ACTWATCH RESEARCH BRIEF

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Background

The target for malaria case management in Kenya is to ensure that 100 percent of all fever cases receive a parasitological diagnosis, by microscopy or rapid diagnostic test (RDT), followed by appropriate treatment.

MALARIA SITUATION IN KENYA
Kenya’s 2014 population is estimated at 44.9 million people, with an estimated growth of 2.6 percent per year. Children under five account for about 15 percent of the total population. Approximately 70 percent of the population is at risk for malaria, which accounts for about 18 percent of outpatient consultations and 6 percent of hospital admissions.

MALARIA PREVALENCE
Malaria prevalence varies considerably by season and across geographic regions. For the purposes of malaria control, the country has been stratified into four epidemiological zones to address the varied risks. The majority of the at-risk population live in areas of epidemic and seasonal malaria transmission where P. falciparum (pf) parasite prevalence is usually less than 5 percent. An estimated 12 million people live in endemic areas, one-third of whom live in areas where parasite prevalence is estimated to be equal to or greater than 40 percent.

NATIONAL TREATMENT GUIDELINES
The 2014 National Guidelines for the Diagnosis, Treatment and Prevention of Malaria in Kenya recommend diagnosis-based treatment as part of effective case management. The target for case management is to ensure that 100 percent of all fever cases receive a parasitological diagnosis, by microscopy or rapid diagnostic tests (RDT), followed by appropriate treatment.

Kenya uses the Artemisinin-based Combination Therapy (ACT) Artemether Lumefantrine (AL) as the first-line treatment for uncomplicated malaria and parenteral quinine, artesunate, or artemether for severe malaria, policies which were adopted in 2004.

GOAL OF THE KENYA MALARIA CONTROL STRATEGY
The revised Kenya Malaria Strategy 2009-2018 target for community case management is to have at least 100 percent of fever cases presenting to a health provider managed according to the National Malaria Treatment Guidelines by 2018. Broad objectives of the malaria strategy related to appropriate case management include:

1. Build capacity of health workers to diagnosis and treat malaria,
2. Expand access to affordable malaria medicines and diagnostics in the private sector,
3. Expand use of Community Health Workers (CHW),

KEY INTERVENTIONS
Kenya implemented a national rollout of RDT to health dispensaries and health centers in late 2012, provides first-line ACT for all public health facilities, and supports national in-service training for malaria diagnostics and case management. RDT and ACT are being made available to CHW to discourage use of informal drug outlets by persons with fever.

Between 2010 and 2013, multiple strategies were implemented to introduce and scale up the use of quality-assured AL and malaria RDT in the public and private sector. Funding through the Affordable Medicines Facility-malaria (AMFm), provided first-line buyers with access to highly subsidized (co-paid) quality-assured ACT. Medicines subsidized through the AMFm were marked with a ‘green leaf’ logo on the packaging.

Phase 1 of the AMFm was implemented from 2010-2012. Co-paid ACT arrived in-country for the private sector by August of 2010 and for the public sector by June of 2011. By the end of 2011, approximately 14.35 million co-paid quality-assured ACT treatments were delivered to the public sector and 14.1 million to the private sector. Consequently, Kenya has not had a stock-out of AL at the central level for more than three years, an improvement over previous years when nationwide stock-outs occurred regularly.
ACTwatch at a glance

WHAT IS ACTWATCH?
ACTwatch is a multi-country research project implemented by Population Services International (PSI). Standardized tools and approaches are employed to provide comparable data across countries and over time. ACTwatch is designed to provide timely, relevant, and high quality antimalarial market intelligence, including information on ACT and RDT. The project was launched in 2008 with funding from the Bill and Melinda Gates Foundation (BMGF), and is currently funded through 2016 by the BMGF, UNITAID, and the Department of International Development (DFID). Research methods implemented include outlet and household surveys, supply chain studies, and key informant interviews.

GOAL
The goal of the ACTwatch project is to provide policymakers with evidence to inform and monitor national and global policy, strategy, and funding decisions for improving malaria case management and elimination efforts.

RELEVANCY
ACTwatch market monitoring in Kenya from 2010 to 2014 has been implemented in the context of national strategies designed to improve coverage of appropriate malaria case management. These efforts include:
- National efforts to improve availability of malaria blood testing in public health facilities and ensure continuous stock of ACT.
- National efforts to extend malaria blood testing and antimalarial treatment to community level through equipping CHW with RDT and ACT.
- Multiple strategies to introduce and scale up the use of AL and malaria RDT in public and private sectors.

Under the Global Fund AMFm, public and private first-line buyers had access to subsidized or co-paid ACT from 2009 to 2012, and this was continued in the private sector in 2013.

OUTLET SURVEYS
Outlet surveys are the core component of the ACTwatch project. The outlet surveys in Kenya were designed to monitor key antimalarial market indicators at the national level and within urban/rural domains.

This summary report presents trends from the three most recent outlet surveys conducted in 2010, 2011 and 2014.

41
Number of outlet surveys implemented between 2008 and 2016.

+200,000
Total number of outlets screened across all survey rounds.

+250,000
Number of antimalarials audited in sub-Saharan Africa and the Greater Mekong Sub-region to date.
What questions are answered by the outlet survey?

