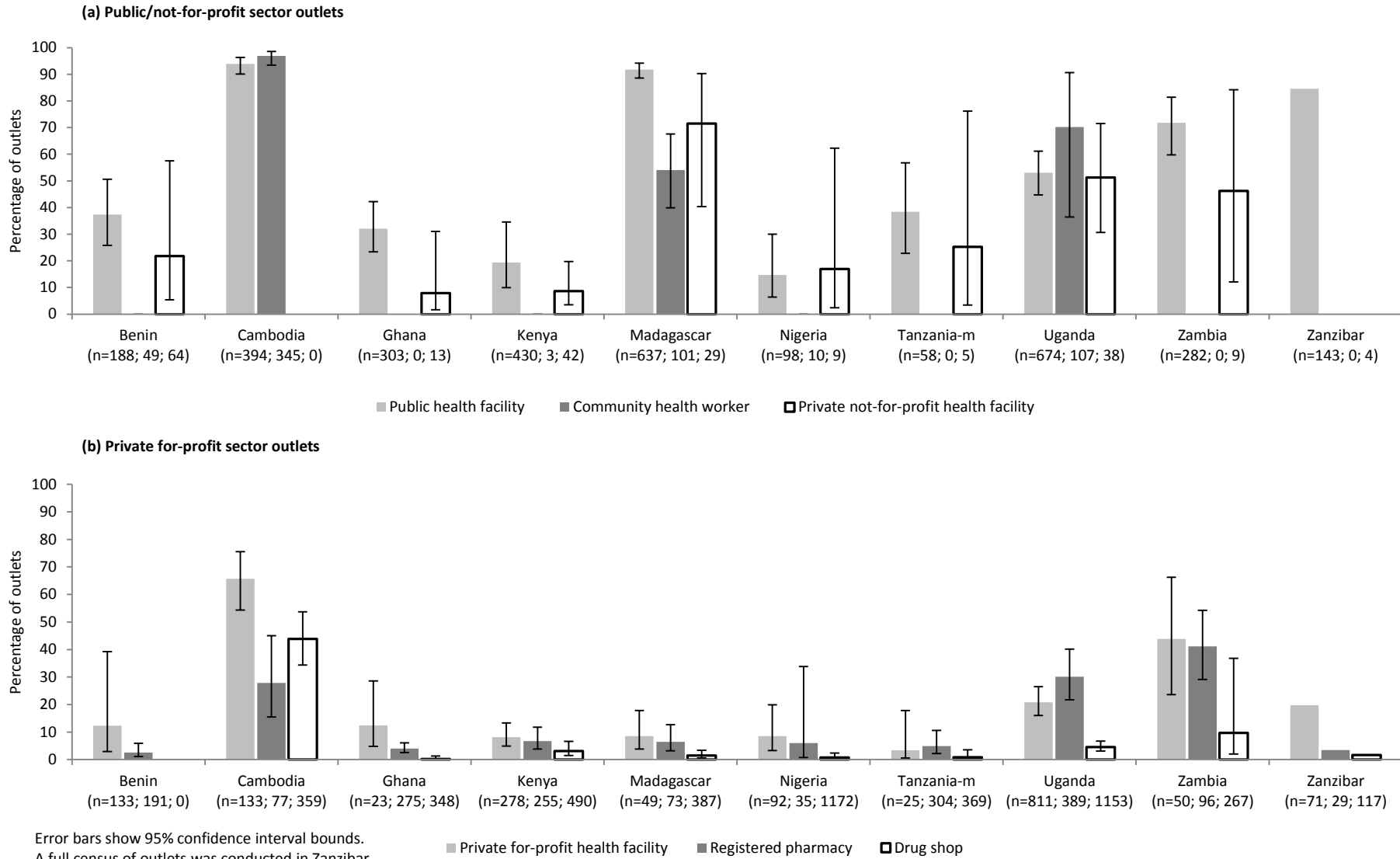
(a) Public/not-for-profit sector outlets

■ Public health facility   ■ Community health worker   ☐ Private not-for-profit health facility

(b) Private for-profit sector outlets

Error bars show 95% confidence interval bounds.
A full census of outlets was conducted in Zanzibar.

