Multi-Country Independent Evaluation Report

Independent Evaluation of the

Affordable Medicines Facility - malaria (AMFm) Phase 1

Final Report

September 28, 2012

Submitted to:

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Submitted by:

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This version of the report includes the following information not previously included in the Preliminary Report of July 18, 2012: (i) results from the remote areas study; (ii) results from the logo study (exit interviews and focus group discussions); (iii) an annex describing the Consultative Forum held in June 2012 in Nairobi; and (iv) some new content to Section 1.2 Overview of the AMFm, including orders requested, approved and delivered as of end September 2012. None of this new information has affected the assessment of the achievements of the Phase 1 benchmarks that were included in the preliminary report of July 18, 2012.

This version of the report does not include findings from the endline household surveys. Those findings will be included in a supplemental report when endline data become available.

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List of abbreviations

ACT	Artemisinin-Based Combination Therapy
ADDO	Accredited Drug Dispensing Outlets
AETD	Adult Equivalent Treatment Dose
AGOA	Africa Growth Opportunity Act
AHC	Ad Hoc Committee
AL	Artemether-Lumefantrine
ALMA	African Leaders Malaria Alliance
AM	Antimalarial
AMT	Artemisinin monotherapy
AMFm	Affordable Medicines Facility – malaria
AMFmCC	AMFm Coordinating Committee
API	Active Pharmaceutical Ingredient
ARI	Acute Respiratory Infection
ASAQ	Amodiaquine and Artesunate
BCC	Behavior change communication
CAPSS	Consortium for ACT Private Sector Subsidy
CCA	Community Change Agent
CCM	County Coordinating Mechanism
CEM	Cohort Event Monitoring
CERMES	*Centre de Recherches Médicales et Sanitaires*
CHAG	Christian Health Association of Ghana
CHAI	Clinton Health Access Initiative
CHW	Community Health Worker
CI	Confidence Interval
CIERPA	*Centre International d'Etudes et de Recherches sur les Populations Africaines*
CIF	Cost-Insurance-Freight
CMS	Central Medical Stores
CP	Condition Precedent
CPC	Consumer Protection Council
CPD	Continuing Professional Development
CRDH	*Centre de Recherche pour le Développement Humain*
CRS	Catholic Relief Services
CSI	*Centre de Santé Intégré*
DAMM	*Direction d'Agence de Medicament de Madagascar*
DCs	Data Contributors
DFID	Department for International Development
DHAP	Dihydroartemisinin-Piperaquine
DHS	Demographic and Health Survey
DLDB	*Duka la Dawa Baridi*
DNDi	Drugs for Neglected Diseases initiative
DOMC	Division of Malaria Control
ERP	Expert Review Panel
E2Pi	Evidence to Policy Initiative
FBO	Faith-Based Organization

FCO	Focal Coordinating Office
FGD	Focus group discussion
FLB	First Line Buyer
FMOH	Federal Ministry of Health
FOB	Free on Board
GDP	Gross Domestic Product
Gh₵	Ghana Cedis
GHS	Ghana Health Service
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GoU	Government of Uganda
HAI	Health Action International
HBC	Home Based Care
HMM	Home Management of Malaria
HPLC	High-performance Liquid Chromatography
ICCM	Integrated Community Care and Management
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IE	Independent Evaluation/Evaluator
IEC	Information, Education and Communication
IPT	Intermittent Preventive Treatment
IMCI	Integrated Management of Childhood Illnesses
IOM	Institute of Medicine
IQR	Interquartile Range
IRB	Institutional Review Board
IRS	Indoor Residual Spraying
IOM	Institute of Medicine
ITN	Insecticide-Treated Net
JHU	Johns Hopkins University
JMS	Joint Medical Stores
KAP	Knowledge, Attitude, and Perception
KCM	Kenya Country Mechanism
KEMSA	Kenya Medical Supplies Agency
KII	Key Informant Interview
LANSPEX	*Laboratoire National de Santé Publique et d'Expertise*
LCS	Licensed Chemical Sellers
LFA	Local Fund Agent
LGA	Local Government Area
LLIN	Long-lasting Insecticidal Net
LTR	Local Technical Representative
LSHTM	London School of Hygiene and Tropical Medicine
MEEDS	Malaria Early Epidemic Detection System
MICC	Malaria Interagency Coordinating Committee
MICS	Multiple Indicator Cluster Survey
MIS	Malaria Indicator Survey
MMV	Medicines for Malaria Venture
MOF	Ministry of Finance
MOFEA	Ministry of Finance and Economic Affairs

MOH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MSA	Master Supply Agreement
MVU	Mobile Video Unit
NAFDAC	National Agency for Food and Drug Administration and Control
nAT	Non-Artemisinin Therapy
NDA	National Drug Authority
NGO	Nongovernmental Organization
NHIS	National Health Insurance Scheme
NHS	National Health System
NMCP	National Malaria Control Program
NMS	National Medical Stores
NOC	National Oversight Committee
nQAACT	Non-Quality-Assured Artemisinin-Based Combination Therapy
NSA	National Strategy Application
OJT	On-the-Job Training
ONEN	*Organisation National des Educateurs Novateurs*
OS	Outlet survey
ONPPC	*Office National des Produits Pharmaceutiques et Chimiques*
OTC	Over-the-Counter
PCN	Pharmacists Council of Nigeria
PDA	Personal Digital Assistant
PHCC	Primary Health Care Center
PHCU	Primary Health Care Unit
PMI	President's Malaria Initiative
PNLP	*Programme National de Lutte contre le Paludisme*
POM	Prescription-Only Medicines
POP	Part One Pharmacy
PPB	Pharmacy & Poisons Board
PPS	Probability Proportional to Size
PR	Principal Recipient
PSI	Population Services International
PSM	Procurement Supply Management
PV	Pharmacovigilance
PwC	PricewaterhouseCoopers
QAACT	Quality-Assured Artemisinin-Based Combination Therapy
QCIL	Quality Chemicals Industries Limited
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RFP	Request for Proposal
RMCG	Role Model Care Givers
RMS	Regional Medical Stores
RRP	Recommended Retail Price
RSE	Relative standard error
SADC	Southern Africa Development Community

SC	Steering Committee
SI	Supporting Intervention
SMOH	State Ministry of Health
SOP	Standard Operating Procedures
SP	Sulfadoxine-Pyrimethamine
SR	Sub-Recipient
SSA	sub-Saharan Africa
SSF	Single Stream Funding
SuNMaP	Support to National Malaria Control Program
SURE	Securing Ugandans' Rights to Essential Medicines
TANAM	Tanzania National Malaria Movement
TERG	Technical Evaluation Reference Group
TFDA	Tanzania Food and Drug Authority
TLC	*Technologie de l'Information et de Communication*
TWG	Technical Working Group
TZ-RDIP	Tanzania Remote Distribution Incentive Program
UGP	*Unité de Gestion de Projet*
UN	United Nations
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
USD	United States Dollar
VHT	Village Health Team
VPP	Voluntary Pooled Procurement
WHO	World Health Organization
WHO/AFRO	World Health Organization/Africa region
YGC	Yakubu Gowon Centre
ZFDB	Zanzibar Food and Drug Board
ZILS	Zanzibar Integrated Logistics System
ZMCP	Zanzibar Malaria Control Program

Definition of key terms

Key terms	Definition
Adult Equivalent Treatment Dose (AETD)	An AETD is the number of milligrams (mg) of an antimalarial drug needed to treat a 60 kg adult.
Antimalarial	Any medicine recognized by WHO for the treatment of malaria. Medicines used solely for the prevention of malaria are excluded from analysis in this report.
Artemisinin-Based Combination Therapy (ACT)	An antimalarial that combines artemisinin or one of its derivatives with an antimalarial or antimalarials of a different class.
Artemisinin monotherapy	An antimalarial medicine that has a single active compound, where this active compound is artemisinin or one of its derivatives.
Booster Sample	A booster sample is an extra sample of units (or in this case outlets) of a type not adequately represented in the main survey, but which are of special interest. In this survey, we have included a booster sample of public health facilities and Part One pharmacies in the entire district that includes the selected subdistrict, consisting of all of the public health facilities and Part One pharmacies in the district that are not in the selected subdistrict.
Censused subdistrict	A subdistrict where field teams conducted a full census of all outlets with the potential to sell antimalarials.
Combination therapy	The use of two or more classes of antimalarial drugs/molecules in the treatment of malaria that have independent modes of action.
Dosing/treatment regimen	The posology or timing and number of doses of an antimalarial used to treat malaria. This schedule often varies by patient weight.
Enumerated Outlets	Outlets that were visited by a member of one of the field teams and from which at a minimum basic descriptive information was collected (Sections C1-C9 of the outlet survey questionnaire).
First-line treatment	The government-recommended treatment for uncomplicated malaria.
Monotherapy	An antimalarial medicine that has a single mode of action. This may be a medicine with a single active compound or a synergistic combination of two compounds with related mechanisms of action.
Non-artemisinin therapy	An antimalarial medicine that does not contain artemisinin or any of its derivatives.
Outlet	Any point of sale or provision of a commodity to an individual. Outlets are not restricted to stationary points of sale and may include mobile units or individuals.
Pediatric formulation	Antimalarial drug packaged specifically for children.
Quality-Assured Artemisinin-Based Combination Therapies (QAACTs)	QAACTs are ACTs that comply with the Global Fund to Fight AIDS, Tuberculosis and Malaria's Quality Assurance Policy. For the purpose of the Independent Evaluation, a QAACT is any ACT that appeared on the Global Fund's indicative list of antimalarials meeting the Global Fund's quality assurance policy prior to baseline or endline data collection (see http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#General), or which previously had C-status in an earlier Global Fund quality assurance policy and was used in a program supplying subsidized ACTs. At baseline, QAACTs were defined as any ACT that appeared on the Global Fund's indicative list of antimalarials meeting its quality assurance policy as at June 2010, or which previously had C-status in an earlier Global Fund quality assurance policy and was used in a program supplying subsidized ACTs. At endline, QAACTs were defined as any ACT that appeared on the Global Fund's indicative list of antimalarials meeting its quality assurance policy as of September 2011, or which previously had C-status in an earlier Global Fund quality assurance policy and was used in a program supplying subsidized ACTs.
Rapid-Diagnostic Test (RDT) for malaria	A test used to confirm the presence of malaria parasites in a patient's bloodstream.
Screened	An outlet that was administered the screening questions (S1 to S4) of the outlet survey questionnaire (see screening criteria).
Screening criteria	The set of requirements that must be satisfied before the full questionnaire is administered. In this survey, an outlet met the screening criteria if (1) it had antimalarials in stock at the time of the survey visit, or (2) it reported having stocked them in the past three months.
Subdistrict (SD)	The primary sampling unit, or cluster, for the outlet survey. It is an administrative unit that has a population size of approximately 10,000 to 15,000 inhabitants. These units frequently are defined by geographical, health or political boundaries.
Treatment/dosing regimen	The posology or timing and number of doses of an antimalarial used to treat malaria. This schedule often varies by patient weight.

Executive Summary

Overview of the independent evaluation

The success of malaria control efforts depends on a high level of coverage in the use of effective antimalarials such as artemisinin-based combination therapies (ACTs). Although these antimalarials have been procured in large amounts by countries, evidence suggests that ACT use still remains far below target levels.

In response to this issue, the Affordable Medicines Facility – malaria (AMFm) hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) was set up. AMFm comprises three key elements: (i) price reductions through negotiations with ACT manufacturers; (ii) a buyer subsidy through a 'co-payment' for ACTs at the top of the global supply chain; and (iii) supporting interventions to promote appropriate use of ACTs. Examples of these supporting interventions include training providers and outreach to communities to promote ACT use. All ACTs subsidized through AMFm bear a green leaf logo on their packaging.

The four main objectives of AMFm are to: (i) to increase ACT affordability; (ii) to increase ACT availability; (iii) to increase ACT use, including among vulnerable groups; and (iv) to "crowd out" oral artemisinin monotherapies, chloroquine and sulfadoxine-pyrimethamine (SP) by gaining market share. AMFm is being tested in a first phase that includes nine pilots in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Republic of Tanzania (mainland and Zanzibar) and Uganda.

The Independent Evaluation (IE) of AMFm was designed to assess whether, and to what extent, AMFm Phase 1 achieves its objectives. The IE is part of a multi-faceted monitoring and evaluation framework developed for AMFm Phase 1. Through a competitive bid, the Global Fund contracted ICF International and the London School of Hygiene and Tropical Medicine (LSHTM) to conduct the IE. The IE was carried out in all of the currently operational Phase 1 pilots (Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania mainland, Uganda, and Zanzibar). In addition, the Global Fund contracted with Data Contributors (DCs) that were responsible for in-country fieldwork and data analysis for the outlet surveys. These institutions are Population Services International (PSI), Drugs for Neglected Diseases initiative (DNDi), and Centre de Recherche pour le Développement Humain (CRDH). PSI was responsible for the work in Kenya, Madagascar, Nigeria, Uganda, Tanzania mainland (which was subcontracted to the Ifakara Health Institute) and Zanzibar. For the surveys in Madagascar, Nigeria and Uganda the IE has drawn on outlet surveys commissioned prior to AMFm and carried out by PSI's ACTwatch Project (www.actwatch.info) through a grant from the Bill and Melinda Gates Foundation, which either partially or fully funded outlet survey rounds in these Phase 1 pilots. DNDi subcontracted with the Komfo Anokye Teaching Hospital, Kumasi, to undertake the work in Ghana. CRDH subcontracted with the Centre International d'Etudes et de Recherches sur les Populations Africaines (CIERPA) to undertake the work in Niger.

The IE is based on a non-experimental design with a pre- and post-test intervention assessment in which each participating country is treated independently as a case study. The evaluation includes two major components: (1) a pre-intervention (baseline) and post-intervention (endline) study of key outcomes through nationally representative outlet surveys and use of secondary household survey data; and (2) documentation of key features of the context at baseline and endline and the AMFm implementation process in each country through key informant interviews and document review, to facilitate interpretation of the changes in outcomes over the implementation period and to judge whether any observed changes are likely to be due to AMFm. These data sources are supplemented by additional primary data on outlets in remote areas in Ghana and Kenya; and primary data on user views of the AMFm logo in four pilots (Ghana, Kenya, Madagascar and Nigeria). Operational research conducted by other groups was also reviewed. The results of the baseline and endline outlet and household surveys are compared to the AMFm success metrics (see below). The findings on achievement of success metrics are synthesized with the process and context data collected for each country and the other studies outlined above to assess the performance of AMFm in each operational pilot, and to help learn how and why this new model unfolds in a variety of contexts, while drawing lessons that can help future operations.

Methods for the IE outlet surveys were built on those developed for the ACTwatch project, and cover outlets across the public, private for-profit and private not-for-profit sectors in rural and urban areas. Baseline outlet surveys were conducted between April and December 2010 (except Nigeria which was conducted from September to November 2009), and endline outlet surveys were conducted between October 2011 and January 2012. The midpoint of endline survey fieldwork was between 6.5 and 15.5 months after the arrival in the country of the first AMFm copaid drugs.

For the purpose of analysis, antimalarials were split into three categories: non-artemisinin therapy (nAT) (e.g., SP, amodaquine, and quinine), artemisinin monotherapy (AMT) and artemisinin-based combination therapy (ACT). AMTs were further classified into oral and non-oral AMTs, as while non-oral AMT are recommended for treatment of severe malaria, the removal of oral AMTs from the market is a key policy goal. ACTs were further subdivided into those that met the Global Fund's standards as "quality-assured ACTs" (QAACTs) and those that did not. At endline, QAACTs are further classified based on whether the AMFm green-leaf logo was present on the packaging, as a proxy for whether the product was subsidized by AMFm. Antimalarial volume and price data are reported in terms of adult equivalent treatment doses (AETDs). An AETD is defined as the number of milligrams (mg) of an antimalarial drug needed to treat a 60 kg adult. Price data were adjusted to 2010 USD.

Existing nationally representative household survey reports and data were used to extract information for the ACT use indicators from four types of national surveys (DHS, MICS, MIS and ACTwatch). At the time this report was written, no endline household survey data were available for any countries. A supplemental report, including revised tables and a

discussion of the household survey results in the interpretation of the success metrics in Chapter 8, will be prepared if a sufficient quantity of endline data becomes available in the coming months.

Interpretation and operationalization of success metrics

The Global Fund's AMFm Ad Hoc Committee commissioned the Evidence to Policy Initiative (E2Pi) to propose benchmarks for outcomes which could realistically be expected in the first and second years of the pilots. To inform the setting of the benchmarks, the E2Pi team conducted a literature review and key informant interviews to review the experience of relevant programs and developed metrics and benchmarks for QAACT availability, price, market share and ACT use.