- What types of outlets in the public and private sectors are distributing antimalarials and providing malaria blood testing?
- What types of antimalarials and RDT are available and distributed by public and private sector?
- What proportion of public and private sector antimalarial medicine outlets are stocking: 1) quality-assured ACT; 2) non quality-assured ACT; and 3) malaria blood testing?
- What is the antimalarial market share of quality-assured ACT relative to the market share for other types of antimalarials?
- What is the consumer price for antimalarial medicines and malaria blood testing among private sector outlets?

The ACTwatch Countries, 2016
Methods

ACTwatch implements standardized methods and questionnaires that allow for comparisons between countries and survey rounds. A full census of all outlets providing malaria care and a full audit of all available antimalarials provides a complete picture of the antimalarial market.

HOW IS THE SAMPLING CONDUCTED?
A nationally representative sample of outlets providing antimalarials to consumers was selected. In Kenya, a one-stage probability-proportional-to-size cluster design was used to select clusters (Locations) within each stratum, with cluster population serving as the measure of size. The primary sampling unit, or cluster, is usually an administrative unit with 10,000 to 15,000 inhabitants.

WHAT TYPES OF OUTLETS ARE SAMPLED?
The main types of outlets sampled include public and not-for profit health facilities, CHW, private health facilities, registered and unregistered pharmacies, general retailers, and itinerant drug vendors.

HOW ARE THE OUTLETS IDENTIFIED?
The ACTwatch outlet survey includes all outlets with the potential to sell antimalarial medicines. As many of these outlets may be unregistered, mobile or recently opened, official listings of these shops and their locations are not typically available. A census approach was therefore implemented, supported by the use of key informant interviews with local officials, local maps, and lists of registered outlets where available.

WHAT IS AN OUTLET CENSUS?
This involves a team of data collectors moving systematically through a defined area in order to identify all outlets that have the potential to sell or distribute antimalarials.

WHAT HAPPENS AFTER AN OUTLET IS IDENTIFIED?
The outlet is screened for availability of malaria medicines or diagnostic testing. Outlets are included in the survey if they have antimalarials or malaria diagnostic tests in stock at the time of survey or in the previous 3 months. Permission to conduct the interview is obtained from the main provider.

HOW IS INFORMATION ON ANTIMALARIALS AND RDT CAPTURED?
Among outlets with antimalarials or/malaria tests in stock, a full audit of the antimalarials and diagnostic tests is conducted. Information is recorded for each unique antimalarial and RDT identified in the outlet.

WHAT INFORMATION IS RECORDED ON THE AUDITS?
An audit sheet is completed for each unique antimalarial and RDT in stock. The audit sheet captures product information from the product package including the brand name, the manufacturer, country of manufacturer, formulation and strength. The audit sheet also captures information from the provider including the amount sold in the last seven days and the retail price. If a particular product is available in multiple package sizes, strengths, or formulations, an audit sheet is completed for each unique product.

Comprehensive product information and provider reports on amount distributed and retail price allow for calculating estimates of antimalarial availability, price, and relative market share.
Sample

Antimalarial outlet types

**HOW MANY OUTLETS WERE INCLUDED IN THE SAMPLE AND SCREENED?**
Across the survey rounds, between 13,500 and 18,000 outlets were enumerated (i.e. identified as outlets with potential to sell or distribute antimalarials). Of these, 76 percent in 2010, 85 percent in 2011, and 89 percent in 2014 were screened for antimalarial availability (and malaria blood testing availability in 2014). Among those that were screened, the percent that were interviewed across the survey rounds was similar over time: 18 percent in 2010, 18 percent in 2011, and 19 percent in 2014.

Notes:
1: Antimalarials in stock on day of visit
2: Antimalarials reportedly in stock during the previous 3 months but not on the day of the visit
3: Malaria blood testing available but no antimalarials in stock
* Outlets enumerated: Identified as outlets with potential to sell or distribute antimalarials and/or provide malaria blood testing during the census or booster sampling.
** Outlets screened: Administered questions to assess current or recent (previous 3 months) availability of antimalarials and malaria blood testing (microscopy or RDT).
~ Outlets interviewed: A partial or complete interview was conducted with an outlet representative.
1 in 5
Number of outlets that met the screening criteria across survey rounds

A 2011
Outlets enumerated 13,376
Outlets not screened 1,990
Outlets that met screening criteria 2,112
1 = 1,871
2 = 241
3 = n/a
Outlets interviewed 2,088
1 = 1,856
2 = 232
3 = n/a

B Outlets screened 11,386
Outlets that did not meet screening criteria 9,274
Outlets not interviewed 24

C Outlets that met screening criteria 2,477
1 = 2,159
2 = 272
3 = 46

D Outlets interviewed 2,449
1 = 2,133
2 = 272
3 = 44

A 2014
Outlets enumerated 14,127
Outlets not screened 1,451
Outlets that met screening criteria 2,477
1 = 2,159
2 = 272
3 = 46
Outlets interviewed 2,449
1 = 2,133
2 = 272
3 = 44

Outlets that did not meet screening criteria 10,199
Outlets not interviewed 28

1 in 5
Market composition

WHAT IS ANTIMALARIAL MARKET COMPOSITION?
Antimalarial market composition illustrates the distribution of all outlets that were found to have at least one antimalarial in stock on the day of survey. The pie charts illustrate the distribution of these antimalarial-stocking outlet types according to the public and private sector, by each outlet category.