■ Private for-profit health facility   ■ Registered pharmacy   ☐ Drug shop

Table 2. **Identified manufacturers and brands of RDT products audited among outlets in the public/not-for-profit sector and private-for-profit sector (2011)**

Manufacturer	Brand	Submitted for product testing Rounds 1-3	Benin Public/ NFP	Benin For profit	Cambodia Public/ NFP	Cambodia For profit	Ghana Public/ NFP	Ghana For profit	Kenya Public/ NFP	Kenya For profit	Madagascar Public/ NFP	Madagascar For profit	Nigeria Public/ NFP	Nigeria For profit	Tanzania-ml Public/ NFP	Tanzania-ml For profit	Uganda Public/ NFP	Uganda For profit	Zambia Public/ NFP	Zambia For profit	Zanzibar Public/ NFP	Zanzibar For profit
Access Bio Inc	CareStart	Yes	X		X	X	X	X	X	X	X	X	X					X				
Acon Biotech	*Unspecified* / Plasmostest[a]	Yes				X	X						X	X				X				
Acumen Diagnostics	Diaspot	No											X	X								
Aragen Biotech	*Unspecified*	No																X				
Astel Diagnostics	Astel Pf Cassette	No															X	X				
Atlas Link Technology	Nova Test	No															X	X				
Atlas Medical	Rapid Test Strip	No	X																			
Bhat Biotech India	MaleriScan	Yes				X												X				
Bioland	NanoSign	Yes										X										X
Biosynex	*Unspecified*	Yes																X				
Bio Vege Med	*Unspecified*	No	X																			
Blue Cross Bio-Medical	Malaria Pf	Yes					X															
Chian Pharmed Co	*Unspecified*	No				X																
CTK Biotech	On Site Rapid Test	Yes																X		X		
Cypress Diagnostics	Malaria Quick Test	No										X					X	X				
Diagnostics Automation	*Unspecified*	Yes																				X
Euromedi	Eurocheck	No										X										
Global Device	*Unspecified*	No											X	X								
Highgate	Whole Blood Cassette	No																X				
Human GMBH	Hexagon Malaria	Yes																X				
ICT Diagnostics	ICT	Yes	X	X					X	X						X			X	X		X
InTec Products	Advanced Quality	Yes				X																
Inverness Medical	Binax Now Malaria	Yes			X																	
Jei Daniel Biotech	*Unspecified*	No	X																			
Lab-care Diagnostics	Accucare One Step	No															X	X				
Launch Diagnostics	Accusay	No															X					
Medsource Ozone Biomedicals	Malaria Antibody Test	No	X																			
Nano Biotech	Nano Malaria	No																X				
Nantong Egnes Biotech	*Unspecified*	No																X				
Omega Diagnostics	Micropath	No												X								
Orchid Biomedical Systems	Paracheck	Yes	X	X	X				X	X	X		X	X				X	X		X	X
Pistis Diagnostic Ltd	*Unspecified*	No											X									
Premier Medical Corporation	First Response	Yes					X	X	X	X			X	X			X	X		X		
Span Diagnostics	Parahit	Yes																X				
SSA Diagnostics and Biotech Systems	*Unspecified*	Yes																X				
Standard Diagnostics	SD Bioline	Yes	X	X					X	X	X	X	X	X	X	X	X	X	X	X	X	X
Vision Biotech	Clear View[b]	No												X			X	X				X
Wondfo Biotech	One Step Whole Blood Test[c]	Yes			X	X	X		X	X				X			X	X				
Zephyr Biomedicals	*Unspecified*	Yes									X											X
Unspecified	Life Tech Whole Blood Strip	n/a															X					

RDT: rapid diagnostic test; NFP: not-for-profit

[a] Brand details were recorded as Plasmotest in Benin, but not recorded for RDTs from Acon Biotech in other countries; [b] Brand details were not recorded for 2 Vision Biotech RDTs audited in Madagascar and 1 RDT audited in Zanzibar;

[c] Brand details were not recorded for 2 Wondfo Biotech RDTs audited in Ghana; in Cambodia 25 RDTs from Wondfo Biotech were branded as *Malacheck*, the brand name used by PSI's subsidised RDT program.