The IE has refined and operationalized these metrics for use in this report as follows:

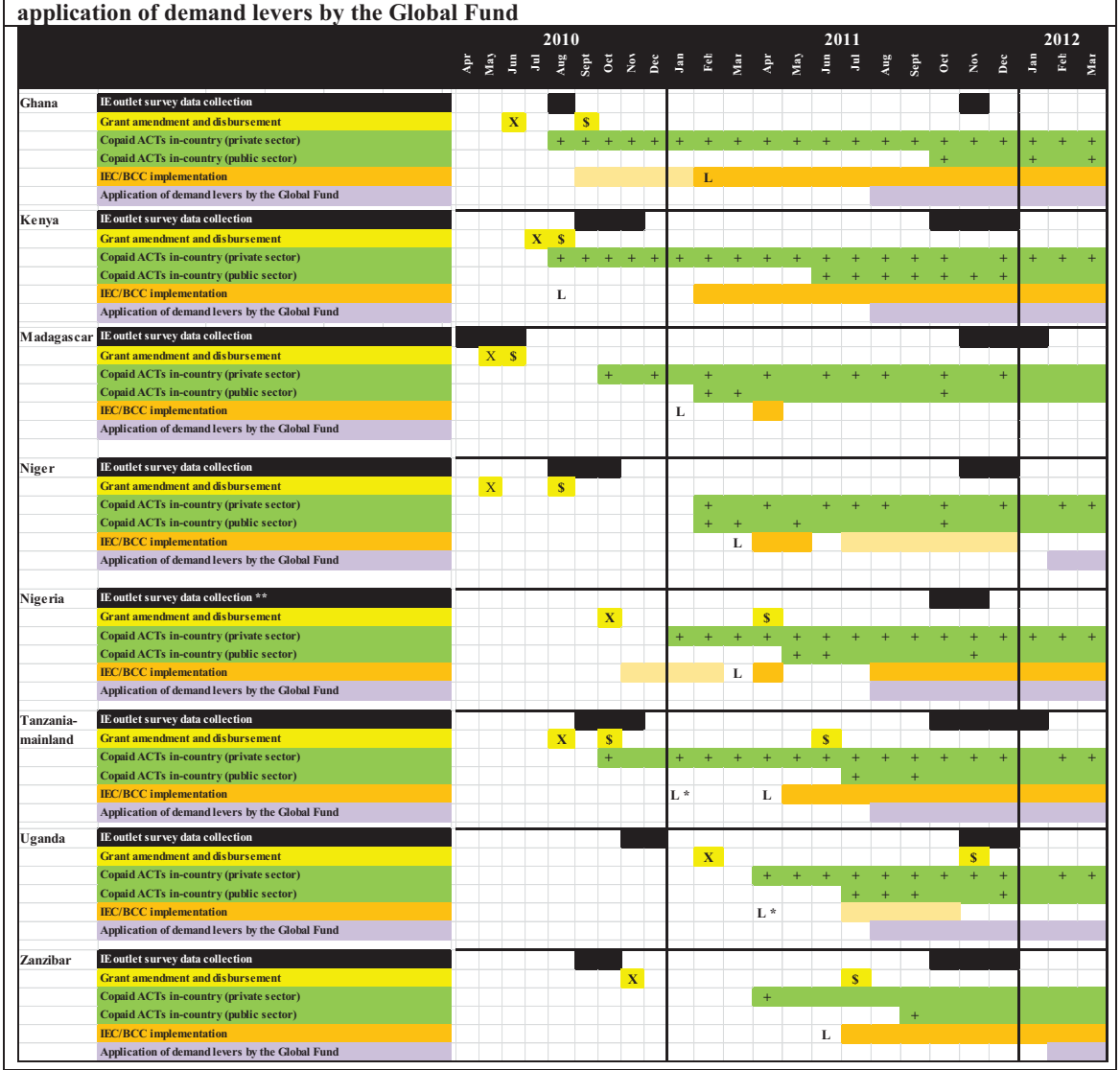
- Benchmark 1: At least a 20 percentage point increase from baseline to endline in the percentage of outlets stocking ALL QAACTs (both with and without the AMFm logo)
- Benchmark 2: In private for-profit outlets, a ratio of the median price of QAACTs with the AMFm logo to the median price of the most popular antimalarial that is not a QAACT in tablet form of less than 3.
- Benchmark 3: In private for-profit outlets, a median price of QAACTs with the AMFm logo of less than the median price of AMT tablets
- Benchmark 4: At least a 5 percentage point increase from baseline to endline in the percentage of children under age 5 years with fever in the last 2 weeks who received ACT treatment
- Benchmark 5: At least a 10 percentage point increase from baseline to endline in the market share of ALL QAACTs (both with and without the AMFm logo)
- Benchmark 6: A decrease from baseline to endline in the market share of AMTs (all oral dosage forms)

Price metrics are calculated for the private for-profit sector only because in most settings QAACTs are free in public and private not-for-profit health facilities. Price metrics are calculated for QAACTs with the logo only in order to focus on the extent to which the subsidy provided through AMFm has been passed through to final retail prices.

These benchmarks are based on the thresholds proposed by E2Pi for one year after "the effective start date of AMFm at the country level." It should be noted that while half of the pilots had at least some copaid drugs in the country for more than 12 months before the endline outlet survey (16.5 months in Ghana, 15 months in Kenya, 14 months in Madagascar and 13.5 months in Tanzania), the time between the arrival of drugs and the endline outlet survey in the remaining countries ranged from 6.5-9.5 months. Implementation of supporting interventions often trailed the arrival of copaid drugs in country, in some cases by six months, and in 3 pilots (Madagascar, Niger, Uganda) no large scale sustained communications campaign for AMFm had been established by the time of endline data collection. Figure 2 provides an overview of the timeline of AMFm implementation in each pilot, from the signing of the grant amendment to grant disbursements, arrival of copaid drugs, and implementation of the IEC/BCC campaign (this supporting intervention has been highlighted

as it is a key intervention included in all pilot AMFm proposals). The figure also shows the timing of the implementation of demand levers, and the dates of the Independent Evaluation baseline and endline outlet survey data collection. This duration of effective implementation needs to be taken into account when interpreting country performance against the benchmarks, together with other elements of implementation process and country context.

Figure 2: Timeline of AMFm Phase 1 Independent Evaluation data collection; grant amendments and disbursements; arrival in-country of copaid QAACTs; launch events; IEC/ BCC implementation; and application of demand levers by the Global Fund



Notes: = Baseline and endline data collection for Independent Evaluation outlet surveys. = Signing of grant amendment and Global Fund grant disbursements for implementation of Supporting Interventions. = Copaid QAACTs in-country (although not necessarily in continuous supply); + = copaid QAACTs delivered, = Implementation of AMFm public awareness (IEC/BCC) campaign at scale. =Interim AMFm public awareness (IEC/BCC) campaign i.e. Ghana: talk shows only; Niger: activities not at scale; Nigeria: stop-gap soft launch; Uganda: stop-gap radio. = Application of Global Fund demand levers. GA= grant amendment; $= disbursement for implementation of SIs; L= launch; L *= "Soft" Launch; in Tanzania- mainland a "soft" launch was held with a press conference on January 25, 2011; in Uganda a "soft" launch was held on April 29, 2011- linked to World Malaria Day celebrations, however no IEC/BCC or trainings began until after endline data collection. **Nigeria: Baseline data collection completed Sept-Nov 2009

Key findings

The key findings begin with a presentation of the aggregate orders for copaid drugs and their breakdown by country. The results of the baseline and endline outlet surveys and the changes over time in availability, price and market share indicators across all countries are subsequently presented. This is followed by presentation of results from household surveys, the remote areas study, the public awareness/logo study and findings from operational research. An assessment of the achievement of the AMFm Success Benchmarks is given for each country individually, which draws on the country case studies of implementation process and context in order to understand the extent to which observed changes in key outcomes can plausibly be attributed to AMFm.

Key findings on aggregate orders and demand levers

The total number of QAACT doses delivered to 81 first line buyers (FLB) by the end of 2011 was 155.8 million (Table 1). Just over one-third of these doses were delivered to Nigeria. Ghana, Kenya, Uganda and Tanzania mainland were the next largest recipients with much smaller amounts delivered to Niger, Madagascar and Zanzibar. The majority were delivered to private for-profit FLBs in Ghana, Madagascar, Nigeria, Tanzania mainland and Zanzibar. In Kenya, the public sector received similar quantities as the private for-profit sector, and in Niger and Uganda the public sector was the main recipient.Table 2 shows the quantity of copaid QAACTs delivered between January and September 2012.

Table 1: Quantity of copaid quality-assured ACTs delivered, July 2010 – December 2011 1.1.1

Quantity of copaid quality-assured ACT treatments delivered* to countries, by sector, according to country

Country	Public	Private not-for-profit	Private for-profit	Total
Ghana	1,404,325	0	23,269,401	24,673,726
Kenya	14,347,410	0	14,109,228	28,456,638
Madagascar	489,050	0	1,199,128	1,688,178
Niger	1,783,480	0	441,640	2,225,120
Nigeria	7,827,690	5,389,830	44,043,781	57,261,301
Tanzania – mainland	4,917,600	0	8,122,020	13,039,620
Uganda	20,705,490	599,900	6,921,310	28,226,700
Zanzibar	91,075	0	150,000	241,075

* Manufacturers must provide proof of delivery to The Global Fund with all invoices for co-payment. Due to the delay between delivery and submission of an invoice by manufacturers, the actual treatment quantities delivered may be higher than what is officially reported in this table.

Source: Global Fund data base

Table 2: Quantity of copaid quality-assured ACTs delivered, January 2012 – September 2012

Quantity of copaid quality-assured ACT treatments delivered* to countries, by sector, according to country

Country	Public	Private not-for-profit	Private for-profit	Total
Ghana	1,801,710	0	11,896,780	13,698,490
Kenya	2,233,980	0	9,736,660	11,970,640
Madagascar	218,100	0	563,664	781,764
Niger	381,390	0	1,250,360	1,631,750
Nigeria	827,425	3,036,140	29,407,679	33,271,244
Tanzania – mainland	4,917,780	0	10,625,308	15,543,088
Uganda	2,166,360	500,000	7,555,960	10,222,320
Zanzibar	0	0	0	0

* Manufacturers must provide proof of delivery to The Global Fund with all invoices for co-payment. Due to the delay between delivery and submission of an invoice by manufacturers, the actual treatment quantities delivered may be higher than what is officially reported in this table.

Source: Global Fund data base

There are some systematic differences in the purchasing behavior of public and private sector first-line buyers. For the public sector, typically there is a single first-line buyer that places a single order (with staggered deliveries) to cover the entire public sector need for a full year, following a competitive tender process. In contrast, to cover the private sector needs, several private sector first-line buyers place multiple, relatively smaller orders periodically throughout the year, after directly contacting a manufacturer and reaching an agreement.

Up until July 2011 all orders made by FLB were approved by the Global Fund in the same quarter. However, it became apparent that the demand for AMFm copaid ACTs was greater than the resources available for co-payment during Phase 1. In order to ensure the availability of co-payment funding until additional resources might be secured, the AMFm Secretariat developed a framework for rationing co-payment. Since August 2011, each request for co-payment received is evaluated on the basis of several criteria (for example, the ratio of cumulative approved orders to estimated demand, relative proportion of pediatric formulations/pack sizes, and sector) and approved within the constraint of USD 8-10 million per month.

The immediate result of the application of these levers was a drastic reduction in the proportion of orders approved for co-payment, particularly for the private sector as all public sector requests for co-payment received in 2011 were approved for co-payment. In Q3 and Q4 of 2011, the AMFm approved only 32% of the private not-for-profit and private for-profit sector requests for co-payment received; Nigeria, Ghana, Kenya, and Uganda were the most affected, with only 24%, 27%, 56% and 57%, respectively, of private sector orders approved during this period. By contrast, all requests had been approved for Madagascar and Niger, and relatively few orders were pending or cancelled in Tanzania mainland and Zanzibar. Although orders take several months to arrive in country and be distributed, it is likely that non-approval of orders due to demand levers, particularly in Q3 of 2011, may have influenced QAACT availability by the time of the endline outlet surveys in at least four of the pilots.

The relative percentage of child versus adult packs of AL, which represents 85% of all co-paid ACTs approved, has evolved over time. In March 2011, the co-payment structure was revised to favor pediatric packs, which began to have an effect, with child packs of AL increasing from 32% to 49% of approved orders in the period March to July 2011. Following implementation of the demand-shaping levers, this resulted in further increases in the relative proportion of child packs, to 65% for the period August to December 2011 and to 69% for the period January to August 2012.

Key findings from the outlet surveys

Figures 3 and 4 show the breakdown of the structure of the antimalarial market (that is, all antimalarials, including quality-assured ACTs as well as other products) in the eight pilots for all outlet types (Figure 3) and for private for-profit outlets (Figure 4). Over 75% of outlets stocking antimalarials at endline were private for-profit outlets, except in Zanzibar where this

was 63%. Differences across pilots were seen, however, in the composition of the private for-profit sector (Figure 4). In Ghana, Nigeria, Tanzania mainland, Uganda, and Zanzibar, drug stores were the most common type of private for-profit sector outlet stocking antimalarials, while in Kenya, Madagascar, and Niger, general stores were the most common such outlet at endline. Of note, itinerant vendors were only frequently found in Niger where they made up 28% of the total private for-profit outlets stocking antimalarials at endline.

Figure 3: Breakdown of outlets stocking antimalarials by outlet type at endline Figure

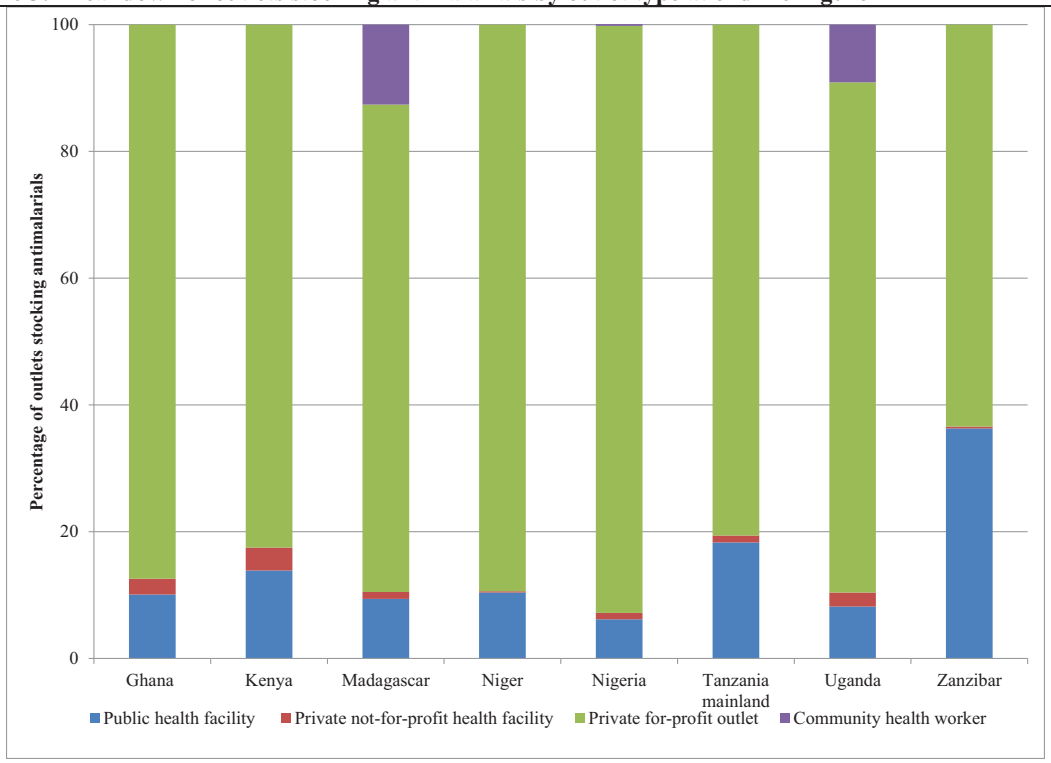
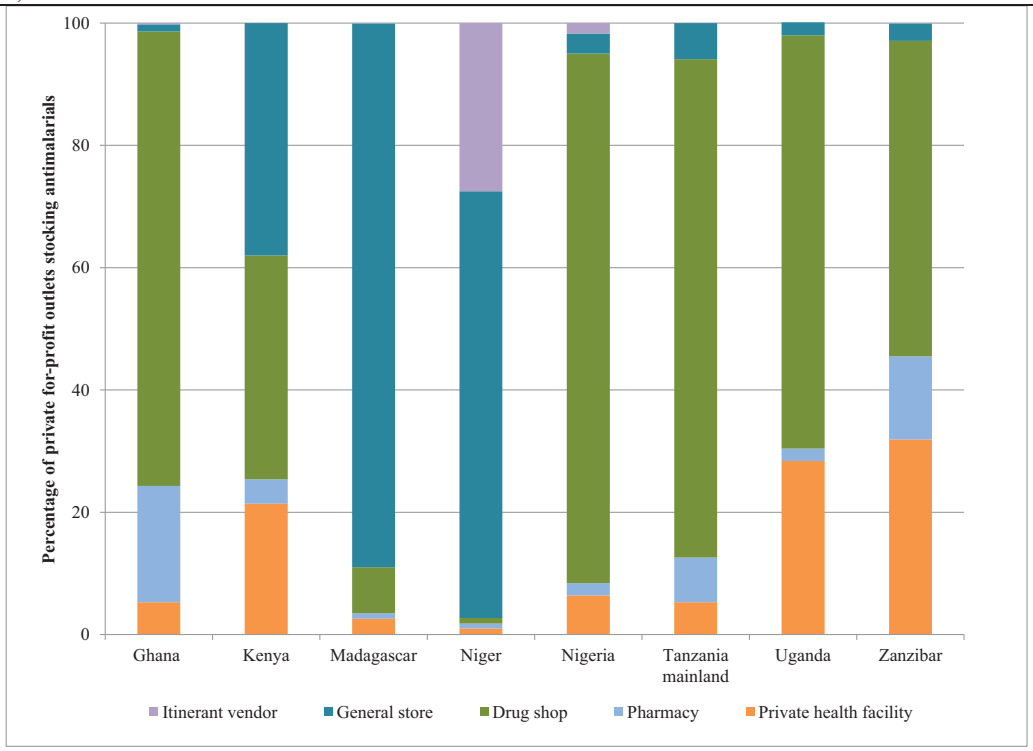


Figure 4: Breakdown of private for-profit outlets stocking antimalarials market structure by outlet type at endline, 2011



Availability of quality-assured ACTs

At endline, QAACT availability across all sectors ranged from 19% to 85% (Figure 5). QAACT availability was lowest in Niger (19%) and Madagascar (28%), ranged from 54% to 70% in Kenya, Nigeria, Tanzania mainland and Uganda, and exceeded 80% in Ghana and Zanzibar. In Ghana and Zanzibar, QAACT availability was over 80% in both public facilities and private for-profit outlets (results for private non-profit outlets and community health workers are not generally presented separately due to the small samples for these outlet types) (Figure 6). In Kenya, Tanzania mainland and Uganda availability in private for-profit outlets was over 60%, but this was lower than availability in the public sector (over 80%). There were much bigger differences in availability between the public and private for-profit sectors in Madagascar (94% vs. 9%) and Niger (73% vs. 14%). Nigeria stands out as having similar levels of availability in the public and private for-profit sectors, with public sector availability lower than in other countries (57% in public facilities vs. 53% in private for-profit outlets).