HOW HAS ANTIMALARIAL MARKET COMPOSITION SHIFTED OVER TIME?
The private sector accounted for more than 80 percent of antimalarial-stocking outlets at each survey round. However, the market composition of the private sector has shifted over time, showing an increased contribution from private for-profit health facilities and registered pharmacies. Specifically, the proportion of outlets accounted for by private for-profit health facilities and registered pharmacies increased from 15 percent in 2010 to 33 percent in 2014. In contrast, the proportion of outlets accounted for by unregistered pharmacies and general retail outlets decreased over time from 68 percent in 2010 to 53 percent in 2014.

The public sector market composition remained relatively stable over time, though some slight declines are noted between 2011 and 2014.

MARKET COMPOSITION, BY OUTLET TYPE IN 2010, 2011, AND 2014

- Public Health Facility
- Community Health Worker
- Private Not For-Profit Facility
- Private For-Profit Facility
- Registered Pharmacy
- Unregistered Pharmacy
- General Retailer

N=1,471 in 2010; N=1,348 in 2011, and N=1,501 in 2014
HOW DOES ANTIMALARIAL MARKET COMPOSITION DIFFER AMONG URBAN AND RURAL AREAS IN 2014?

It is important to consider the market composition according to differences in urban and rural areas. For example, the contribution of the public sector in rural areas was greater than in urban areas. One-quarter of antimalarial-stocking outlets in rural areas were from the public sector compared to 10 percent in urban areas. Observing the private sector, approximately half of the antimalarial-stocking outlets in both urban and rural areas were informal private sector outlets. However, in urban areas, these were primarily unregistered pharmacies (41 percent) while in rural areas these were primarily general retailers (40 percent). In urban areas, where the public sector composition is lower, private for-profit health facilities (26 percent) and registered pharmacies (16 percent) were much more common, compared to rural areas.

These findings show diversity in the market landscape composition according to urban and rural differences, and are indicative of the types of antimalarial outlets that may be ready to provide access to antimalarial treatment for febrile patients in Kenya.

The urban and rural market landscapes are different.
Public health facility market composition was greater in rural areas.
General retailers dominated the private sector in rural areas, while unregistered pharmacies were most common in urban areas.
Antimalarial availability

Antimalarial outlet types

WHAT IS THE AVAILABILITY OF ANTIMALARIALS AMONG SCREENED OUTLETS?

The census approach involved a search for all outlets that had the potential to sell antimalarial medicines in each selected area. This graph shows the percentage of outlets that were found to have at least one antimalarial in stock on the day of the survey, among all outlets that were screened across the three survey rounds.

In the public sector, availability of antimalarials on the day of the survey in public health facilities remains high over time (greater than 90 percent). However, in 2014, a slight decline was observed in private not-for-profit facilities, from over 90 percent in 2011 to less than 80 percent in 2014. For each of the survey rounds, the availability of antimalarials among community health workers was low - less than 5 percent.

In the private sector, antimalarial availability among registered pharmacies and unregistered pharmacies remained high over time (>90 percent). However, between 2011 and 2014 there was a drop in the availability of antimalarials in private for-profit facilities. General retailers were rarely stocking antimalarials as compared to other private sector outlet types.

ARE THERE DIFFERENCES IN THE URBAN AND RURAL AREAS WITH REGARDS TO ANTIMALARIAL AVAILABILITY?

In 2014, antimalarial availability was similar across urban and rural locations among private for-profit health facilities, registered pharmacies and unregistered pharmacies. Among public health facilities, 84 percent of all screened outlets in urban locations stocked antimalarials compared with 99 percent in rural locations, suggesting universal access to antimalarials for febrile patients seeking care from rural public health facilities.

### AVAILABILITY OF ANTIMALARIALS AMONG ALL SCREENED OUTLETS OVER TIME

- **Public Health Facility**: 100% availability over time.
- **Community Health Worker**: Over 90% availability over time.
- **Private-Not-For-Profit Facility**: Over 90% availability over time.
- **Private-For-Profit Facility**: Over 90% availability over time.
- **Registered Pharmacy**: Over 90% availability over time.
- **Unregistered Pharmacy**: Over 90% availability over time.
- **General Retailer**: Over 90% availability over time.

### Key Points

- **+90%**: Availability of antimalarials in the public health facilities & pharmacies over time.
- **<5%**: Availability of antimalarials among CHW over time.
- **↓ 10%**: Decrease in antimalarial availability in not-for-profit & private for-profit facilities between 2011 & 2014.
Antimalarial market share

Role of the public and private sector

**WHAT IS ANTIMALARIAL MARKET SHARE?**
Market share of antimalarials, or the relative public and private sector distribution for all antimalarials, is estimated using information about reported distribution of each antimalarial sold or provided during the week preceding the survey.

**HOW HAS THE MARKET SHARE OF THE PUBLIC AND PRIVATE SECTOR CHANGED OVER TIME?**
Notable shifts regarding the relative market share of the public and private sector were observed over time. For the public sector, antimalarial market share hovered around 35 percent in 2010 and 2011. In 2014, public sector market share declines, with only 12 percent of antimalarials being distributed through this channel in the last survey round. In 2014, the private sector captured most of the antimalarial market share, distributing over 88 percent of antimalarials.