Table 3. **Median retail price to patients[1] [and inter-quartile range] for one RDT in 2011 US dollars[2] (2011)**

	Public health facility	Community health worker	Private not-for-profit health facility	Total public / not-for-profit	Private for-profit health facility	Pharmacy	Drug shop	Total private for-profit
	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]
Benin	0.00 [0.00-0.00] N=70	-- N=0	0.00 [0.00-1.73] N=9	0.00 [0.00-0.00] N=79	1.73 [0.00-1.73] N=10	2.65 [1.08-3.19] N=4	-- N=0	1.73 [0.00-1.73] N=14
Cambodia	0.00 [0.00-0.00] N=364	0.00 [0.00-0.00] N=335	-- N=0	0.00 [0.00-0.00] N=699	0.51 [0.51-0.76] N=87	0.51 [0.38-0.64] N=21	0.51 [0.51-0.76] N=179	0.51 [0.51-0.76] N=287
Ghana	0.00 [0.00-0.00] N=94	-- N=0	0.00 [0.00-0.00] N=1	0.00 [0.00-0.00] N=95	0.00 [0.00-1.28] N=3	1.92 [1.61-2.57] N=12	0.00 [0.00-0.00] N=1	1.28 [0.00-1.61] N=16
Kenya	0.00 [0.00-0.00] N=67	-- N=0	0.58 [0.35-0.58] N=6	0.00 [0.00-0.35] N=73	0.93 [0.58-1.16] N=23	1.16 [1.16-1.75] N=29	1.16 [0.58-1.16] N=15	1.16 [0.58-1.16] N=67
Madagascar	0.00 [0.00-0.00] N=597	0.00 [0.00-0.00] N=67	0.00 [0.00-0.00] N=24	0.00 [0.00-0.00] N=688	0.00 [0.00-0.00] N=13	3.67 [0.25-3.77] N=4	0.00 [0.00-0.15] N=6	0.00 [0.00-1.01] N=23
Nigeria	1.24 [0.00-1.24] N=19	-- N=0	1.85 [1.85-1.85] N=3	1.24 [0.00-1.85] N=22	2.47 [1.85-7.41] N=10	-- N=0	0.31 [0.31-0.93] N=6	0.93 [0.31-2.47] N=16
Tanzania-mainland	0.00 [0.00-0.00] N=22	-- N=0	0.00 [0.00-0.00] N=1	0.00 [0.00-0.00] N=23	-- N=0	0.64 [0.64-1.28] N=8	0.96 [0.64-0.96] N=3	0.96 [0.64-0.96] N=11
Uganda	0.00 [0.00-0.00] N=403	0.00 [0.00-0.00] N=60	0.00 [0.00-0.80] N=18	0.00 [0.00-0.00] N=481	1.20 [0.80-1.60] N=179	0.88 [0.80-1.04] N=107	0.80 [0.40-1.20] N=59	1.20 [0.80-1.20] N=345
Zambia	0.00 [0.00-0.00] N=194	-- N=0	0.00 [0.00-0.00] N=3	0.00 [0.00-0.00] N=197	4.18 [3.13-6.27] N=28	3.13 [2.09-5.43] N=39	1.04 [1.04-1.25] N=8	3.13 [1.25-5.22] N=75
Zanzibar	0.00 [0.00-0.00] N=139	-- N=0	-- N=0	0.00 [0.00-0.00] N=139	0.64 [0.00-1.28] N=11	2.30 [1.31-3.07] N=4	0.16 [0.00-0.32] N=2	0.64 [0.32-1.92] N=17

RDT: rapid diagnostic test; IQR: Interquartile range

The unit of analysis is RDT products; generally an outlet or facility would only have one product type (brand) in stock on the day of interview.

A full census of outlets was conducted in Zanzibar.

[1] In Ghana, Kenya, Madagascar, Nigeria, Tanzania, Uganda and Zanzibar, the median price is the price charged to purchase an RDT for a child; in the other countries no age group was specified in the question to respondents.

[2] Prices converted to US dollars using the average country exchange rate for 2011, but not adjusted to reflect local purchasing power in each country.