The change in QAACT availability between baseline and endline is used to assess Success Benchmark 1 (Figure 5). Between baseline and endline there were large and significant increases in QAACT availability among all outlets in Ghana, Kenya, Nigeria, Tanzania mainland, Uganda and Zanzibar, with increases of 24-52 percentage points, with the majority of the increase observed in the private for-profit sector in all cases (Figure 6). Niger had a more modest increase of 10 percentage points. In public health facilities, there were increases in QAACT availability in Kenya, Madagascar, Niger and Zanzibar. In the remaining pilots,

there was no evidence of change in public health facilities. Increases in QAACT availability were seen in both urban and rural areas in all countries (Figure 7). No change was observed in Madagascar.

Figure 5: Percentage of outlets with QAACTs in stock at baseline and endline, and the Success Benchmark 1 threshold (20 percentage point increase in availability of QAACTs)

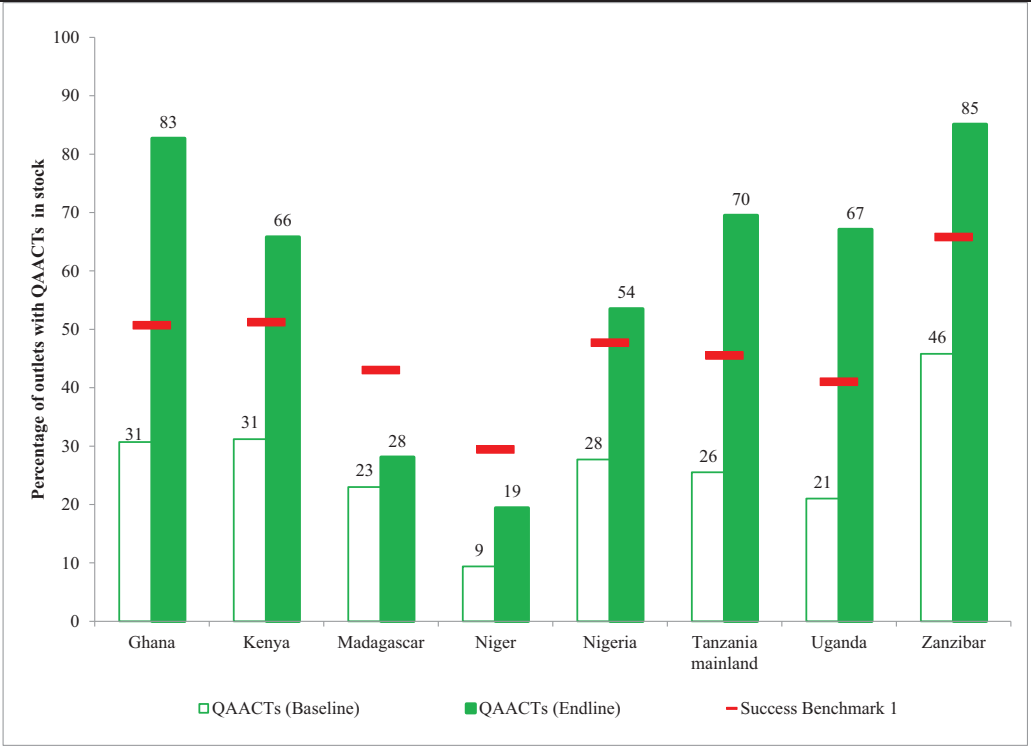


Figure 6: Percentage of public health facilities and private for-profit outlets with QAACTs in stock at baseline and endline

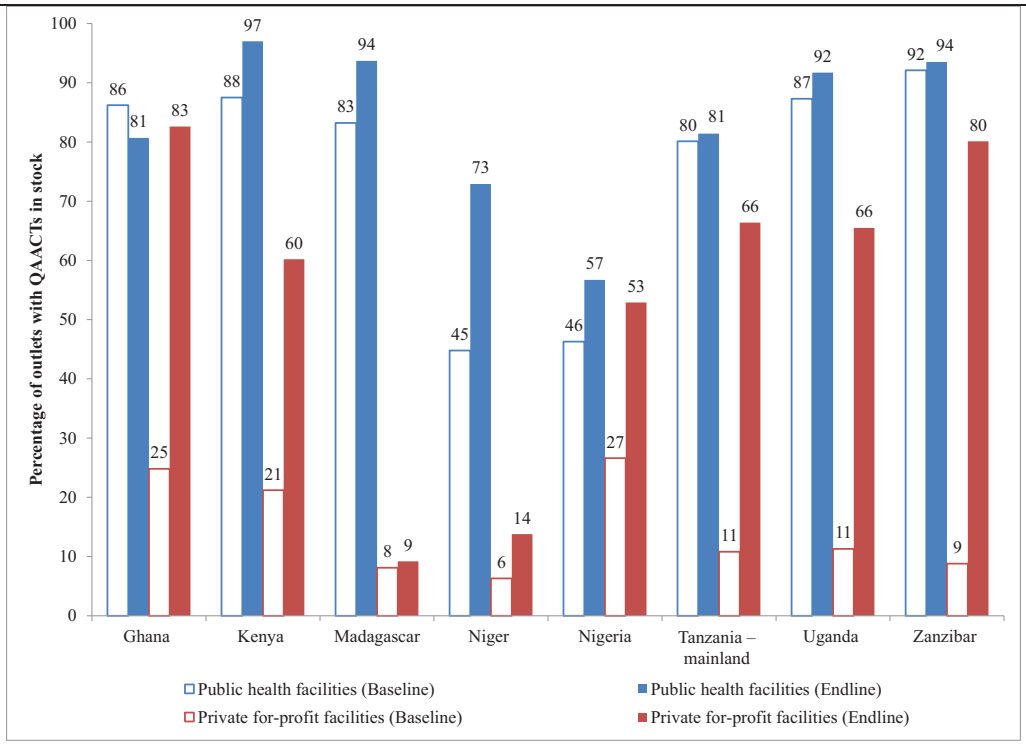
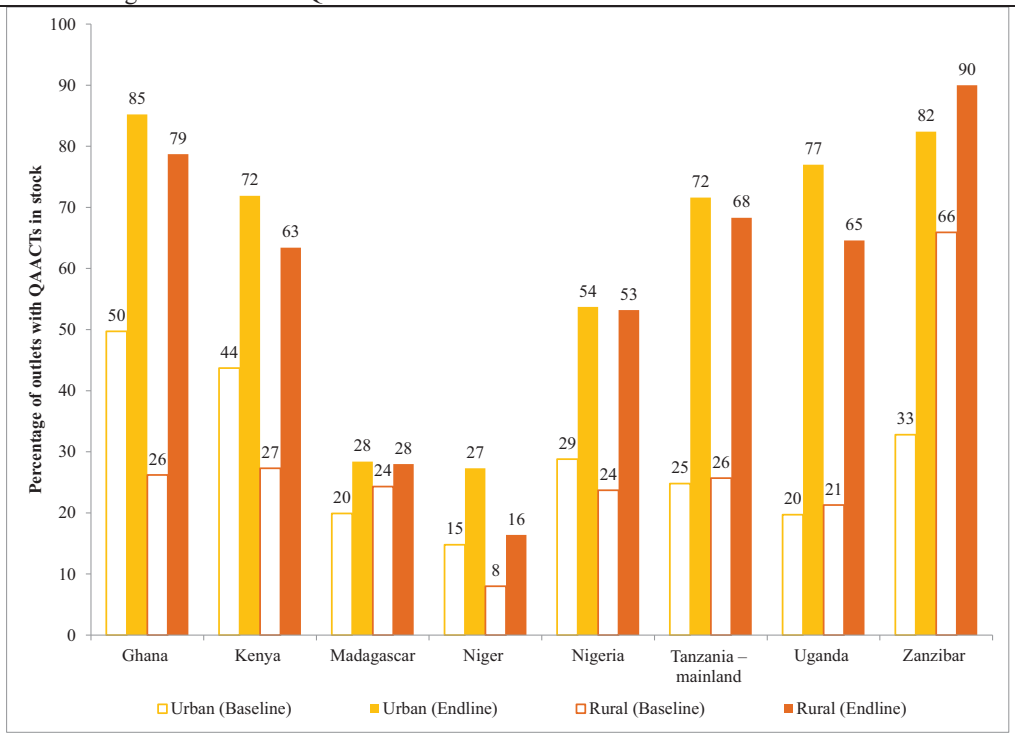


Figure 7: Percentage of outlets with QAACTs in stock in urban and rural areas at baseline and endline



At endline, availability of QAACTs with the AMFm logo was substantially higher than those without the logo everywhere except Madagascar and Niger. The availability of QAACTs without the logo varied from 6% to 21% (Figure 8).

At endline, the availability of oral artemisinin monotherapy (AMT) was high in Ghana (41%) and Nigeria (34%) [Figure 9]. Everywhere else oral AMT was stocked by less than 1% of outlets. There was little change between baseline and endline in all countries other than Zanzibar, where oral AMT availability fell from 17% at baseline to a negligible level at endline. In Ghana, oral AMT was primarily available in the private for-profit sector (47% of outlets at endline). In Nigeria, oral AMT availability at endline was 15% in public facilities and 35% in private for-profit outlets. At endline, nATs remained common in all countries, with availability among all outlets over 75% except in Zanzibar, where it was 47% (Figure 9).

Figure 8: Percentage of outlets with QAACTs in stock by presence of the AMFm logo at endline

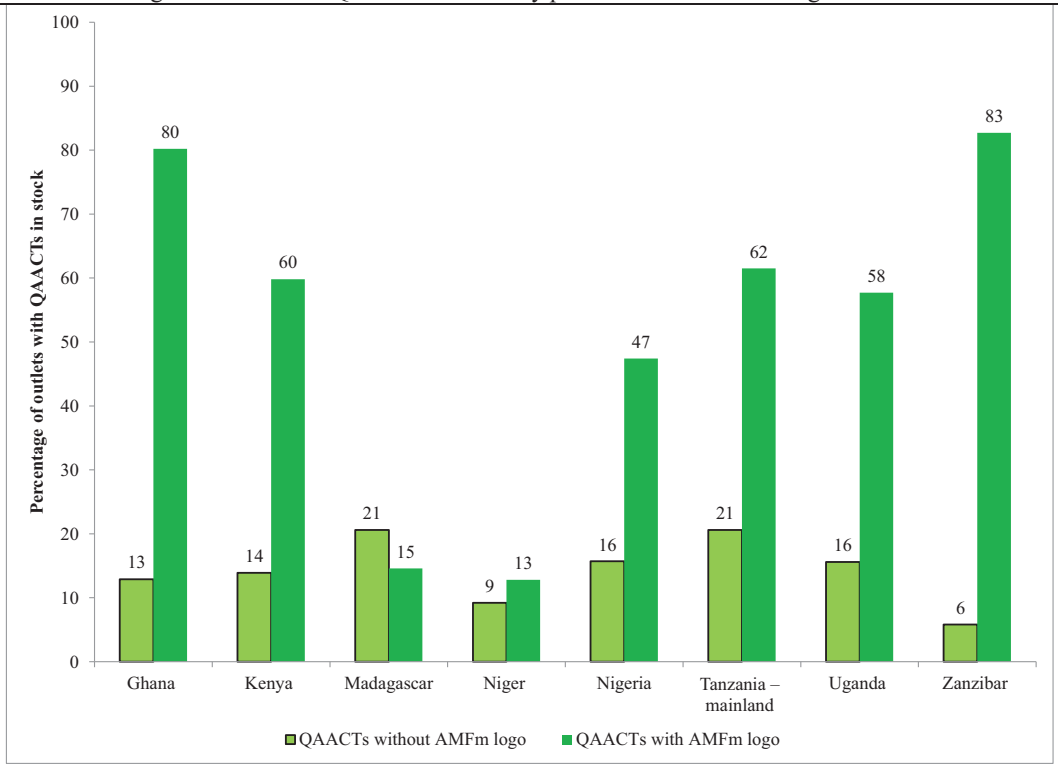
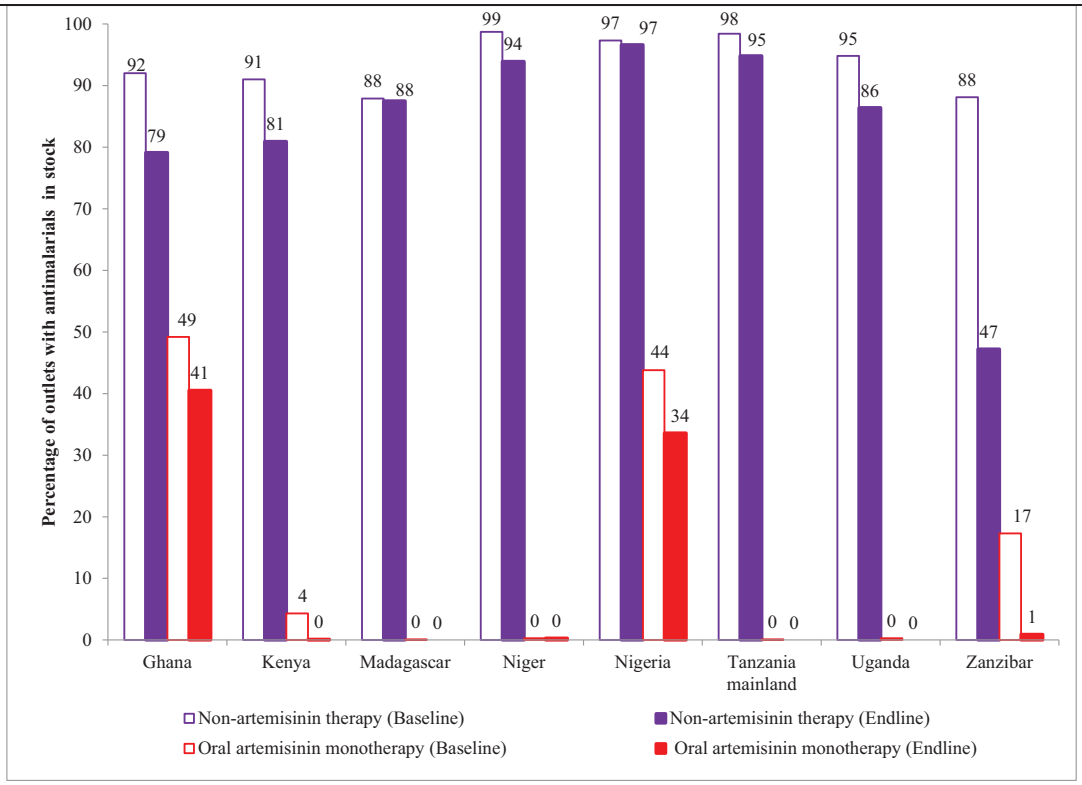


Figure 9: Percentage of outlets with oral AMT and non-artemisinin therapies in stock at baseline and endline



Affordability of quality-assured ACTs

In the public sector the median price per AETD of QAACTs was zero in all countries except Ghana at baseline and endline, reflecting widespread free provision of QAACTs (Figure 10). In Ghana, the median QAACT price fell from USD 2.74 at baseline to USD 0.94 at endline. It is recognised that patients face a variety of other costs when using the public sector, including consultation fees, transport costs, etc, and these may pose a considerable barrier to care even when drugs are supplied free of charge. Given the predominance of free QAACTs in the public sector, this section focuses on prices in the private for-profit sector.

In the private for-profit sector, the lowest median prices were in Kenya (USD 0.58) and Madagascar (USD 0.60), followed by Tanzania mainland (USD 0.94). In other countries, prices were USD 1.13 in Ghana, USD 1.17 in Zanzibar, USD 1.19 in Niger, USD 1.48 in Nigeria and USD 1.96 in Uganda (Figure 10). Prices for pediatric QAACT doses in the private for-profit sector ranged from USD 0.19 in Madagascar to USD 0.89 in Nigeria.