**ARE THERE URBAN AND RURAL DIFFERENCES?**
The private sector distributed 92 percent of the antimalarials in urban locations as compared with 72 percent in rural locations, suggesting that most antimalarials were distributed through the private sector, even in rural areas.

The findings regarding the role of the private sector in 2014 contradict preliminary evidence from the most recent Kenya Malaria Indicator Survey (MIS), which suggests that most febrile patients first seek treatment from the public sector. The ACTwatch market share differences may be explained by increased confirmatory malaria diagnosis of febrile patients in the public sector. Consequently, the public sector may be treating fewer malaria cases, and thus the decline in volumes of antimalarials being sold or distributed in the public sector may reflect more appropriate case management of febrile patients. That said, there was an overall decline in the availability of quality-assured ACT in stock on the day of survey in the public sector, suggesting that constant supply of quality-assured ACT may also explain some of the decline (see public sector readiness section). In either case, supply-side evidence points towards the relevancy of the private sector as a treatment source and the need to actively engage this channel.

90%
Private sector market share.
The private sector is responsible for nearly all antimalarial distribution in 2014.
Types of antimalarials dispensed

WHAT TYPES OF ANTIMALARIALS ARE DISPENSED IN THE PUBLIC AND PRIVATE SECTOR?
The market share information is further broken down to show the relative distribution of different types of antimalarials sold or dispensed in the public and private sector.

ARTEMISININ-BASED COMBINATION THERAPY
Overall, quality-assured ACT market share increased from 26 percent in 2010 to 57 percent in 2011 following AMFm implementation. In 2014, slight declines were observed, as overall market share of quality-assured ACT drops to 51 percent in 2014.

In 2011, most of the quality-assured ACT were marked with the ‘green leaf’ logo and accounted for half of all antimalarials distributed. However, in 2014, market share of ACT with the logo decreased to 40 percent. This overall decline in quality-assured ACT with the logo may be explained by procurement challenges and delays in the delivery of the subsidized ACT after the AMFm pilot.

The evidence suggests that the subsidy continues play a role in shaping what the private sector stocks and distributes. Quality-assured ACT market share has grown in the private sector since 2010 and most of these medicines have the leaf logo. Almost all of the quality-assured ACT audited were AL tablets, with a fraction of quality-assured ACT Artesunate Amodiaquine (ASAQ) tablets in the private sector.

NON-ORAL ARTEMISININ THERAPY
The most common type of non-artemisinin therapy sold or distributed over time is SP. Overall declines in the public sector SP market share were observed, most notably in 2014. However, SP was still commonly distributed in the private sector. While declines were observed from 2010 to 2011, increases were found in 2014 where one in four antimalarials distributed in the private sector was SP. According to government guidelines, SP should be used for Intermittent Preventive Treatment among pregnant women (IPTp) in specific coastal and lake endemic areas of the country and thus, distribution in the private sector should be limited.
Role of the public and private sector

WHAT DOES MARKET SHARE LOOK LIKE WITHIN SECTOR?
To take a closer look at the market share sector, the data are presented within each sector as a means to illustrate some important changes between 2011 and 2014 with regard to the emergence of non-quality-assured ACT. In this indicator, the market share results are presented within each sector to show distribution of antimalarials in the past week.

In the private sector, quality-assured ACT market share increased from 12 percent in 2010 to 62 percent in 2011. However, in 2014, this drops to 48 percent in the context of increasing market share for non-quality-assured ACT.

While there were many different types of non-quality assured ACT on the market, most were tablet formulations (>75 percent). Over a quarter of these were also ACT in the form of suspensions (see readiness of the private sector for more information).

The increase in non-quality assured ACT market share in the private sector may be attributed to the price of quality-assured ACT which has doubled since 2011. The increasing role of the private sector may also be attributed to increased confirmatory diagnosis and testing in the public sector and challenges with constant supply of quality-assured ACT.

Of the antimalarials distributed through the public sector, quality-assured ACT market share has increased the most: from 54 percent of sales in 2010 to 77 percent in 2014. Nearly half of these were ‘green leaf’ logo quality-assured ACTs in 2014. This increase comes in the context of decreasing market share for SP, from 20 percent in 2010 to 12 percent in 2014.

3 of 4
Number of antimalarials distributed to patients in the public sector in 2014 that were quality-assured ACT.

62
Number of non-quality-assured ACT products audited in the public sector in 2014

**Quality-assured ACT market share in the private sector was highest in 2011, immediately after the AMFm pilot, but has since showed decline in both sectors.**
Unpacking the private sector market share

**WHAT TYPES OF PRIVATE SECTOR OUTLETS DISPENSE OR SELL ANTIMALARIALS?**
The private sector antimalarial market share in 2014 represented 88 percent of all antimalarials sold. This proportion was comprised of relative market share for unregistered pharmacies (31 percent) and registered pharmacies (41 percent). Private for-profit health facilities (12 percent) and general retailers (5 percent) had less of a role.