Table 4. **Median number of RDTs sold or used during the 7 days preceding the survey [and inter-quartile range] for RDT products in stock in outlets at the time of the survey[1] (2011)**

	Public health facility	Community health worker	Private not-for-profit health facility	Total public / not-for-profit	Private for-profit health facility	Pharmacy	Drug shop	Total private for-profit
	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]	Median [IQR]
Benin	3 [0-11] N=57	-- N=0	3 [1-3] N=9	3 [0-10] N=66	0 [0-7] N=10	0 [0-2] N=5	-- N=0	0 [0-7] N=15
Cambodia	3 [0-7] N=353	2 [0-5] N=335	-- N=0	2 [0-6] N=688	2 [0-18] N=88	0 [0-1] N=22	2 [1-5] N=179	2 [0-6] N=289
Ghana	10 [6-35] N=92	-- N=0	-- N=0	10 [6-35] N=92	35 [20-80] N=3	1 [0-2] N=11	1 [1-1] N=1	9 [1-35] N=15
Kenya	10 [1-23] N=64	-- N=0	0 [0-6] N=6	6 [0-23] N=70	2 [2-4] N=23	3 [1-4] N=28	4 [2-5] N=13	2 [2-4] N=64
Madagascar	5 [1-12] N=568	1 [0-3] N=70	17 [6-35] N=22	2 [0-7] N=660	4 [0-7] N=13	1 [0-30] N=4	0 [0-8] N=5	1 [0-8] N=22
Nigeria	8 [3-8] N=18	-- N=0	6 [6-6] N=3	8 [3-8] N=21	7 [7-20] N=11	0 [0-0] N=1	2 [0-3] N=9	5 [0-10] N=21
Tanzania-mainland	15 [5-25] N=21	-- N=0	50 [50-50] N=1	15 [5-25] N=22	0 [0-0] N=1	25 [2-200] N=10	1 [1-1] N=3	1 [1-1] N=14
Uganda	24 [0-59] N=381	0 [0-3] N=60	5 [3-17] N=17	1 [0-12] N=458	5 [2-10] N=181	4 [0-10] N=108	2 [0-6] N=60	3 [1-10] N=349
Zambia	50 [12-119] N=185	-- N=0	13 [13-13] N=2	48 [13-113] N=187	7 [3-10] N=28	4 [0-10] N=32	0 [0-0] N=8	3 [0-10] N=68
Zanzibar	22 [10-40] N=136	-- N=0	-- N=0	22 [10-40] N=136	4 [12-22] N=12	2 [0-2] N=3	1 [0-2] N=2	4 [2-20] N=17

RDT: rapid diagnostic test; CHW: Community health worker; IQR: Interquartile range

A full census of outlets was conducted in Zanzibar.