Large and significant falls in median QAACT price per AETD were seen in the private for-profit sectors of six of the eight pilots, with the decline ranging from USD 1.28 to USD 4.82. No significant price change was observed overall in Uganda, but there was a significant fall of USD 2.68 in urban areas. In Madagascar, there was a significant increase in the median price of USD 0.46, but the median price at baseline was only USD 0.14, reflecting the

presence of an ACT subsidy program at baseline (brand name ACTipal), which included a very low recommended retail price (USD 0.10-0.20 for an adult equivalent treatment dose). QAACTs were slightly more expensive in urban than rural areas, except in Uganda where the median prices were the same, and in Nigeria where the price was higher in rural areas (Figure 11).

Figure 10. Median cost to patients of one adult equivalent treatment dose (AETD) of QAACTs in public and private for-profit outlets (2010 US dollar equivalent), at baseline and endline

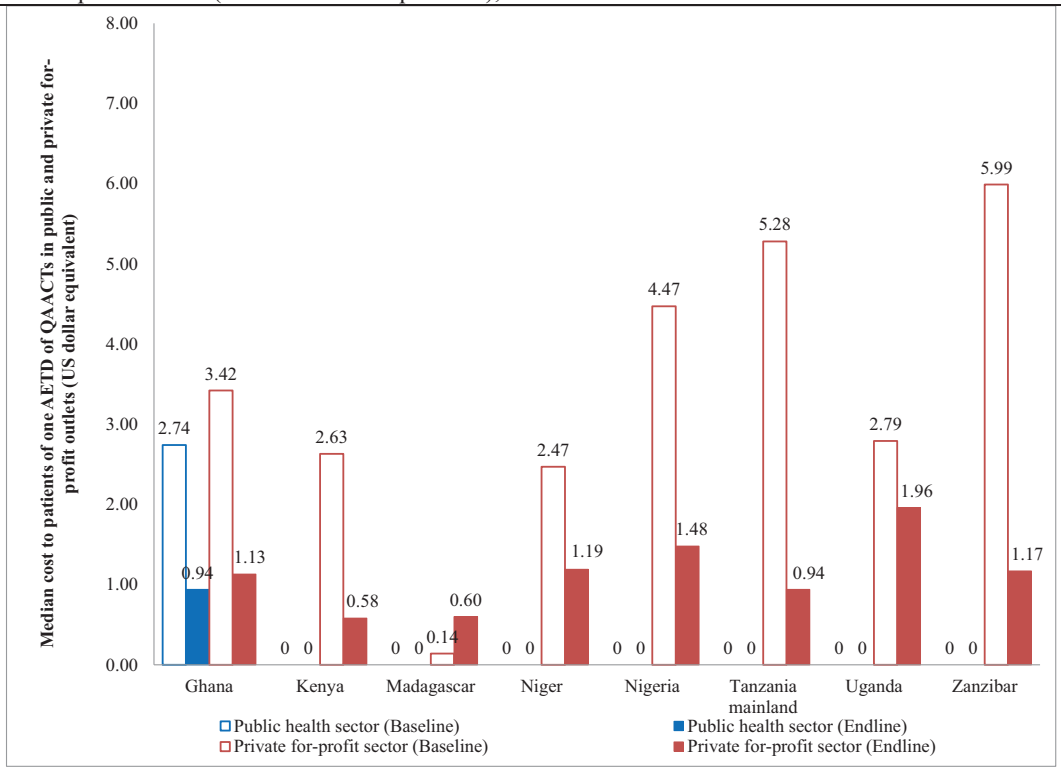
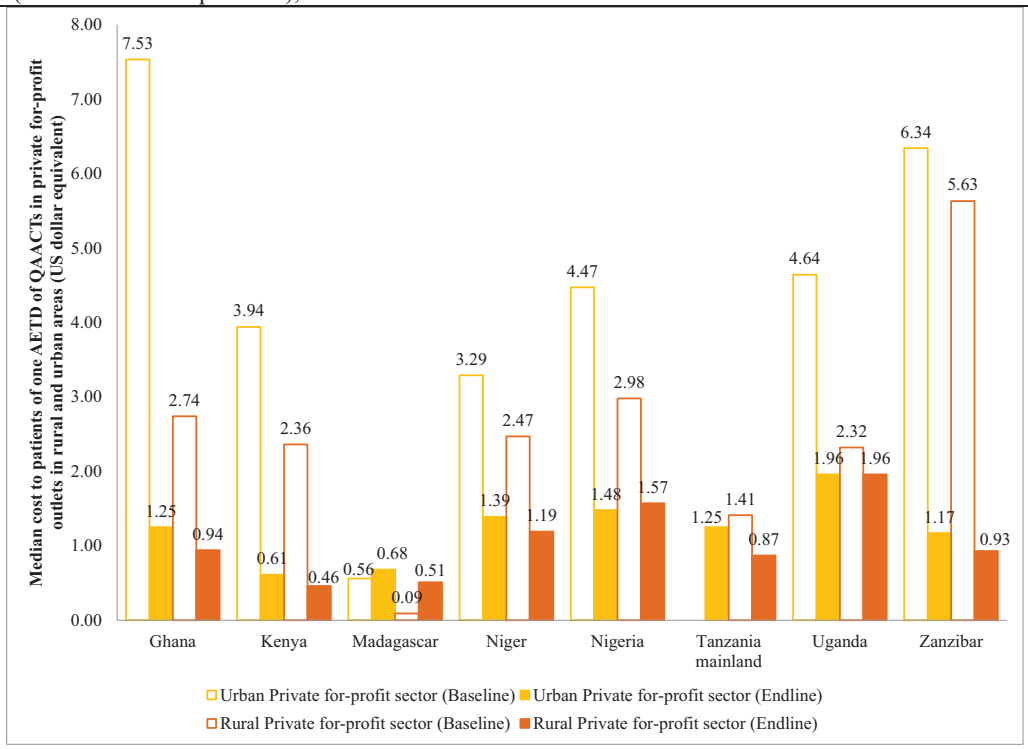


Figure 11. Median cost to patients of one AETD of QAACTs in private for-profit outlets in rural and urban areas (2010 US dollar equivalent), at baseline and endline



In the private for-profit sector at endline, quality-assured ACTs with the AMFm logo were generally much less expensive than those without the logo. In Ghana and Zanzibar, the price of QAACTs without the logo in the private for-profit sector was around seven times higher than those with the logo. In Kenya, Niger and Nigeria, QAACTs without the logo were somewhat more expensive. In Uganda, the median price was the same for the two types of products, while in Tanzania mainland, QAACTs without the logo were less expensive in rural areas, but considerably more expensive in urban areas (Figure 12). In Madagascar, QAACTs without the logo were much more expensive in urban areas than those with the logo, but in rural areas they were less expensive, possibly reflecting the presence of the subsidized ACT product ACTipal.

Figure 13 shows the cost to patients of QAACTs with the AMFm logo in comparison to the recommended retail price (RRP) for QAACTs with the logo, showing that, on the whole, median prices charged were higher than the RRP.

Figure 14 shows the median cost of QAACTs with the logo and the cost of the most popular antimalarial which is not a QAACT in tablet form at endline in private for-profit outlets. These data are used to assess Success Benchmark 2. The most popular antimalarial which is not a QAACT in tablet form was SP in Ghana, Kenya, Nigeria, Tanzania mainland and Uganda; amodiaquine in Zanzibar; and chloroquine in Madagascar and Niger. QAACTs with the logo were the same price as the most popular antimalarial which is not a QAACT in Kenya and Tanzania mainland. In Zanzibar and Madagascar, they were 1.5 and 1.6 times

more expensive, respectively, and in Niger they were 2.5 times more expensive. In Ghana, Nigeria and Uganda, QAACTs with the logo were three or more times as costly as the most popular antimalarial which is not a QAACT.

Figure 12. Median cost to patients of one AETD of QAACTs in private for-profit outlets by presence of the AMFm logo (2010 US dollar equivalent), at baseline and endline

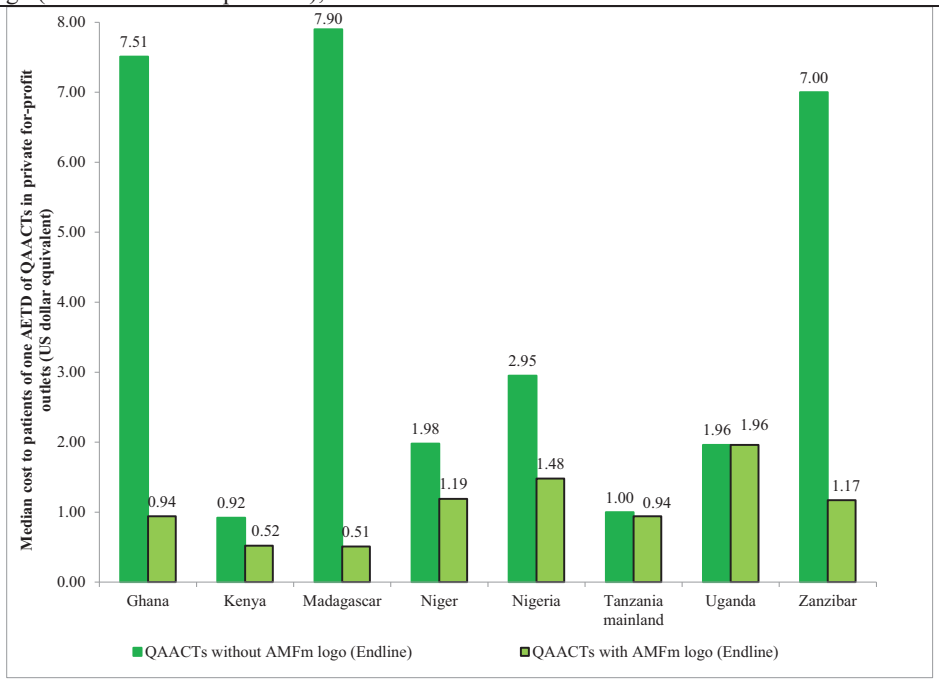


Figure 13: Median cost to patients of one AETD of QAACTs with the AMFm logo and the recommended retail price in private for-profit outlets (2010 US dollar equivalent) at endline

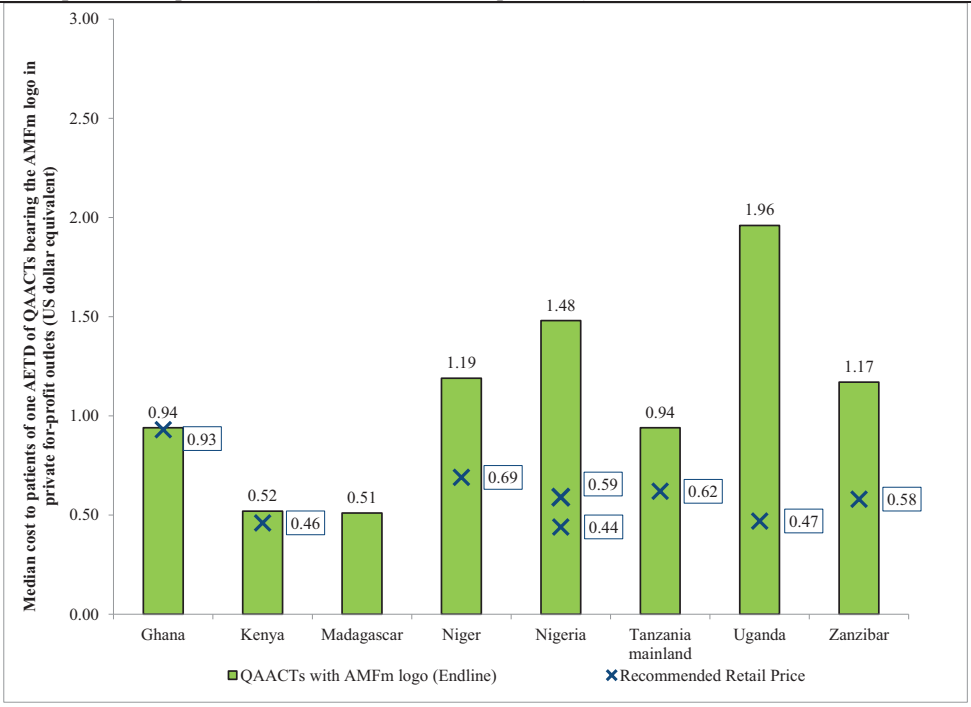
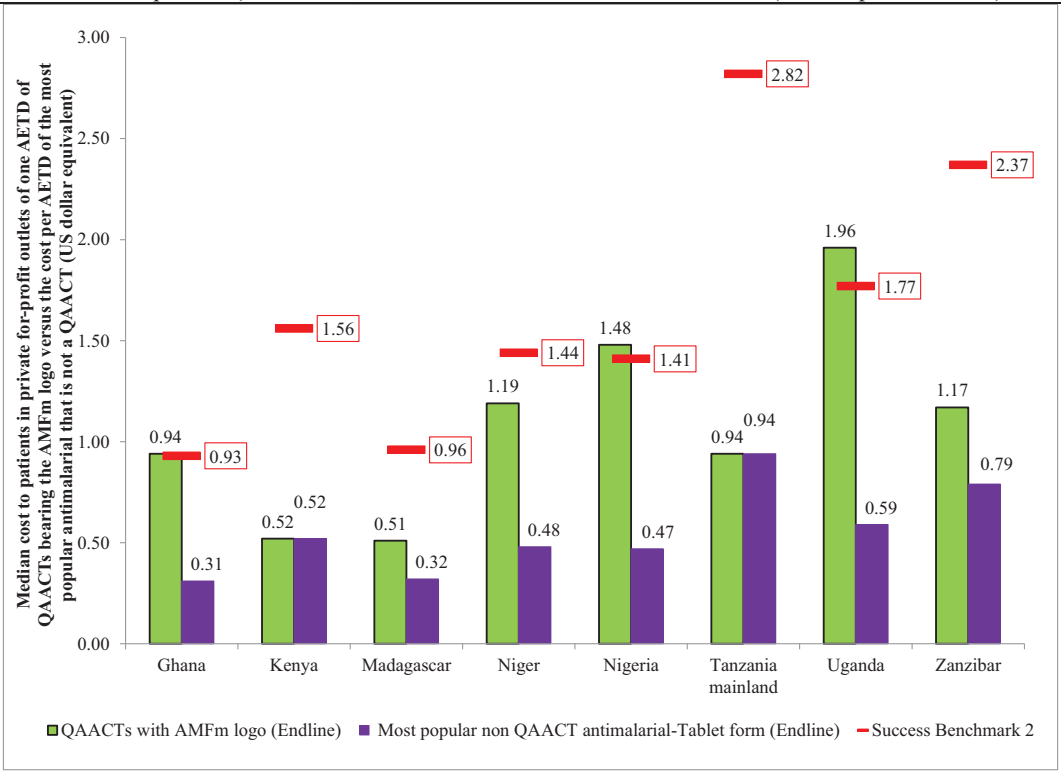


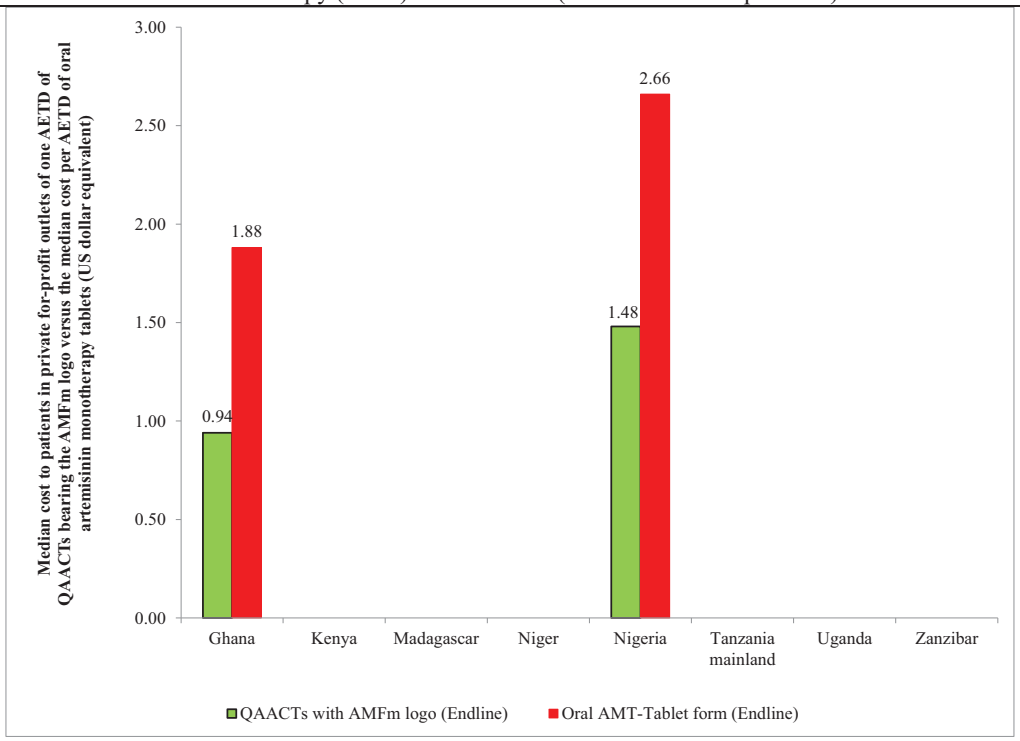
Figure 14: Median cost to patients in private for-profit outlets of one AETD of QAACTs bearing the AMFm logo compared with the cost per AETD of the most popular antimalarial that is not a quality-assured ACT (2010 US dollar equivalent) at endline, and the Success Benchmark 2 threshold (median price ratio <3)



Note: The most popoular antimalarial which is not a QAACT (tablet form) was calculated in terms of total sales volumes of tablets in private for-profit outlets

Figure 15 shows the cost to patients of QAACTs with the AMFm logo and the cost of artemisinin monotherapy tablets at endline in private for-profit outlets in Ghana and Nigeria (data are not shown for other countries due to the low number of observations for artemisinin monotherapy tablets). These data are used to assess Success Benchmark 3. QAACTs with the logo were much less costly than oral AMT tablets in both countries.