Observing the types of antimalarial medicines being distributed in the private sector outlets, the most commonly-distributed antimalarial in registered pharmacies was quality-assured ACT at 43 percent, followed by SP at 29 percent. Distribution through unregistered pharmacies was similar: 53 percent of antimalarials sold were quality-assured ACT, 29 percent were SP. Most quality-assured ACTs sold had the ‘green leaf’ logo: about four of every five QA ACTs sold had the logo.

**40%**
Percent of antimalarials distributed by registered pharmacies in 2014.

**30%**
Percent of antimalarials distributed by unregistered pharmacies in 2014.

**1 in 2**
Number of antimalarials distributed in the private sector that were quality-assured ACTs.
Malaria blood testing availability

Outlet types that offer malaria blood testing

WHEN PEOPLE SEEK TREATMENT FOR FEVER, WHERE WILL THERE BE AN OPPORTUNITY TO CONFIRM THEIR DIAGNOSIS?

This graph shows the percentage of outlets that had a diagnostic test available, either microscopy or an RDT, among all antimalarial-stocking outlets.

In the public sector, availability of any malaria diagnosis on the day of survey among antimalarial-stocking public health facilities increased over time from 46 percent in 2010 to over 50 percent in 2011, and 94 percent in 2014.

In the private sector, for-profit health facilities showed a slight decline in malaria diagnostic availability between 2010 and 2011, but increases were then observed in 2014 with over 70 percent of these outlets having malaria diagnostic blood testing available. Among registered and unregistered pharmacies, availability of malaria diagnosis remained relatively constant over time and hovered around 20 percent in 2014.

ARE THERE DIFFERENCES IN DIAGNOSTIC AVAILABILITY ACROSS URBAN AND RURAL AREAS?

Data trends suggest slightly higher availability of malaria blood testing (RDT or microscopy) among antimalarial-stocking outlets in urban versus rural areas, with the exception of public health facilities which had generally similar levels of availability.

94%
Availability of diagnostic testing in public health facilities in 2014

~20%
Availability of diagnostic testing among registered and unregistered pharmacies

↑30%
Increase in malaria diagnosis availability in private for-profit facilities between 2011 and 2014.

While 72 percent of antimalarials were sold through registered and unregistered pharmacies, fewer than 20 percent of these offered diagnostic testing.
Malaria blood testing market share

Was microscopy or RDT used most often in 2014?

**HOW IS MARKET SHARE OF MALARIA DIAGNOSTICS ESTIMATED?**
Market share of malaria diagnostics - the relative public and private sector distribution for all diagnostic tests administered - was estimated using information regarding the number of malaria tests provided during the week preceding the survey.

In 2014, more than half of all malaria blood tests were performed by public sector outlet providers and 47 percent by private sector outlets. The majority of tests performed used microscopy. Overall, malaria RDT accounted for less than one-third of all tests performed (25 percent) despite increases in RDT availability.

Among RDT performed within public sector outlets, the majority (99 percent) were manufactured by Access Bio Inc. Within the private sector, Access Bio Inc. accounted for 64 percent of the market share followed by Standard Diagnostics with 19 percent.

**WHAT TYPES OF PRIVATE SECTOR OUTLETS DISPENSE OR SELL MALARIA DIAGNOSTIC TESTS?**
Private for-profit facilities conducted most of the malaria blood tests performed by the private sector (42 percent of all tests performed, and 94 percent of all private sector tests). Other private sector providers, including registered and unregistered pharmacies, did not typically dispense malaria tests, despite commonly distributing antimalarial medicines. This indicates that, within these private sector outlets, many febrile patients do not receive a confirmatory diagnostic test prior to treatment.

**Graph:**
- **53%**
  - Market share of tests distributed through the public sector

- **3 of 4**
  - Tests performed were microscopy rather than RDT

**MALARIA BLOOD TESTING MARKET SHARE, BY OUTLET TYPE, 2014**
This section focuses specifically on the public sector in Kenya and how the antimalarial and diagnostic market landscape has changed over time. These data are a means to investigate the public sector readiness, performance, and improvement for malaria case management. The results for the public sector focus on the availability of ACT, SP, treatment for severe malaria, and diagnostic capacity among the antimalarial-stocking public health facilities.

ACT AVAILABILITY IN PUBLIC HEALTH FACILITIES
ACT availability increased between 2010 and 2011, but declines were observed during the last survey round, where availability dropped by 15 percentage points. Similar patterns were seen for quality-assured ACT, where availability increased from 88 percent in 2010 to 97 percent in 2011 but dropped again in 2014 to 83 percent.

The availability of co-paid quality-assured ACT marked with the ‘green leaf’ logo decreased among antimalarial-stocking public health facilities from around 70 percent in 2011 to 30 percent in 2014.

The image below depicts availability of each antimalarial type among public health facilities, as a proportion of all antimalarial-stocking public facilities.
SP AVAILABILITY IN PUBLIC HEALTH FACILITIES
Kenya has designated areas for the use of SP for IPTp in parts of the country where transmission is intense throughout the year, and *P. falciparum* malaria prevalence is historically greater than 20 percent.

In 2010, SP was available in three quarters of the public health facilities, which declined to around 60 percent in 2011. By 2014, availability of antimalarial stocking public health facilities was 15 percent.

A further analysis by target areas (endemic areas where SP should be administered according to national policy) and non-target areas showed SP availability among antimalarial-stocking health facilities in target areas was higher on average than availability in non-target areas. Half of the public health facilities in target areas had SP on-hand, compared to 2 percent of public health facilities in non-target areas.