[1] Providers were asked to report how many tests had been sold or used during the past 7 days for each RDT product in stock on the day of interview. In some cases the providers refused or could not recall the number of tests. These data have been set to missing for this analysis and account for the following proportion of total RDT cases in each country: Benin (15%), Ghana (6%), Kenya (6%), Madagascar (5%), Nigeria (5%), Tanzania-mainland (10%), Uganda (4%), Zambia (6%), Zanzibar (4%).
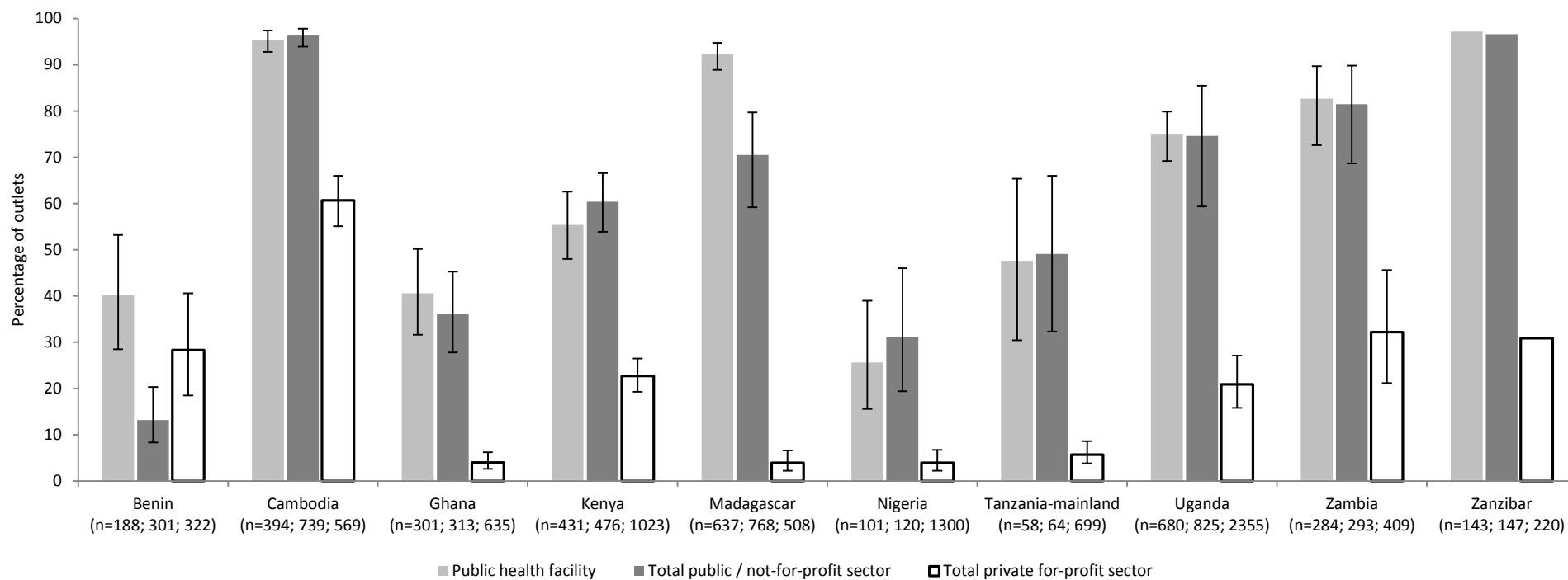
Supplementary Table 1. **Availability of any RDT in outlets that stocked antimalarials in the past three months, including the day of interview (2011)**

	Public health facility	Community health worker	Private not-for-profit health facility	Total public / not-for-profit	Private for-profit health facility	Pharmacy	Drug shop	Total private for-profit
	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)
Benin	37.4 (25.8, 50.6) N=188	0 N=49	21.8 (5.4, 57.5) N=64	11.2 (7.3, 16.8) N=301	12.3 (2.9, 39.2) N=133	2.6 (1.1, 5.9) N=191	-- N=0	10.6 (2.7, 33.7) N=324
Cambodia	93.9 (90.1, 96.3) N=394	96.9 (93.4, 98.6) N=345	-- N=0	95.7 (93.2, 97.3) N=739	65.7 (54.3, 75.5) N=133	27.9 (15.5, 45.0) N=77	43.8 (34.4, 53.7) N=359	46.1 (38.5, 54.0) N=569
Ghana	32.1 (23.4, 42.2) N=303	-- N=0	7.9 (1.6, 31.0) N=13	27.5 (19.7, 37.0) N=316	12.4 (4.8, 28.6) N=23	4.0 (2.6, 6.1) N=275	0.2 (<0.1, 1.3) N=348	1.4 (0.9, 2.4) N=646
Kenya	19.4 (9.9, 34.6) N=430	0 N=30	8.6 (3.5, 19.7) N=42	16.6 (9.1, 38.4) N=475	8.2 (4.9, 13.3) N=278	6.7 (3.8, 11.8) N=255	3.1 (1.5, 6.6) N=490	5.2 (3.6, 7.3) N=1,023
Madagascar	91.8 (88.6, 94.2) N=637	54.1 (39.9, 67.6) N=101	71.5 (40.4, 90.3) N=29	70.3 (69.1, 79.5) N=767	8.5 (3.8, 17.8) N=49	6.5 (3.2, 12.7) N=73	1.5 (0.6, 3.4) N=387	3.7 (2.2, 6.3) N=509
Nigeria	14.7 (6.4, 30.0) N=98	0 N=10	16.9 (2.4, 62.3) N=9	14.2 (7.0, 26.5) N=117	8.5 (3.3, 19.9) N=92	6.0 (0.8, 33.8) N=35	0.8 (0.3, 2.4) N=1,172	1.5 (0.6, 3.6) N=1,299
Tanzania-mainland	38.4 (22.8, 56.8) N=58	-- N=0	25.2 (3.4, 76.2) N=5	37.8 (22.7, 55.6) N=63	3.4 (0.6, 17.8) N=25	4.9 (2.2, 10.6) N=304	0.9 (0.2, 3.6) N=369	1.2 (0.4, 3.3) N=698
Uganda	53.0 (44.7, 61.2) N=674	70.2 (36.4, 90.6) N=107	51.3 (30.7, 71.5) N=38	61.5 (42.0, 77.9) N=819	20.8 (16.0, 26.5) N=811	30.1 (21.7, 40.1) N=389	4.6 (3.1, 6.7) N=1,153	9.6 (7.1, 12.9) N=2,353
Zambia	71.8 (59.8, 81.4) N=282	-- N=0	46.2 (12.1, 84.2) N=9	69.1 (55.9, 79.7) N=291	43.8 (23.6, 66.2) N=50	41.1 (29.1, 54.2) N=96	9.7 (2.0, 36.8) N=267	20.4 (12.2, 32.1) N=413
Zanzibar	84.6 N=143	-- N=0	0 N=4	82.3 N=121	19.7 N=71	3.5 N=29	1.7 N=117	7.8 N=217