Figure 15: Median cost to patients in private for-profit outlets of one AETD of QAACTs bearing the AMFm logo and oral artemisinin monotherapy (AMT) in tablet form (2010 US dollar equivalent) at endline



Note: Results are only presented for Ghana and Nigeria as in the other countries the number of AMT tablets products was very small.

The gross percentage markup at the outlet level for QAACTs bearing the AMFm logo at endline in private for-profit outlets ranged from 36% in Niger to 133% in Uganda (Figure 16). Note that these are gross markups that include both profit margin and the cost of doing business. Between baseline and endline, percentage markups increased somewhat (except in Niger), bringing them up to a level similar to those of nATs, which ranged from 41% in Nigeria to 85% in Niger. With the dramatic fall in the median QAACT price in most countries, an increase in percentage markups may not imply any increase in absolute markups.

Figure 16: Median gross percentage markup between purchase price and retail selling price of QAACTs bearing the AMFm logo and non-artemisinin therapy in private for-profit outlets at endline

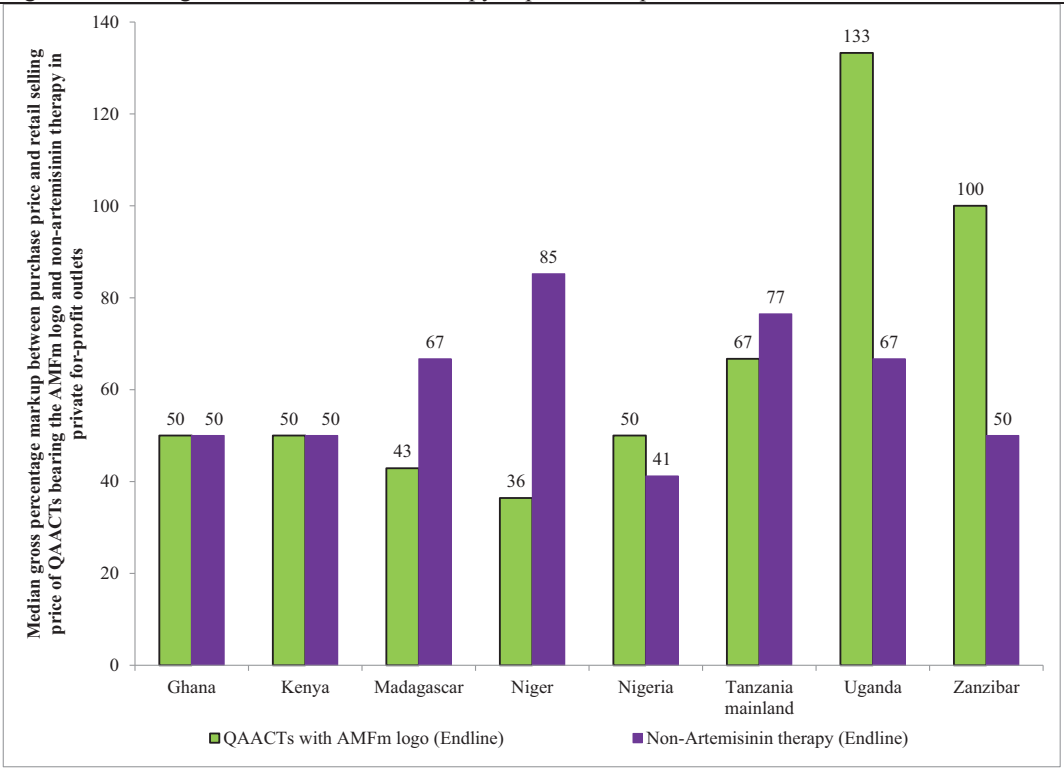
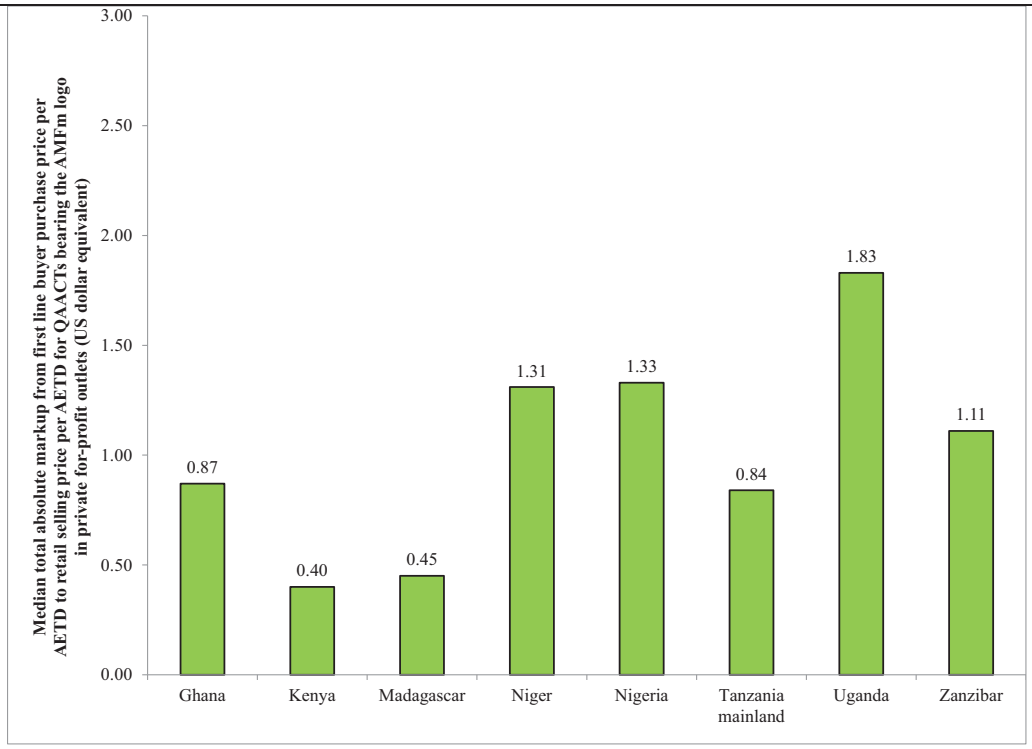


Figure 17 shows the total gross markup in USD for QAACTs with the AMFm logo in private for-profit outlets from the point of purchase by first line buyers to the point of sale to patients, capturing both the additional costs and profit margins that are added by first line buyers, any intermediate wholesalers and retailers. Total gross markup varied from USD 0.40 in Kenya to USD 1.83 in Uganda.

Figure 17: Median total absolute markup from first line buyer purchase price per AETD to retail selling price per AETD for QAACTs bearing the AMFm logo in private for-profit outlets (2010 US dollar equivalent) at endline

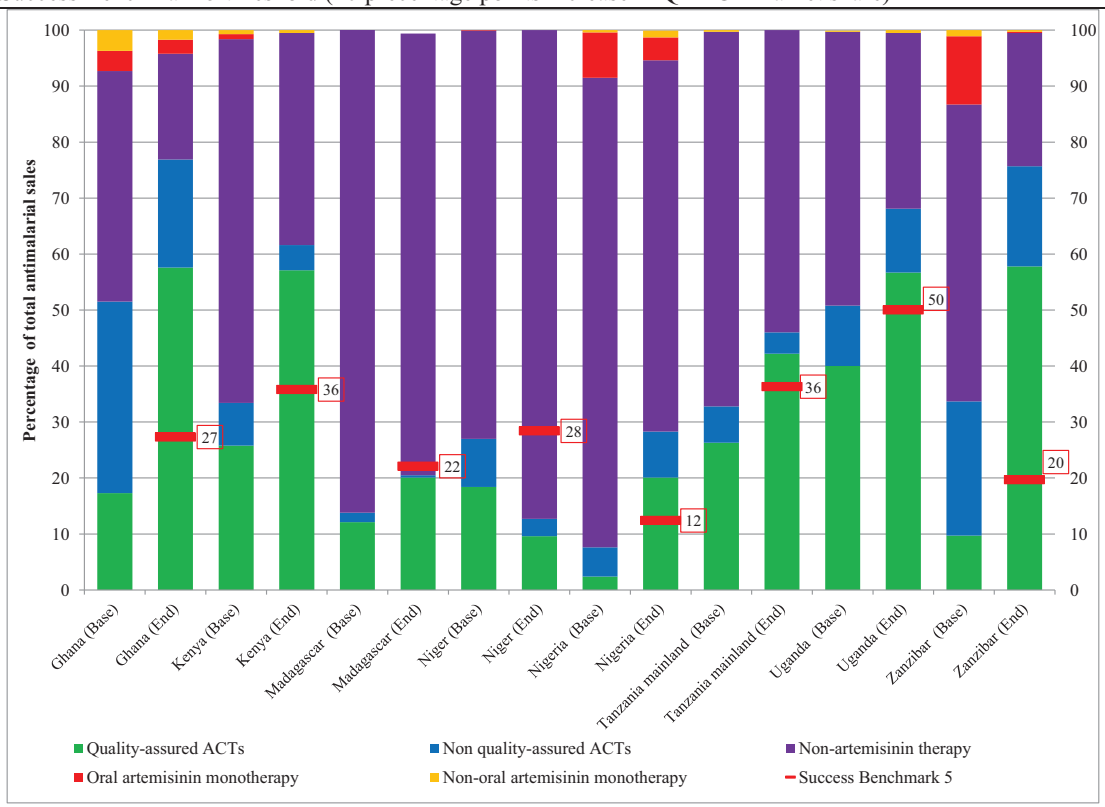


Market share of quality-assured ACTs

Across all outlet types, the QAACT market share at endline ranged from 10% in Niger to 58% in Ghana and Zanzibar (Figure 18). The change in QAACT market share between baseline and endline is used to assess Success Benchmark 5. Large and significant increases in QAACT market share were seen between baseline and endline in Ghana, Kenya, Nigeria, Tanzania mainland, Uganda and Zanzibar, ranging from 16 percentage points in Tanzania mainland to 48 percentage points in Zanzibar. Madagascar saw a significant increase in QAACT share in urban areas of 23 percentage points. There was a large decrease in the market share of nAT in all countries, except Madagascar, where the decrease was small, and Niger which saw an increase in the share of nAT and a corresponding fall in QAACT share. It should be noted that there are legitimate uses of nATs, such as use of SP for intermittent preventive treatment for pregnant women and infants, and quinine for management of severe malaria. It is therefore not a policy objective to reduce availability or market share of these products to zero. Ghana also saw a decrease in the share of non-quality-assured ACTs. Zanzibar saw a substantial decrease in the market share of oral AMT, from 12% to less than 1%, while the market share of oral AMTs fell by 4 percentage points to 4% at endline in Nigeria. These data are used to assess Success Benchmark 6, but this Benchmark is of limited relevance to other countries as the market share of oral AMT was already minimal at baseline. In Ghana, Kenya, Nigeria and Uganda, increases in QAACT market share were similar in rural and urban areas, while all of the increase in QAACT market share in Tanzania mainland occurred in rural areas, and in Zanzibar, urban areas saw the greater increase. In

Niger, there was a significant decrease in the QAACT share, with an equivalent increase in the share of nAT.

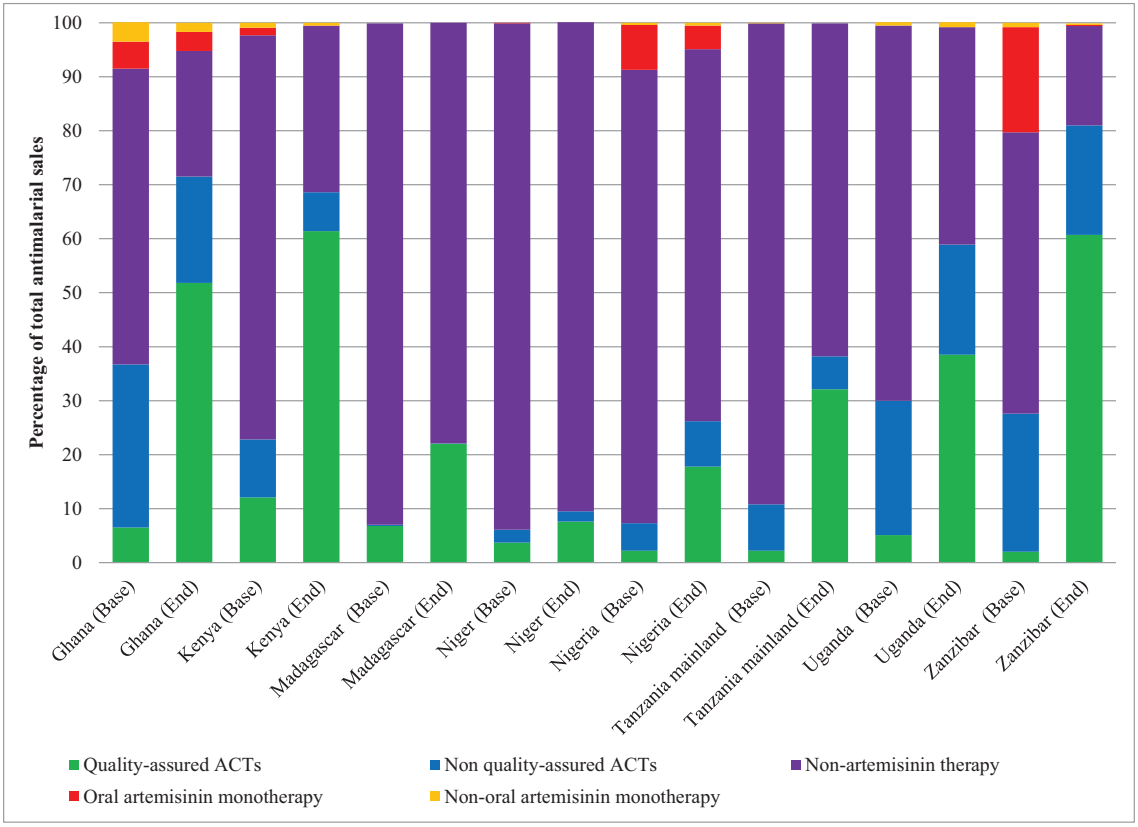
Figure 18: Market share of antimalarials by antimalarial type at baseline and endline, all sectors combined, and Success Benchmark 5 threshold (10 precentage points increase in QAACT market share)



Considering the private for-profit sector alone, the results for QAACT market share were very similar to those for all outlet types combined. The exceptions were Tanzania mainland and Uganda, where the QAACT market share overall was higher than in the private for-profit sector (42% vs. 32% in Tanzania mainland and 57% vs. 39% in Uganda) (Figure 19).

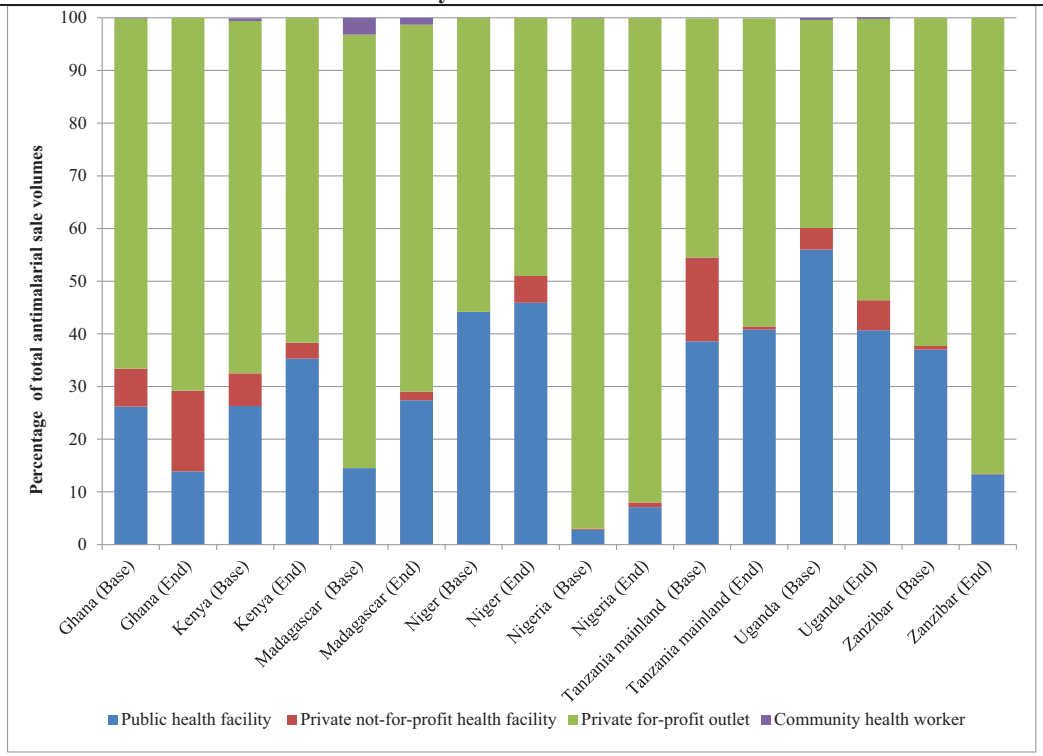
The vast majority of QAACTs sold in the private for-profit sector bore the AMFm logo in all countries except Niger, where both product types had a very low market share (each less than 5%). In the public sector, the picture was more mixed. In this sector, the majority of QAACTs carried the logo in Ghana, Kenya, Madagascar, Uganda and Zanzibar, but similar levels of QAACTs with and without the logo were seen in Niger, and those without the logo predominated in Tanzania mainland and Nigeria.