IS TREATMENT FOR SEVERE MALARIA AVAILABLE IN PUBLIC HEALTH FACILITIES?
Treatments for severe malaria include artesunate intravenous (IV) or intramuscular (IM), quinine IV/IM, artemether IV/IM, artemotil IV/IM, and artesunate suppositories. Severe malaria treatment availability among antimalarial-stocking public health facilities was similar over time and some slight increases were observed between 2010, at around 70 percent availability, to 80 percent in 2014, indicating the readiness of the public sector to provide treatment for severe malaria among patients in need.

Fifty percent of public health facilities had artesunate injection, the first line treatment for severe malaria, available in 2014.

1 in 2
Number of the public health facilities in endemic target areas that had SP in stock, compared to 2 percent of public health facilities in non-target areas.
Types of malaria diagnostic tests that were administered in public health facilities

MICROSCOPY AND RDT AVAILABILITY IN THE PUBLIC SECTOR

The capacity for the public sector to provide malaria confirmatory diagnostic testing in Kenya is high. Blood testing availability increased among antimalarial-stocking public health facilities from 46 percent in 2010 to over 50 percent in 2011 and 94 percent in 2014. This is attributed to both increases in microscopy and RDT.

Malaria microscopy availability increased over time among antimalarial-stocking public health facilities from 41 percent in 2010 to 61 percent in 2014. While malaria RDT availability was less than 10 percent in the public sector in 2011, by 2014 availability increased to 68 percent. This increase in availability of RDT is indicative of the roll out and scale up by the National Malaria Control Program, however, in 2014, most tests performed were still microscopy as indicated by the market share data.

ARE THERE DIFFERENCES IN THE URBAN AND RURAL AREAS WITH REGARDS TO MALARIA DIAGNOSTIC AVAILABILITY IN THE PUBLIC SECTOR?

In general there was slightly higher availability for microscopy in urban areas as compared to rural areas. Malaria microscopy was more commonly available among urban versus rural public health facilities (71 percent versus 54 percent). Similar patterns were found for RDT availability among antimalarial-stocking outlets, which was higher among public health facilities in rural (73 percent) versus urban areas (62 percent).

7 in 10
Public health facilities that had RDT available in 2014.

Increases in availability of RDT is indicative of the roll out and national scale up, however, as of 2014 most tests performed were still microscopy.
Private sector readiness

This section addresses the private sector readiness to provide appropriate case management according to Kenya’s national treatment guidelines. It addresses availability of ACT, including non-quality-assured ACT, SP, and malaria diagnostic capacity. Price is also presented.

In 2014, most of the quality-assured ACT have the ‘green leaf’ logo. This is suggestive that the Global Fund subsidy continues to play a role in shaping what the private sector stocks and distributes.

ACT AVAILABILITY
In the private sector, ACT availability remained high among registered pharmacies over time (>90 percent). ACT availability among antimalarial-stocking outlets increased over time among private for-profit facilities from around 60 percent in 2010 to 84 percent in 2011 and over 90 percent in 2014. Unregistered pharmacies showed a similar pattern where availability from 2011 to 2014 was around 90 percent. While stocking ACT among general retailers is lower than other outlet types, increases were also observed over time. While no general retail outlets were stocking ACT in 2010 or 2011, in 2014 around one in four general retailers had ACT in stock.

QUALITY-ASSURED ACT AVAILABILITY
Similar to patterns in ACT availability, quality-assured ACT availability among antimalarial-stocking private sector outlets increased over time between 2010 and 2011. These increases were maintained in 2014 among private for-profit facilities (2010, 37 percent; 2011, 78 percent; 2014, 84 percent), unregistered pharmacies (2010, 33 percent; 2011, 85 percent; 2014, 84 percent) and general retailers (2010, 0 percent; 2011, 23 percent; 2014, 26 percent). Most of these quality-assured ACT had the ‘green leaf’ logo.

QUALITY-ASSURED ACT AVAILABILITY WITH THE LOGO
The availability of co-paid quality-assured ACT marked with the ‘green leaf’ logo remained high (>70%) between 2011 and 2014 among private for-profit health facilities, registered pharmacies and unregistered pharmacies. One-fifth of antimalarial-stocking general retailers had quality-assured ACT with the ‘green leaf’ logo in stock in 2011 and 2014.
1 in 4
Number of general retailers stocking ACT in 2014

>80
Percent of private facilities and pharmacies stocking quality-assured ACT in 2014

>70
Percent of private facilities and pharmacies stocking quality-assured ACT with the ‘green leaf’ logo in 2014
Notable increases in non-quality-assured ACT market share were observed in Kenya in 2014. This was also reflected in private sector availability of non-quality-assured ACT which had increased over time, namely among private for-profit facilities and unregistered pharmacies.

NON-QUALITY ASSURED ACT AVAILABILITY

The majority of antimalarial-stocking registered pharmacies had non-quality assured ACT in stock across survey rounds (more than 85 percent). Availability increased over time among unregistered pharmacies from almost one in three stocking non-quality assured ACT in 2010 to one in two in 2014. Availability of non-quality assured ACT among private for-profit facilities hovered around 40 percent. General retailers rarely stocked non-quality assured (less than 5 percent) ACT across survey round.