RDT: rapid diagnostic test; CI: confidence interval

A full census of outlets was conducted in Zanzibar.

Supplementary Figure 1. **Availability of any diagnostic test (microscopy or RDT) in outlets that stocked antimalarials in the past three months, including the day of interview (2011)**

Error bars show 95% confidence interval bounds.
A full census of outlets was conducted in Zanzibar.

Supplementary Table 2. **Availability of any RDT from a manufacturer that has submitted product(s) for testing during WHO/FIND Rounds 1-3 in outlets that stocked antimalarials in the past three months, including the day of interview (2011)**

	Public health facility	Community health worker	Private not-for-profit health facility	Total public / not-for-profit	Private for-profit health facility	Pharmacy	Drug shop	Total private for-profit
	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)
Benin	36.3 (25.2, 49.1) N=186	0 N=49	18.2 (3.1, 60.8) N=63	10.6 (7.0, 15.6) N=298	10.6 (2.1, 40.3) N=131	2.6 (1.1, 5.9) N=191	-- N=0	9.2 (1.9, 34.4) N=322
Cambodia	93.9 (90.1, 96.3) N=393	96.9 (93.4, 98.6) N=345	-- N=0	95.7 (93.2, 97.3) N=738	63.1 (52.0, 72.9) N=131	27.9 (15.5, 45.0) N=77	41.8 (32.1, 52.1) N=346	44.0 (36.3, 52.0) N=554
Ghana	32.1 (23.4, 42.2) N=303	-- N=0	0 N=12	26.4 (18.7, 35.9) N=315	12.4 (4.8, 28.6) N=23	3.7 (2.3, 5.9) N=274	0.2 (0.0, 1.3) N=348	1.4 (0.8, 2.4) N=645
Kenya	18.9 (9.4, 34.4) N=426	0 N=3	5.0 (1.3, 17.5) N=41	15.5 (8.0, 27.7) N=470	7.3 (4.0, 12.8) N=271	5.5 (3.2, 9.5) N=250	2.7 (1.3, 5.5) N=489	4.5 (3.0, 6.7) N=1,010
Madagascar	91.7 (88.4, 94.1) N=636	54.1 (39.9, 67.6) N=101	71.5 (40.4, 90.3) N=29	70.2 (59.0, 79.4) N=766	7.4 (3.3, 15.8) N=49	6.5 (3.2, 12.7) N=73	1.5 (0.6, 3.4) N=387	3.5 (2.0, 5.9) N=509
Nigeria	7.2 (3.0, 16.5) N=98	0 N=10	16.5 (2.3, 62.5) N=9	7.9 (3.7, 16.0) N=117	6.8 (2.3, 18.3) N=92	0 N=35	0.8 (0.3, 2.4) N=1,172	1.3 (0.5, 3.4) N=1,299
Tanzania-mainland	36.5 (20.5, 56.1) N=55	-- N=0	25.2 (3.4, 76.2) N=5	35.9 (20.5, 55.0) N=60	3.4 (0.6, 17.8) N=25	2.9 (0.8, 10.3) N=300	0.9 (0.2, 3.6) N=369	1.1 (0.4, 3.3) N=694
Uganda	51.3 (43.4, 59.2) N=673	70.2 (36.4, 90.6) N=107	36.5 (18.2, 59.8) N=38	59.3 (39.1, 76.8) N=818	15.1 (11.2, 20.1) N=802	11.1 (6.8, 17.6) N=387	3.7 (2.3, 5.9) N=1,152	7.0 (5.1, 9.6) N=2,341
Zambia	71.8 (59.8, 81.4) N=282	-- N=0	46.2 (12.1, 84.2) N=9	69.1 (55.9, 79.9) N=291	43.8 (23.6, 66.2) N=50	40.2 (27.8, 54.0) N=96	7.5 (1.6, 28.4) N=266	19.0 (12.0, 29.0) N=412
Zanzibar	84.6 N=143	-- N=0	0 N=4	82.3 N=147	19.7 N=71	3.5 N=29	1.7 N=117	7.8 N=217