Figure 19: Market share of antimalarials sold in private for-profit outlets by antimalarial type at baseline and endline



A key feature of the antimalarial markets was the predominance of the private for-profit sector, which had the largest market share in all countries at endline, ranging from 49% in Niger to 92% in Nigeria (Figure 20). No change in the private for-profit share was seen in Ghana, Kenya, Niger or Nigeria between baseline and endline. However, increases in the private for-profit sector share were seen in Uganda (from 40% to 53%), Tanzania mainland (from 45% to 59%) and in Zanzibar (from 62% to 87%). In Uganda this shift mainly took place in rural areas, while it took place in both rural and urban areas in Zanzibar. Madagascar saw a fall in the private sector share, from 82% to 70%.

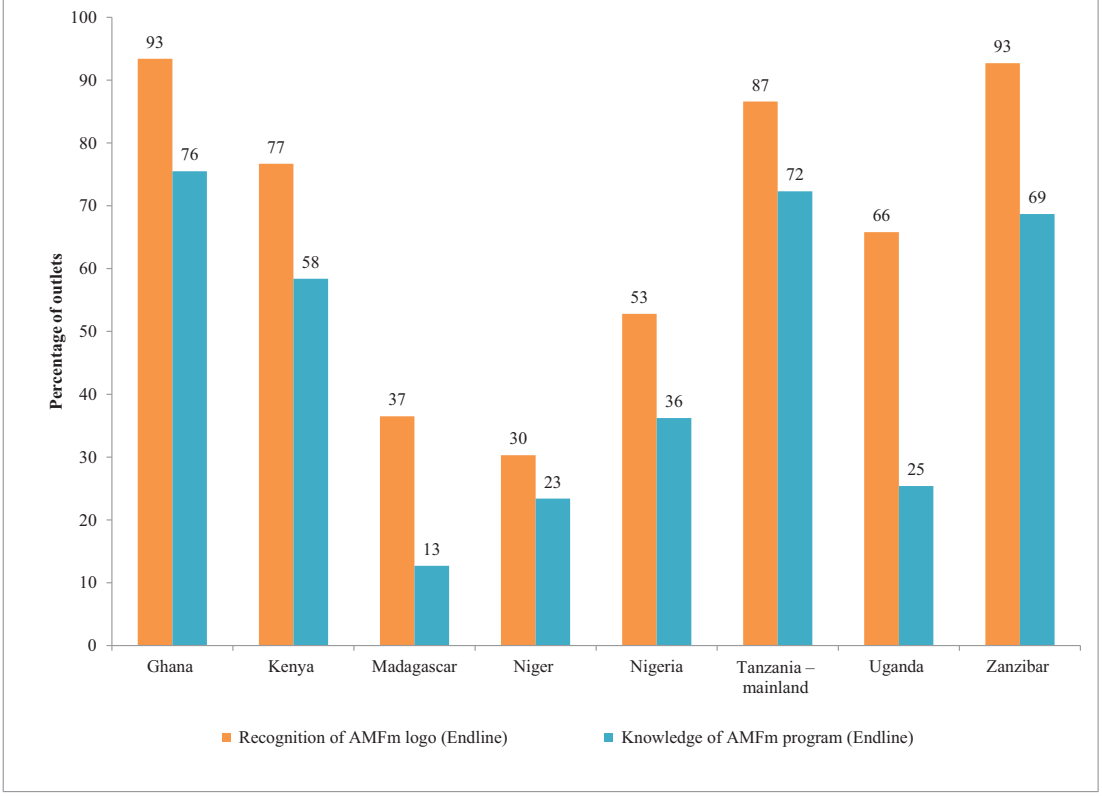
Figure 20: Market share of all antimalarials by sector at baseline and endline



AMFm logo, recommended retail prices and provider knowledge

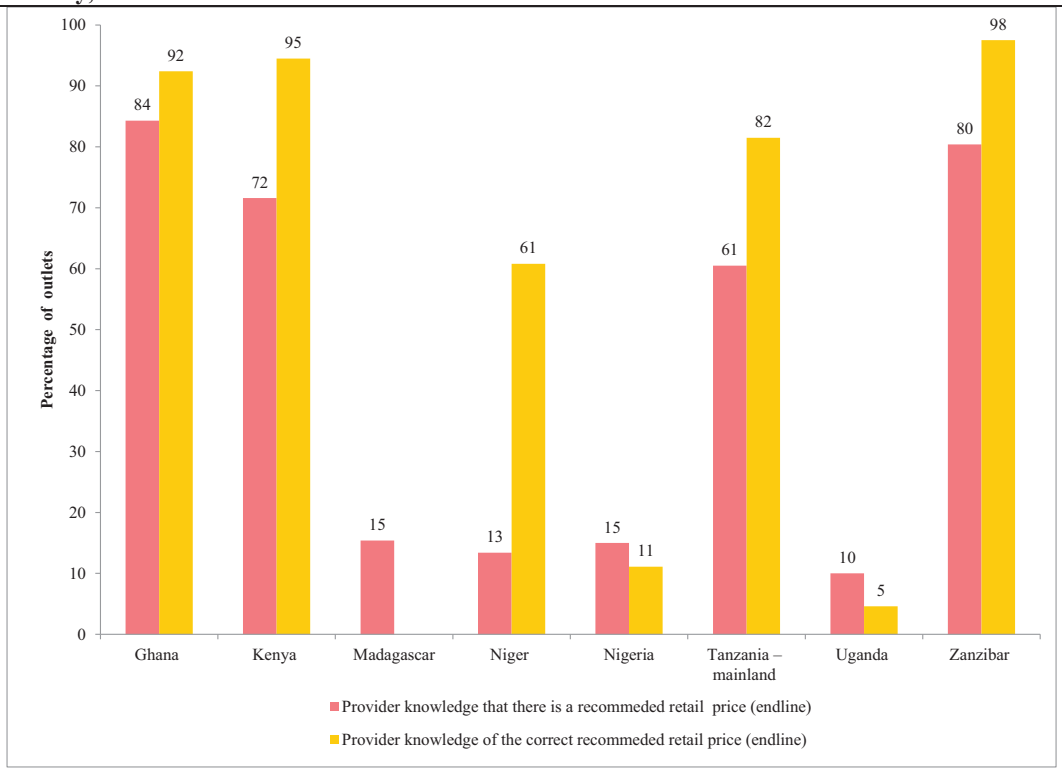
Provider recognition of the AMFm logo at endline was lowest in Niger (30%) and Madagascar (31%) and highest in Tanzania mainland (87%), Ghana and Zanzibar (both 93%) (Figure 21). Recognition of the logo was higher in urban areas than in rural areas in Ghana, Madagascar, Niger and Zanzibar. The most common responses on the meaning of the logo were that it meant an effective/quality antimalarial, an affordable antimalarial, an antimalarial or an ACT. Provider knowledge of the AMFm program was lower than recognition of the logo everywhere, but followed a similar pattern, with knowledge being lowest in Niger and Madagascar and highest in Tanzania mainland, Ghana and Zanzibar.

Figure 21: Percentage of outlets where the AMFm logo was recognised and respondents had knowledge of the AMFm program, endline only, all outlets combined



Recommended retail prices for copaid QAACTs were set in all countries except Madagascar. The percentage of respondents stating that there was an RRP for QAACTs bearing the green leaf logo varied from 13% in Niger to 84% in Ghana (Figure 22). Knowledge of the RRP was higher in urban areas than in rural areas in Ghana, Niger and Zanzibar. Of those that knew there was an RRP, the percentage of respondents stating the correct RRP for an adult dose was over 90% in Ghana, Kenya and Zanzibar, but as low as 5% in Uganda.

Figure 22: Percentage of outlets where the provider knew that there was a recommended retail price (RRP), and of those that knew there was an RRP, percentage where the provider knew the correct RRP, endline only, all outlets combined

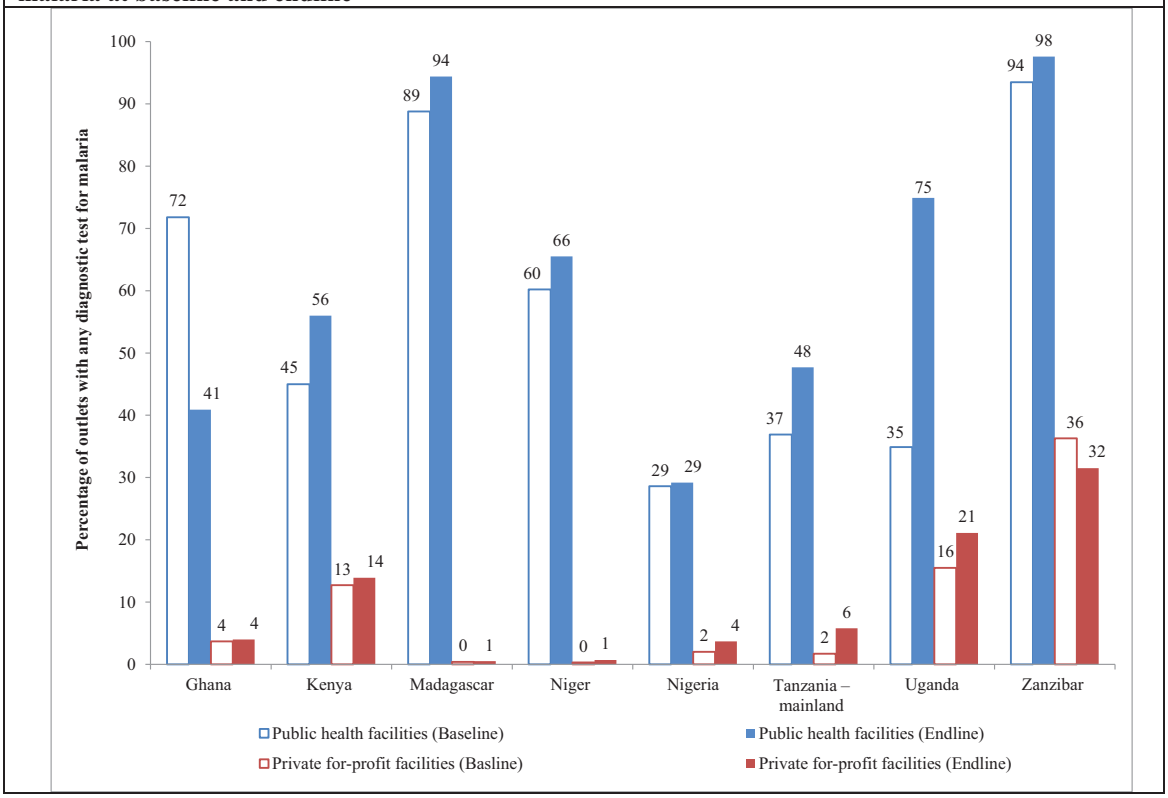


Note: No data are shown for Madagascar as an RRP was not set for copaid ACTs in this country

Malaria Diagnosis

Availability of any diagnostic test for malaria (microscopy or rapid diagnostic test (RDTs)) overall at endline varied from 6% in Nigeria to 56% in Zanzibar (Figure 23). Availability of diagnostics was significantly higher in the public sector than in private for-profit outlets in all countries. Kenya, Uganda and Zanzibar stand out as the only countries with substantial availability in the private for-profit sector, with diagnostics available in 14%, 21% and 32% of outlets, respectively.

Figure 23: Availability in public health facilities and private for-profit outlets of any diagnostic test for malaria at baseline and endline



Key findings from the household surveys

[To be included when endline household survey results become available]

Key findings from the remote areas surveys

The remote area studies were conducted only at the endline so no baseline data were available to assess changes over time in availability, price and market share of QAACTs in these areas. However, using the baseline data from rural areas, we attempted to estimate changes in availability, assuming that the baseline estimates for remote areas were likely to have been the same or lower than estimates from rural areas. This is a conservative approach, but does not imply that baseline estimates from rural areas are statistically comparable with those from remote areas at endline.

The results show that QAACTs were widely available in remote areas in both Ghana and Kenya at endline. The availability of QAACTs was particularly high in public health facilities (96% in each country), but still substantial in private for-profit outlets (66% in Ghana and 45% in Kenya). Although the availability of QAACTs was lower in remote areas than in non-remote areas, there was a substantial increase in availability if we use the level of availability in rural areas at baseline as a reference (26% in Ghana and 27% in Kenya). In remote areas in both countries, QAACTs had a substantial market share (59% in Ghana and 48% in Kenya), and this was dominated by QAACTs with the AMFm logo. Overall, the findings suggest that

the AMFm program has been instrumental in making QAACTs more available in remote areas in these two countries.

The median price of QAACTs with the AMFm logo at endline was similar in remote and non-remote areas (about USD 1.00 in both areas in Ghana and USD 0.46 in both areas in Kenya). These median prices are very much in line with the recommended retail prices of USD 0.94 in Ghana and USD 0.46 in Kenya. The median prices of all QAACTs in private for-profit facilities in remote areas at endline (USD 1.25 in Ghana and USD 0.81 in Kenya) were much lower than the median prices of all QAACTs in rural areas at baseline (USD 2.74 in Ghana and USD 2.36 in Kenya).

The availability of diagnostic tests for malaria was very low in both remote and non-remote areas in both countries, especially in the private for-profit sector. When the tests were available, they were fairly inexpensive; however, due to the small number of cases, the price data should be interpreted with caution.

In both countries the majority of providers in the remote areas were able to recognize the AMFm logo, suggesting that IEC/BCC efforts were able to reach these areas. The majority of QAACTs in remote areas had the AMFm logo.

Despite the challenges in geographical access posed by remote areas, the results suggest that the AMFm intervention has been able to reach these areas in Ghana and Kenya. This contributed to making QAACTs more available and more affordable in these disadvantaged areas.

Key findings from the public awareness/logo studies

Exit interviews

These findings indicate that the promotion of ACTs as the main treatment for malaria is well underway in Kenya, and to a lesser degree in Ghana, but that the situation is much different in Nigeria and Madagascar. In Madagascar in particular, few people had heard of ACTs or seen the logo. More than half of those who had seen the logo in Madagascar did not know what it means, which is not surprising since the supporting interventions on the logo had not started in Madagascar by the time of the logo study survey. The reliance on the recommendations of health care personnel and pharmacists (respondents may have been referring to drug store staff) suggests that the promotion of ACTs through those channels will be crucial in encouraging the use of ACTs in the future. It should be noted that while this study provides interesting insights about the population-level awareness of the AMFm program, the results should be interpreted with caution because of the small number and the non-random selection process of participants. The results cannot be generalized to groups other than the participants. However, some of the keys issues raised can be the subject of further assessment to better understand the implications for the implementation of the AMFm program in these countries.

Focus group discussions

It should be noted that the findings of the focus group discussions (FGD) do not necessarily address the coverage or effectiveness of the awareness campaigns, but highlight some of the social perceptions about malaria medicine and the AMFm logo. The FGD revealed the following:

- FGD participants in Madagascar spoke more about the importance of consulting a health care professional for malaria treatment than did those from other countries.
- In all countries, individuals with experience of using ACTs find they are very effective in treating malaria.
- FGDs revealed a great deal of variation in whether or not participants knew about ACTs or had used them themselves.
- Most participants in these FGDs associate the AMFm logo with leaves or herbal medicine, although many of the participants had not seen the logo before or had not been exposed to accompanying communications. In part, this could be the result of the late introduction and limited reach of the supporting interventions on the AMFm logo, especially in Madagascar and Nigeria.

Summary of relevant operational research

During the Phase 1 timeframe, a number of operational research studies were conducted by other research groups alongside AMFm implementation in the pilot countries. These studies offer potential insights into the effects of additional or complementary interventions aimed at improving malaria case management. Results of projects for which results were available at the time of writing of this report are summarized here. These were all commissioned and managed by the Clinton Health Access Initiative (CHAI) through a grant from the Bill and Melinda Gates Foundation.

These studies cover a range of different types of interventions that have the potential to improve malaria case management and targeting of antimalarials, particularly in private for-profit outlets. They also provide important background information on the context in which the ACT subsidy is being introduced, such as the low level of adherence to ACT treatment and the generally high use of ACTs for treatment of non-malarial fevers, both of which are consistent with the evidence from the broader literature, and reflect the complex set of factors affecting both of these behaviors.