WHAT TYPES OF NON-QUALITY ASSURED ACT WERE AUDITED?

A variety of non-quality-assured ACT products were audited in the private sector. The majority of these were tablet formulations (more than 75 percent) including non-quality-assured AL tablets (19 percent) and non-quality-assured Dihydroartemisinin-piperaquine (DHA PPQ) tablets (32 percent).

Common manufacturers of non-quality assured AL and DHA PPQ included Bliss GVS Pharmaceuticals (AL and DHA PPQ) and Beijing Holley-Cotec Pharmaceuticals (DHA PPQ).
Types of malaria diagnostic tests that were administered in the private sector

MICROSCOPY AND RDT AVAILABILITY IN THE PRIVATE SECTOR
Malaria microscopy availability increased over time among antimalarial-stocking private for-profit facilities (2010, 49 percent; 2011, 40 percent; 2014, 61 percent). Malaria microscopy was generally not available among registered pharmacies (8 percent in 2014) and unregistered pharmacies (6 percent in 2014). Availability of malaria RDT among antimalarial-stocking outlets was less than 10% across all outlet types in 2010. By 2014, RDT availability remained relatively low among private for-profit facilities (29 percent), registered pharmacies (15 percent) and unregistered pharmacies (12 percent).

ARE THERE DIFFERENCES IN THE PRIVATE SECTOR ACROSS URBAN AND RURAL AREAS WITH REGARDS TO MALARIA DIAGNOSTIC AVAILABILITY?
Malaria microscopy was more commonly available among urban versus rural private for-profit health facilities (66 percent versus 45 percent). Among private sector outlet types, data trends suggest slightly higher availability in urban versus rural areas.

MALARIA RDT AVAILABILITY OVER TIME IN THE PRIVATE SECTOR, 2014

MALARIA MICROSCOPY AVAILABILITY OVER TIME IN THE PRIVATE SECTOR, ACROSS SURVEY ROUND
A closer look at SP availability in the private sector

SP is still recommended by the World Health Organization and used across sub-Saharan Africa for IPTp. Kenya has recently identified specific sub-national target areas for IPTp in endemic areas. Declines in readiness for IPTp at the national level in public health facilities may be explained by this targeting. However, the vast majority of antimalarial-stocking private sector outlets continued to stock and distribute the non-artemisinin therapy SP.

### A SNAPSHOT OF SP IN THE PRIVATE SECTOR

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of SP packages audited in the private sector</td>
<td>1,261</td>
</tr>
<tr>
<td>Percent of SP that are tablet formulation</td>
<td>99%</td>
</tr>
<tr>
<td>Number of SP packages that contain 3 tablets per package</td>
<td>4 in 5</td>
</tr>
<tr>
<td>Number of SP manufacturers</td>
<td>12</td>
</tr>
<tr>
<td>Percent of audited SP that is manufactured locally in Kenya</td>
<td>81%</td>
</tr>
<tr>
<td>Percent of SP that are quality-assured according to WHO and Global Fund guidelines</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
1 SP distributed in the private sector was usually available in packages containing 3 tablets and typically marketed for use of IPTp. The most common SP brands audited in Kenya in 2014 included Fanlar® manufactured by Dawa LTD (37 percent), Malodar® (22 percent) manufactured by Laboratory and Allied LTD, and Malafin® manufactured by Universal Corporation LTD (10 percent of all brands audited) – all three brands are manufactured in Kenya.

2 Some products specify that SP is indicated for Intermittent preventive treatment of malaria in pregnancy (see below example of Fanlar®).

3 Product audits identified several brands and manufacturers of SP. 12 unique SP brands were available in Kenya.

4 The majority of SP products audited were manufactured locally in Kenya (80 percent). Locally-manufactured SP in Kenya is also distributed to neighboring countries. For example, many of the SP products audited in Madagascar’s recent outlet survey originated from Kenya.

**FANLAR: AN EXAMPLE**

Fanlar was commonly audited in Kenya, accounting for around 37 percent of all of the 3,000 SP brands that were audited. Fanlar packaging indicates usage for IPTp.

**MALAFIN**

Malafin was commonly audited in Kenya, accounting for around 10 percent of all of the 3,000 SP brands that were audited.
Private sector price

Price of ACT, SP and malaria diagnostics

WHAT IS THE PRICE OF ACT COMPARED TO SP?
The median private sector price for one adult equivalent treatment dose (AETD) of quality-assured ACT decreased between 2010 and 2011. However, the price of quality-assured ACT more than doubled between 2011 and 2014 and in 2014 remained more than 2.5 times more expensive than SP. The price of SP remained similar over time.
The price of non-quality-assured ACT has increased over time ($4.61 in 2010 to $5.25 in 2014). In 2014, non-quality-assured ACT (tablet formulation) was three times as expensive as quality-assured ACT. The median private sector price for one AETD of quality-assured ACT with the ‘green leaf’ logo was similar to the price of quality-assured ACT without the logo in 2011 and 2014.

WHAT IS THE PRICE OF RDT?
The median private sector price for malaria blood testing with an RDT, inclusive of service and consultation fees, was $1.13 across all private sector outlet types for both adults and children under five.