RDT: rapid diagnostic test; CI: confidence interval

A full census of outlets was conducted in Zanzibar.

Supplementary Table 3. **Availability of any RDT from a manufacturer that has not submitted product(s) for testing during WHO/FIND Rounds 1-3 in outlets that stocked antimalarials in the past three months, including the day of interview (2011)**

	Public health facility	Community health worker	Private not-for-profit health facility	Total public / not-for-profit	Private for-profit health facility	Pharmacy	Drug shop	Total private for-profit
	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)
Benin	0 N=186	0 N=49	2.6 (0.7, 8.9) N=63	0.2 (0.0, 1.6) N=298	0.2 (0.0, 1.4) N=131	0 N=191	-- N=0	0.2 (0.0, 1.2) N=322
Cambodia	0 N=393	0 N=345	-- N=0	0 N=738	0 N=131	0 N=77	0 N=346	0 N=554
Ghana	0 N=303	-- N=0	0 N=12	0 N=315	0 N=23	0 N=274	0 N=348	0 N=645
Kenya	0 N=426	0 N=3	1.4 (0.2, 8.9) N=41	0.3 (0.0, 2.1) N=470	0 N=271	0.4 (0.1, 1.6) N=250	0.4 (0.1, 2.3) N=489	0.2 (0.0, 1.3) N=1,010
Madagascar	0 N=636	0 N=101	0 N=29	0 N=766	1.1 (0.3, 3.8) N=49	0 N=73	0 N=387	0.2 (0.1, 0.7) N=509
Nigeria	7.4 (2.6, 19.1) N=98	0 N=10	0.4 (0.0, 3.5) N=9	6.2 (2.3, 16.1) N=117	1.5 (0.3, 7.7) N=92	6.0 (0.8, 33.8) N=35	<0.1 (0.0, 0.1) N=1,172	0.3 (0.1, 0.8) N=1,299
Tanzania-mainland	0 N=55	-- N=0	0 N=5	0 N=60	0 N=25	0 N=300	0 N=369	0 N=694
Uganda	0.2 (0.0, 1.1) N=673	0 N=107	14.8 (3.7, 44.2) N=38	1.6 (0.4, 6.4) N=818	5.4 (3.5, 8.3) N=802	19.3 (12.4, 28.7) N=387	0.7 (0.3, 1.5) N=1,152	2.3 (1.4, 3.8) N=2,341
Zambia	0 N=282	-- N=0	0 N=9	0 N=291	0 N=50	0 N=96	0 N=266	0 N=412
Zanzibar	0 N=143	-- N=0	0 N=4	0 N=147	0 N=71	0 N=29	0 N=117	0 N=217

RDT: rapid diagnostic test; CI: confidence interval

A full census of outlets was conducted in Zanzibar.