The interventions include studies which modify the core AMFm intervention by varying the subsidy level to examine the impact on both ACT use and targeting; and measures which could complement the AMFm subsidy on ACTs, such as providing subsidized RDTs to improve targeting of ACTs to those with malaria and increasing treatment adherence through text messaging. All of the studies show that such interventions are feasible to implement at a small scale (with the exception of the Cambodia study which took place against the backdrop of a national-level program). However, the evidence on their effectiveness is mixed, and

more evidence of the effectiveness and cost-effectiveness of such measures in large-scale programs is needed.

Evidence on such interventions should also be seen in the context of the broader literature on improving malaria case management. A number of review papers have found that medicine sellers are willing to participate in such interventions and that a range of interventions can be effective in improving provider knowledge and treatment practices. These include various forms of training; quality assurance programs such as accreditation, franchising and supervision; demand generation and consumer information; and adapting medicine packaging.

Interpretation of key findings based on success metrics in light of the AMFm implementation

In this section, we present the performance of each AMFm pilot against the Success Benchmarks (see Section 8). Results for all benchmarks, estimated from outlet and household survey data, are presented in a scorecard which allows for the achievements to be seen together. These results are then interpreted using the Theory of Change presented in Section 1.4, which provides a framework for integrating the description of progress in supply of AMFm copaid drugs, the implementation of supporting interventions (SI), and the effects of important contextual factors. This draws on the country case studies of implementation and context undertaken at the time of endline outlet survey implementation (Section 4) and the description of country context provided in the baseline IE report. Together with the results of the benchmarks, this integrated narrative is aimed at helping to assess progress of AMFm after periods of implementation which varied considerably across the different pilots, and to understand the extent to which observed changes in key outcomes can plausibly be attributed to AMFm.

Ghana

AMFm implementation: A total of 32 private for-profit FLBs were registered with the Global Fund as of January 31, 2012, of which 14 had placed orders by the end of 2011. The first orders for copaid QAACTs were placed in July 2010 by a private for-profit FLB and were delivered in August 2010. A total of 15.5 months elapsed between the date the first drugs arrived in Ghana (August 2010) and the midpoint of endline outlet survey fieldwork. Supporting interventions started in February 2011, giving nine months of effective SI implementation, and included public awareness and mass media campaigns; training of public sector workers, pharmacists, private practitioners and licensed chemical sellers; private sector monitoring; operational research; and the setting of the recommended retail price at USD 0.94. A total of 24.7 million copaid QAACT treatments were delivered between July 2010 and December 2011, amounting to 1.01 treatments per capita (the whole population of Ghana is considered at risk of malaria), of which 95% were delivered to private for-profit FLBs. The application of the Global Fund's demand levers in Ghana resulted in only 27% of treatments requested by FLBs in the second half of 2011 being approved.

Availability: QAACT availability across all outlets increased by 52 percentage points, from 31% at baseline to 83% at endline (Benchmark 1). Ghana has therefore easily met the benchmark of a 20 percentage point increase in QAACT availability. The largest rise was in private for-profit outlets, which saw an increase in QAACT availability of 58 percentage points. The urban-rural gap in QAACT availability that was observed at baseline overall and for private for-profit outlets was eliminated at endline. Even in remote areas, 78% of all outlets had QAACTs in stock at the time of the remote areas study (96% of public health facilities and 68% of private for-profit facilities).

Price: A dramatic decrease in median QAACT price was observed between baseline and endline. Across all outlets, the median price per AETD fell from USD 3.42 to USD 0.94. In public health facilities, the QAACT price fell from USD 2.74 to USD 0.94, while in the private for-profit sector, the median price of QAACTs fell from USD 3.42 to USD 1.13, which is slightly higher than the RRP of USD 0.94. At endline, QAACTs were slightly more expensive in urban than rural areas (USD 1.25 vs. USD 0.94), and no difference in price was observed between private for-profit outlets in remote and non-remote areas. The median price in private for-profit outlets for a QAACT carrying the AMFm logo was USD 0.94 per AETD. This is 3.0 times the median price of the most popular antimalarial which is not a QAACT in tablet form (SP) whether this is measured in tablet form or among all dosage types, and therefore Ghana appears to have just missed Benchmark 2, which states that the ratio should be less than 3. The price of copaid QAACTs in the private for-profit sector was lower than that of AMT tablets only (USD 1.88), strongly suggesting that Benchmark 3 was met.

Market share: The market share of QAACTs has more than tripled overall, from 17% to 58% of all antimalarials sold/distributed in the week preceding the survey. There was no difference in the market share between urban and rural areas, and QAACT market share reached the same level in remote areas. Benchmark 5 of a 10 percentage point increase in market share from baseline to endline has easily been achieved overall, with a 40 percentage point increase. The benchmark has also been met in each sector individually (with percentage point increases ranging from 23 to 61). The market share of oral AMTs was very low at baseline (4% in all types of outlets combined) and remained very low at endline (3%). The decrease between baseline and endline (Benchmark 6) is of borderline statistical significance but the relevance of this benchmark to Ghana is questionable given the low share for oral AMTs at baseline.

Context: Relevant contextual factors include the distribution of long-lasting insecticidal nets (LLINs) concurrent with AMFm implementation (5 million nets distributed by the end of 2011). ACTs had over-the-counter status.

Summary: The evidence about impressive changes in the availability and price of QAACTs, together with strong evidence of increased knowledge and awareness, the flow of copaid drug orders and the evidence on SI implementation, provide plausible evidence that AMFm is responsible for the substantial increase observed in QAACT market share. These changes are

unlikely to be due to other contextual factors. The high levels of availability and market share in remote areas underline the success of AMFm in reaching more vulnerable populations. The decrease in the market share of nAT in private for-profit outlets is consistent with AMFm crowding out nATs and not simply shifting demand from other ACTs. Although there was a large decrease in the price of QAACTs, the price benchmark appears to have just been missed. This may be because the relatively high RRP is acting as a floor for the QAACT price and stopping it from falling below this level. This could also be due to the very low price of the most popular antimalarial which is not a QAACT in tablet form (USD 0.31), making this quite a difficult benchmark to reach.

Kenya

AMFm implementation: Seven private sector FLBs registered and established relationships with manufacturers, of which six had placed orders by the end of 2011. The FLB for the public sector was the Kenya Medical Supplies Agency (KEMSA). The first orders for copaid QAACTs were placed in July 2010 by a private for-profit FLB and delivered in August 2010. A total of 15 months elapsed between the date the first drugs arrived in Kenya and the midpoint of endline outlet survey fieldwork. Supporting interventions mainly started in February 2011, giving nine months of effective SI implementation. The supporting interventions included a communication campaign, training of private sector health workers, pharmacovigilance activities and a recommended retail price set at USD 0.46 for all pack sizes. A total of 28.4 million copaid QAACT treatments were delivered between July 2010 and December 2011 (0.9 treatments per person at risk of malaria), half of which were delivered to the private for-profit sector. The application of the Global Fund's demand levers in Kenya resulted in only 56% of treatments requested by FLBs in the second half of 2011 being approved.

Availability: QAACT availability across all outlets increased by 34 percentage points, from 32% at baseline to 66% at endline (Benchmark 1). Kenya has therefore easily met the benchmark of a 20 percentage point increase in QAACT availability. The largest increase was in private for-profit outlets, which saw an increase in QAACT availability of 39 percentage points. Even in remote areas, QAACTs were available in 56% of outlets at the time of the remote areas study. QAACTs with the logo had also substantially penetrated remote areas, with 45% of private for-profit outlets stocking them.

Price: The median price of QAACTs in the private for-profit sector fell dramatically between baseline and endline, from USD 2.63 per AETD to USD 0.58, although the endline median price was still somewhat higher than the RRP of USD 0.46. The median price at endline for a QAACT with the AMFm logo was USD 0.52 in the private for-profit sector, exactly equal to the median price of the most popular antimalarial which is not a QAACT in tablet form (SP) in private for-profit outlets, strongly suggesting that Kenya comfortably met pricing Benchmark 2. It was not possible to compute Benchmark 3 for Kenya, as the number of AMT products audited at endline was fewer than 50. Copaid QAACT prices were slightly higher in remote than non-remote areas (USD 0.69 vs. USD 0.46), although the remote areas study

took place four months after the endline survey when the Global Fund's demand levers may have placed upwards pressure on QAACT prices.

Market share: The market share of QAACTs has increased overall, from 26% to 57% of all antimalarials sold/distributed in the week preceding the survey, with similar increases in urban and rural areas. Benchmark 5 of a 10 percentage point increase in QAACT market share from baseline to endline was achieved overall and within the private for-profit and private not-for-profit sectors. Even in remote areas, QAACT market share was 48% among all outlets (77% in public health facilities and 40% in private for-profit outlets). Overall market share of oral AMTs was negligible at baseline (0.9%) and almost zero at endline (0.05%).

Context: A predicted malaria epidemic led to an emergency response, although the epidemic did not arise. Mass distribution of LLINs took place. There was depreciation of the Kenya shilling. Political support for AMFm was high. ACTs did not have over-the-counter status.

Summary: Kenya has comfortably met Success Benchmarks 1 on QAACT availability, 2 on price, and 5 on market share. Data are not available to assess Benchmark 4 on use, and Benchmarks 3 and 6 on AMTs are not relevant given the negligible amounts of AMT in the market at baseline and endline. Substantial levels of QAACT availability and market share were also observed in remote areas. QAACT prices in private for-profit outlets were slightly higher in remote areas, although the demand levers may have placed upward pressure on prices by the time the remote areas survey was undertaken. The evidence about changes in the availability and price of QAACTs, together with strong evidence of increased knowledge and awareness, the flow of copaid drug orders and evidence on implementation of the IEC/BCC campaign, provide plausible evidence that AMFm is responsible for the substantial increase in QAACT market share observed. Contextual factors that could also have contributed to increased QAACT availability (PMI procurement and epidemic preparedness) operated mainly in the public sector where QAACT market share actually fell, and not in the private for-profit and private not-for-profit sectors, which saw substantial and significant increases. The decrease in the market share of nAT in private for-profit outlets is consistent with a view that AMFm is crowding out less effective antimalarials.

Madagascar

AMFm implementation: Eight private sector FLBs registered, all of whom placed orders with manufacturers, and the FLB for the public sector was the public sector procurement agency, the Unité de Gestion de Projet (UGP). The first orders for copaid QAACTs were placed in September 2010 by a private for-profit FLB, with small quantities being delivered in October and December 2010 and larger quantities in February 2011. A total of 14 months elapsed between the date the first drugs arrived in Madagascar and the midpoint of endline outlet survey fieldwork. Supporting interventions (SIs) started in January 2011. A radio and TV campaign was begun in April 2011, but terminated in May 2011 because it was deemed to contravene the law prohibiting advertising of prescription drugs to the general population.

Training activities focused on doctors, paramedics, lab technicians and CHWs, and there was an intervention involving medical representatives. There was no recommended retail price. By the end of December 2011, a total of 1.2 million treatment doses had been received by private sector FLBs, and 489,000 by the public sector, amounting to only 0.08 treatments per capita (the whole population of Madagascar is considered at risk of malaria), one treatment for every 12 people.

Availability: There was no significant difference in overall QAACT availability between baseline (23%) and endline (28%), meaning that Madagascar did not meet Benchmark 1. There was no change in QAACT availability in the private for-profit sector, which remained low (8% at baseline and 9% at endline). However, there was considerable variation within the private for-profit sector. QAACT availability at baseline and endline was much higher in private for-profit health facilities/pharmacies (47% at baseline and 63% at endline) and drug stores (56% at baseline and endline), than in general retailers (3% at baseline and 2% at endline) - although the latter were not licensed to stock or sell ACTs. A very high number of general stores were screened for the outlet surveys, of which antimalarials were stocked by 32% baseline and 21% at endline (principally cholorquine), meaning that general stores represented a high proportion of private for-profit antimalarial outlets, thereby pulling down average QAACT availability in the private for-profit sector as a whole. In public facilities, QAACT availability was already high at baseline (83%) and increased further to 94% at endline. This represents a significant increase from baseline. QAACT availability was high among community health workers (CHWs) at both baseline (99.8%) and endline (92%).

Price: In the public and private not-for-profit sectors, the median QAACT price remained USD 0.00 at baseline and endline, reflecting the policy of free ACT provision. However, the median price of QAACTs in the private for-profit sector increased significantly between baseline and endline, from USD 0.14 to USD 0.60 per AETD. This mainly reflected significant increases in prices in drug stores and general retailers, especially in rural areas. Low QAACT prices at baseline are due to the pediatric ACT subsidy program for Actipal (artesunate-amodiaquine) that PSI had been operating in Madagascar since 2008 with distribution through CHWs and authorized retailers (pharmacies and depots). The median price at endline for a QAACT with the logo in private for-profit outlets (USD 0.51) was 1.6 times the median price of the most popular antimalarial which is not a QAACT in tablet form (chloroquine) in private for-profit outlets. This suggests that Madagascar comfortably met price Benchmark 2. Benchmark 3 was not relevant in Madagascar as there were no price observations for oral AMT, reflecting its absence from the market.

Market share: Overall market share of QAACTs was 12% at baseline and 21% at endline, but this change did not meet Benchmark 5 of a 10 percentage point increase. However, the power to detect a 10 percentage point increase was below the usual minimum standard of 80%, so the p-value should be interpreted with caution. In the private for-profit sector, market share increased from 7% to 22%. This 15 percentage point change is significantly different from zero, but there is only weak evidence that the 10 percentage point threshold was met in this sector.

Context: ACTs did not have over-the-counter status, and their sale was not permitted in general stores. PSI had been distributing subsidized pediatric ACTs to CHWs and private retailers since 2008. IRS and mass distribution of LLINs were taking place. There were continued effects from the 2009 coup d'état, leading to political and economic deterioration.

Summary: Madagascar has not met success Benchmarks 1 on QAACT availability or 5 on QAACT market share. However, Benchmark 2 on the relative price of copaid QAACTs compared with the most popular antimalarial which is not a QAACT has been met, despite the lack of an RRP. Benchmarks 3 and 6 were not relevant because there was an almost complete absence of oral AMT in the market at baseline and endline. Data are not available to assess Benchmark 4 on use.

Although a significant increase in QAACT market share was observed from baseline to endline in the private for-profit sector, the increase was not sufficient to meet the market share benchmark, especially given the lack of improvement in the public sector. This limited improvement in market share was associated with the low level of copaid drugs delivered to Madagascar, at only one treatment for every 12 people, or 0.08 treatments per capita. This partly reflects long delivery times, but more importantly low copaid drug orders, which amounted to only one treatment for every 11 people, or 0.09 treatments per capita. Reasons for these low orders are likely to reflect low confidence by FLBs in ordering due to a lack of data on the unmet need for ACTs within the private sector and a fear of overstocking. The low level of provider and exit survey respondent awareness and understanding of the logo are no doubt due to the curtailment of the mass media campaign, which is likely to have had a substantial impact on consumer demand for QAACTs. However, the Madagascar experience should be seen in the light of the recent political instability and economic challenges, which provided a highly problematic context for both the public and private sectors during the period of AMFm Phase 1.

Niger

AMFm implementation: Seven first line buyers had registered with the Global Fund as of January 31, 2012, including five private for-profit firms, one UN agency and one public sector agency. Three of the private first line buyers had placed orders by the end of 2011. The first order to be placed by a private for-profit first line buyer (FLB) was in August 2010, and the medicines arrived in Niger in January 2011, giving 9.5 months of implementation between the arrival of the first drugs and the midpoint of endline outlet survey fieldwork. Supporting interventions began at the same time as the arrival of the first drugs, but only about 30% of planned communication activities took place due to delays in receiving funds, delays in the selection of communications firms to undertake the activities and the suspension of the Global Fund AMFm supporting intervention grant in the second half of 2011. An RRP was set at USD 0.40 for a child dose and USD 0.70 for an adult dose. Training activities started in December 2010, but not all planned training took place.

Availability: QAACT availability among all outlets increased by 10 percentage points between baseline and endline, from 9% to 19% (Benchmark 1). This was a statistically significant increase, but did not meet the AMFm benchmark of a 20 percentage point increase. There was a significant increase in public sector outlets (from 45% to 73%) and a smaller, but also significant, increase in private for-profit outlets from 6% at baseline to 14% at endline. A very high number of general stores and itinerant vendors were screened for the outlet surveys, and it was common for them to have antimalarials in stock (42% of general stores and 63% of itinerant vendors enumerated at baseline stocked antimalarials), meaning that they represented a high proportion of private for-profit antimalarial outlets. They had lower stocking rates of QAACTs at endline (13% compared with 62% in private health facilities/pharmacies and 65% in drug stores), which therefore pulled down average QAACT availability in the private for-profit sector as a whole.

Price: The median price per adult equivalent treatment dose (AETD) of QAACTs fell considerably between baseline and endline, from USD 2.06 to USD 0.79 among all outlets. The median price remained zero in public health facilities, and in private for-profit outlets the median price fell from USD 2.47 to USD 1.19, somewhat higher than the RRP of USD 0.69 for an adult treatment. The median price in private for-profit outlets for a QAACT carrying the AMFm logo was USD 1.19 per AETD. This is 2.5 times higher than the median price of the most popular antimalarial which is not a QAACT in tablet form (chloroquine), indicating that Niger achieved AMFm Benchmark 2 which states that the ratio should be less than 3. It was not possible to compute Benchmark 3for Niger, as the number of AMT products audited at endline was fewer than 50.