PRIVATE SECTOR PRICE OF QUALITY-ASSURED ACT AND SP, ACROSS SURVEY ROUND

2010: 5
2011: 1
2014: 2.5

The ratio of the price of quality-assured ACT compared to SP across survey rounds.
Summary

Recent public and private sector strategies to improve malaria case management in Kenya have largely been successful, and point to the importance of a private sector subsidy to improve access to affordable, high-quality ACT. However, there are still challenges, notably in the private sector, where barrier towards adherence to national treatment guidelines exist, specifically ACT price, the emergence of non-quality-assured ACT, and the persistent use, distribution, and low price of SP.

There is high readiness among public health facilities to provide appropriate malaria case management for febrile patients in Kenya. At the time of the 2014 national outlet survey, around 85 percent of antimalarial stocking public health facilities had quality-assured ACT in stock. However, slight declines in quality-assured ACT availability have been noted since the 2011 AMFm pilot, where quality-assured ACT availability was almost 100 percent in 2011.

More than 90 percent of public health facilities had malaria testing available (RDT or microscopy) and this has increased substantially over time.

Readiness to treat patients with severe malaria was also observed, with 80 percent of public health facilities stocking any treatment for severe malaria, and 50 percent stocking the first line treatment for severe malaria, artesunate injection. This is promising given the renewed policy for first line treatment of severe malaria were only implemented in 2013. Changes in treatment policy regarding the provision of IPTp to pregnant women living in endemic areas were also reflected in the findings: SP was available in half of the public health facilities located in these targeted areas. This result indicates improved readiness for public health facilities to deliver IPTp using SP as indicated by national policy.

The majority of antimalarial distribution in Kenya occurred in the private sector in 2014, with 90 percent of all antimalarials distributed through this channel. This reflects some change over time, where contributions from the public sector in 2010 and 2011 were higher, with around 30 percent of antimalarials distributed through this channel. The change in the role of the public and private sector in the antimalarial market may be reflected in increased administration of confirmatory malaria diagnostic tests in the public sector. Nevertheless, in 2014, the private sector accounted for most of the antimalarial distribution, even in rural areas, suggesting the importance of continued engagement with this sector.

Antimalarial distribution in the private sector occurred primarily among registered and unregistered pharmacies. Continued engagement with these private sector outlet types may be the most effective way to ensure adherence to national treatment guidelines in the private sector.

In 2011, the private sector price of quality-assured ACT was almost equivalent to SP. However, in 2014, the private sector price of quality-assured ACT was more than three times as expensive as SP. This reflects a four-fold increase in the price of quality-assured ACT in 2011, when it cost $0.52 per adult dose, to $1.54 in 2014. This relatively higher price may be a barrier to ACT uptake where antimalarial treatment is being sought and dispensed in the private sector for fever case management.

Low availability of malaria testing in the private sector was also seen in 2014, with only one in four antimalarial-stocking private sector outlets having malaria diagnostic capacity. Malaria blood testing was also more commonly available in urban as compared to rural areas. Sub-optimal fever case management practices in the private sector will be important to examine and address to ensure continued progress towards ensuring that all malaria cases are detected and treated according to national policy. Limited availability of malaria testing in the private sector is likely to be a barrier to increasing coverage of confirmatory testing prior to treatment, given the high relative antimalarial market share for the private sector.
Other challenges to quality-assured ACT uptake persist. These include the availability and use of SP for case management in the private sector. SP is available from 12 manufacturers in Kenya and is inexpensive relative to ACT. While the relative market share for SP in the private sector has declined over time, 1 out of every 4 antimalarials distributed in the private sector was SP in 2014. This suggests ongoing demand for this medicine despite discontinuation of its use for case management due to drug resistance. Drug quality of the products manufactured locally or internationally is unknown but is of interest given high availability and use, including that for IPTp.

Almost half of the anti-malarials distributed in Kenya were quality-assured ACT, mostly sold through the private sector. However, a key change in the antimalarial market observed in Kenya in 2014 as compared with previous surveys was the availability and distribution of ACT that was not quality-assured according to global manufacturing standards. Non-quality-assured ACT were previously found in the private sector but increases were observed over time among private for-profit facilities and unregistered pharmacies in 2014. That year, non-quality-assured ACT accounted for one-fifth of all antimalarial distribution, chiefly in the private sector. Availability and distribution of non-quality-assured ACT among private sector outlets was also higher in urban versus rural areas. Availability and use of these non-quality-assured treatments should be closely monitored given the threat that substandard combination therapies pose to artemisinin-based drug efficacy.
ACTwatch is a multi-country research project designed to provide timely, relevant, and high quality antimalarial market evidence. Launched in 2008 with funding from the Bill and Melinda Gates Foundation, it is currently implemented in 13 countries with additional funding from UNITAID and the DFID. Standardized tools and approaches are employed to provide comparable data across countries and over time.

Project achievements include the implementation of over 35 outlet surveys, most of them nationally representative of the public and private sector, a number of peer reviewed publications, and a repository of antimalarial medicines and rapid diagnostic tests on the website (www.actwatch.info). The project has informed malaria control and elimination strategies and priorities for national control programs and their partners.

For more information contact: info@actwatch.info or the Principal Investigator: mlittrell@psi.org