Market share: QAACT market share measured across all outlets fell from 18% at baseline to 10% at endline, although the change is not significantly different from zero; and there was a significant increase in the share of nAT, from 73% at baseline to 87% at endline. This means that Benchmark 5 of a 10 percentage point increase in QAACT market share from baseline to endline has not been achieved in Niger. In the private for-profit sector, the QAACT share doubled, but from a very low starting level of 4% at baseline to 8% at endline.

Context: The security situation in Niger continued to be challenging. Rainfall in 2011 was erratic and uneven. Fewer LLINs were distributed in 2011 than in previous years. Disbursement of the AMFm supporting intervention grant was suspended. ACTs did not have over-the-counter status.

Summary: Niger met Benchmark 2 relating to the price of copaid QAACTs, which specifies that the median price should be less than three times the price of the most popular antimalarial which is not a QAACT in tablet form. It has not, however, achieved Benchmark 1 on availability or Benchmark 5 on market share of QAACTs. The market share of oral AMT (Benchmark 6) was already so low that it is not relevant to assessing the impact of AMFm in Niger. The amount of time elapsed between the arrival of copaid drugs and the endline outlet survey was only around 9.5 months, so the short time for implementation could be responsible for the slow progress of the program. However, it also seems that the quantity

of copaid QAACTs ordered, particularly by private for-profit FLBs, was too low to have made much of an impact on availability and market share. The implementation of supporting interventions, which might have helped to increase demand for copaid QAACTs, and thereby might have stimulated private for-profit orders, was also derailed by delays and the suspension of disbursement of the Global Fund SI grant. Finally, the implementation context in Niger is challenging, with problems of adverse weather interrupting supply chains, difficult transport outside the main cities and problems of insecurity.

Nigeria

AMFm implementation: A total of 54 FLBs were registered with the Global Fund as of January 31, 2012 (51 private for-profit, 2 private non-profit and 1 public sector). Orders had been placed by 28 private first line buyers by the end of 2011. The first orders were placed by private for-profit sector FLBs in October 2010, and arrived in Nigeria in January 2011. Approximately 9.5 months elapsed between the arrival of the first copaid drugs and the midpoint of endline outlet survey fieldwork. Implementation of supporting interventions trailed the arrival of the first copaid drugs by approximately 3 months, giving about 6 months from the start of implementation of SIs before the midpoint of the endline outlet survey. Some delays in initiating communications activities were caused by problems of coordination among the Principal Recipients (PRs). In the interim, a number of activities were undertaken (albeit not at scale) by other stakeholders such as professional associations and pharmaceutical firms. Private sector BCC activities only started in August 2011, and some mass media activities did not start until September 2011. The range of activities implemented from April 2011 onwards included advocacy, mass media communications, community dramas and road shows, training, regulatory changes and an RRP. By the end of 2011, a total of 67,219,660 copaid ACT doses had been delivered to Nigeria (0.42 doses per capita, the whole population of Nigeria is considered at risk of malaria), of which 80% were to private for-profit FLBs, 12% to the public sector and 8% to private not-for-profit FLBs. Only 24% of treatments requested by Nigeria FLBs in the second half of 2011 were approved due to the application of the Global Fund's demand levers.

Availability: QAACT availability in all outlets increased from 28% to 54%, an increase of 26 percentage points (p=0.14) from baseline to endline (Benchmark 1). There is therefore some evidence that Nigeria has met the benchmark of a 20 percentage point increase in QAACT availability, although the large p-value means we do not have strong evidence for this. In public health facilities, availability was 46% at baseline and 57% at endline, but this increase was not statistically significant. The major contributor to the overall increase in availability was the private for-profit sector, in which availability increased significantly from 27% to 53%.

Price: There was a substantial fall in the price of QAACTs between baseline and endline. Among all outlets, the median price per AETD fell from USD 3.72 to USD 1.48 at endline. In private for-profit outlets the decline in median price of QAACTs is even larger, from USD 4.47 to USD 1.48. Despite this large decline in the price of QAACTs in private for-profit

outlets, the ratio of the median price of QAACTs with the AMFm logo to that of the most popular antimalarial which is not a QAACT in tablet form was 3.1, and therefore Nigeria appears to have just missed Benchmarks 2 which states that the ratio should be less than 3. The price of QAACTs with the AMFm logo was less than that of AMT tablets (USD 2.66), so Nigeria did meet Benchmark 3.

Market share: QAACT market share measured across all outlets increased from 2% at baseline to 20% at endline, with very similar results in urban and rural areas. Benchmark 5 of a 10 percentage point increase in market share from baseline to endline was therefore met, with an 18 percentage point increase. The QAACT share of all antimalarials sold increased even more dramatically in the public sector, from 6% at baseline to 48% at endline, while it increased in private for-profit outlets from 2% to 18%. The market share of AMTs decreased from 8% at baseline to 4% at endline, meaning that Nigeria also met Benchmark 6. The increase in QAACT share in both the public sector and the private for-profit sector was accompanied by a reduction in the share of nATs which fell in the public sector from 85% to 38% and in the private for-profit sector from 84% to 69%. The private sector accounted for 97% of all antimalarials distributed at baseline and 92% at endline.

Context: Important contextual factors include the distribution of LLINs and indoor residual spraying (IRS) in some states, introducing RDTs into public and private health facilities in 12 states, a large domestic pharmaceutical manufacturing sector that initially resisted AMFm, and elections in 2011. ACTs had over-the-counter status.

Summary: Nigeria fully met Success Benchmarks 3 (QAACT price relative to AMT), 5 (QAACT market share) and 6 (AMT market share). There is some evidence that Nigeria also met Benchmark 1 (availability). Nigeria just missed the threshold for Benchmark 2 (QAACT prices relative to the most popular antimalarial which is not a QAACT in tablet form). The price of SP tablets was quite low (USD 0.47), making this target difficult to meet, but there was also poor adherence to the RRP. This could reflect the relatively low awareness of the RRP or perhaps market pressures linked to the exercise of the Global Fund demand levers. Benchmark 4 could not be calculated. These results were achieved despite the context of instability caused by the post-election crisis and terrorist attacks, which may have affected supply in some areas. There have been impressive increases in knowledge of the first-line drug, particularly in public health facilities, but achievements in recognition of the AMFm logo and knowledge of the AMFm program are more modest, consistent with the relatively short period of implementation of SIs before the endline outlet survey was conducted.

Tanzania - mainland

AMFm implementation: A total of 10 private for-profit FLBs were registered with the Global Fund, and the Medical Stores Department (MSD) was registered as an FLB for the public sector. Five of the private first line buyers had placed orders by the end of 2011. The first orders for copaid QAACTs were placed in August 2010 by a private for-profit FLB and were delivered in October 2010. A number of delays affected the ordering process in the public sector, resulting in public sector stockouts during 2011. A total of 13.5 months elapsed

between the date the first drugs arrived in Tanzania (October 2010) and the midpoint of endline outlet survey fieldwork. Supporting interventions started in January 2011, giving only 10 months of effective SI implementation. These included a communications campaign; upgrading of drug stores to accredited drug dispensing outlets (ADDOs); pharmacovigilance activities; monitoring and evaluation; and the setting of the recommended retail price at USD 0.62. The start of the communications campaign was delayed, and took place only seven months before endline data collection. A total of 13,039,620 copaid QAACT treatments were delivered between October 2010 and December 2011, amounting to 0.31 treatments per capita, of which 62% were delivered to private for-profit FLBs. The application of the Global Fund's demand levers in Tanzania reduced the orders approved by a modest amount (90% of treatments requested by FLBs were approved in the second half of 2011).

Availability: QAACT availability across all outlets increased by 44 percentage points, from 26% at baseline to 70% at endline (Benchmark 1). Tanzania has therefore easily met the benchmark of a 20 percentage point increase in QAACT availability ($p<0.0001$). There has been no increase in availability in the public sector, which was already 80% at baseline. Rather, the increase was concentrated in private for-profit outlets, which saw an increase in QAACT availability of 56 percentage points, with QAACTs available at endline in 79% of private for-profit health facilities/pharmacies and 69% of drug stores.

Price: In public and private not-for-profit health facilities, the median QAACT price remained at USD 0.00 at baseline and endline, reflecting the policy of free provision of QAACTs. Dramatic decreases in median QAACT prices were observed in the private for-profit sector between baseline and endline, from USD 5.28 to USD 0.94 per AETD, although this was still somewhat higher than the RRP of USD 0.62. The median price in private for-profit outlets for a QAACT carrying the AMFm logo was USD 0.94 per AETD. This is the same as the median price of the dominant antimalarial which is not a QAACT in tablet form (SP), and therefore Tanzania met Benchmark 2, which states that the ratio should be less than 3. As the number of oral AMT products in the market was negligible, Benchmark 3 was not relevant to Tanzania.

Market share: The market share of QAACTs overall increased by 16 percentage points, from 26% at baseline to 42% at endline. The increase took place mainly in the private for-profit sector, which saw a 30 percentage point increase from 2% to 32%. By contrast the market share was unchanged in public health facilities, where a fall in QAACT market share in urban areas was not sufficiently offset by an increase in rural areas. The implications for Benchmark 5 (a 10 percentage point increase in market share from baseline to endline) are that, while the point estimate for all sectors combined was greater than 10, the evidence that the benchmark has been reached is not strong ($p=0.23$). However, the power to detect a 10 percentage point increase was below the usual minimum standard of 80%; so the *p*-values should be interpreted with caution. In the private for-profit sector alone, the increase was significantly greater than 10 percentage points ($p<0.0001$). Benchmark 6 was not relevant to Tanzania given the negligible market share of oral AMTs at both baseline and endline.

Context: AMFm was implemented against the background of a large-scale malaria control communications campaign funded by PMI and the Global Fund. RDTs were being distributed to public facilities. IRS and mass distribution of LLINs were taking place. The Tanzanian shilling depreciated over this period. ACTs did not have over-the-counter status.

Summary: There is strong evidence that Tanzania has met Success Benchmarks 1 (QAACT availability) and 2 (QAACT price relative to the most popular antimalarial which is not a QAACT). It is possible that Benchmark 5 (QAACT market share) was also met across all sectors, but the evidence is not strong. However, we can be confident that a 10 percentage point increase in market share was easily achieved in the private for-profit sector. Benchmarks 3 and 6 are not relevant to Tanzania given the negligible presence of oral AMT in the market at baseline and endline. Data were not available to assess Benchmark 4 on use. The evidence about impressive changes in the availability and price of QAACTs, together with strong evidence of awareness of AMFm, the flow of copaid drug orders and SI implementation, provide plausible evidence that AMFm is responsible for the increases observed in QAACT market share. These changes may have also been supported by the complementary malaria communications campaign funded by other sources. The decrease in the market share of nAT in private for-profit outlets suggests that AMFm may be crowding out nATs and not simply shifting demand from other ACTs.

Uganda

AMFm implementation: Fourteen FLBs were registered with the Global Fund as of January 31, 2012 (nine private for-profit FLBs, three private not-for-profit FLBs and two FLBs for the public sector). Four of the private for-profit FLBs had placed orders by the end of 2011. FLBs from both the private for-profit and private not-for-profit sector placed their first orders in March 2011. The first deliveries for the private sector arrived in April 2011. Delays receiving orders were reported in both the private for-profit and private not-for-profit sectors. In the public sector, a number of factors contributed to delays in the placement of the first order. The first shipment of copaid ACTs for the public sector arrived in July 2011, and no stockouts of the adult package size of AL at the National Medical Stores resulting from the delays were reported. However, stock levels of the adolescent and pediatric package sizes of AL were low by December 2010, and by March 2011 the NMS was out of stock of these pack sizes. A total of 28,226,700 copaid QAACT treatments were delivered between April 2011 and December 2011, amounting to 0.84 treatments per capita (all of the population of Uganda is considered at risk of malaria), of which 73% were delivered to the public sector, 25% to the private for-profit sector, and 2% to the private non-for-profit FLB. The application of the Global Fund's demand levers in Uganda resulted in only 57% of treatments requested by FLBs in the second half of 2011 being approved. Only seven months had elapsed between the date the first drugs arrived in Uganda and the midpoint of the endline outlet survey fieldwork. Approximately USD 28.6 million was available from the Global Fund for supporting interventions. The first disbursement of these funds was delayed until November 2011, and none of this money was spent by the end of 2011.The only supporting interventions that occurred prior to the end of data collection were the National Launch, a small-scale AMFm pre-disbursement marketing campaign, and the establishment of

recommended retail prices. These activities likely had limited influence on AMFm outcomes, due to their scale.

Availability: QAACT availability across all outlets increased by 46 percentage points, from 21% at baseline to 67% at endline. Uganda therefore comfortably met the benchmark of a 20 percentage point increase of QAACT availability. The increase in availability in the public sector was not significant, meaning that most of the overall increase arose in the private for-profit sector. The increase was higher in urban areas than in rural areas (57 vs. 43 percentage points). Availability of QAACTs with the AMFm logo was much higher than that of QAACTs without the logo (58% vs. 16%). Availability of non-quality-assured ACTs decreased significantly, from 48% at baseline to 28% at endline. Availability of oral AMT was negligible at both baseline and endline.

Price: In the public and private not-for-profit sectors and for CHWs, the median price remained USD 0.00 at baseline and endline, reflecting the policy of free ACT provision. In the private for-profit sector, the median QAACT price at endline was USD 1.96 in urban and rural areas. In urban areas, this represented a fall of over 50% from the baseline median of USD 4.41, but in rural areas the decrease from USD 2.21 at baseline was not significant. The median price for QAACTs at endline was much higher than the RRP, which was USD 0.47. The median price in private for-profit outlets for a QAACT carrying the AMFm logo was USD 1.96 per AETD. This is 3.3 times the median price of the dominant antimalarial which is not a QAACT in tablet form (SP), and therefore Uganda did not meet Benchmark 2. The benchmark relating to the price of oral AMTs is not relevant for Uganda, due to negligible quantities of AMTs found in outlets in Uganda. There was no difference in the private for-profit sector between the median price of QAACTs with and without the AMFm logo.

Market share: The market share of QAACTs overall increased significantly from 40% to 57%, an increase of 17 percentage points (95% CI 7.1-26.5). This represents a significant increase from baseline, and provides some evidence that the benchmark of a 10 percentage point increase in QAACT market share had been met, although this evidence is not strong (p=0.08). However, the power to detect a 10 percentage point increase was below the usual minimum standard of 80%, so the p-values should be interpreted with caution. The benchmark of the market share of AMTs was not relevant for Uganda, as the overall market share of oral AMTs was close to zero at both baseline and endline.

Context: ACTs were recently granted over-the-counter status. There was no significant increase in the availability of microscopy between baseline and endline, but availability of RDTs increased significantly in public health facilities (4% to 53%) and in private not for-profit outlets (9% to 51%). There was also a substantial depreciation of the Ugandan shilling against the US dollar between the baseline and endline outlet surveys.

Summary: There is strong evidence that Uganda met the availability benchmark (Benchmark 1), and some evidence that the indicator related to QAACT market share (Benchmark 5) was met. Benchmark 2 comparing the median price of QAACTs to the median price of the most

popular antimalarial which is not a QAACT in tablet form was not met. The price and market share indicators related to AMTs are not relevant for Uganda, as these products are rare. The improvements in QAACT availability and market share were achieved despite the relatively short time between first arrival of copaid drugs and the endline outlet survey (seven months) and the lack of AMFm supporting interventions.

Zanzibar

AMFm implementation: One private for-profit FLB was registered, together with two international FLBs. The first order of copaid QAACTs was placed by the private for-profit FLB in February 2011 and these drugs were delivered in April 2011. A public sector order was placed in July 2011 and delivered in September 2011. By the end of 2011, a total of 241,075 treatments had been delivered, amounting to 0.19 treatments per capita (the entire population of Zanzibar is considered at risk of malaria). Only 6.5 months elapsed between the arrival of the first copaid drugs in Zanzibar (April 2011) and the midpoint of endline outlet survey fieldwork (October 2011). Supporting interventions started one month later, in May 2011, with a media campaign, so that only 5.5 months of SI implementation had occurred before the midpoint of the endline outlet survey. SIs included public awareness and mass media; limited training of public and private health workers; increased enforcement of the AMT ban; and the setting of the recommended retail price of USD 0.58 for an adult dose and USD 0.47 for a child dose.

Availability: QAACT availability across all outlets increased by 39 percentage points, from 46% at baseline to 85% at endline (Benchmark 1), easily meeting the benchmark of a 20 percentage point increase in QAACT availability. Availability was slightly higher in rural than in urban areas at endline (90% vs. 82%). Virtually all of the increase in QAACT availability occurred in private for-profit outlets, as availability in public sector health facilities was already 92% at baseline and increased only marginally to 94% at endline. Within the private for-profit sector, QAACT availability increased by 71 percentage points from 9% at baseline to 80% at endline.

Price: Because nearly all the QAACTs at baseline were in public health facilities (and therefore free), the increased availability in the private for-profit sector led to an increase in the overall median price from USD 0.00 at baseline to USD 0.58. However, there was a very substantial decrease in the median price of QAACTs in private for-profit outlets, from USD 5.99 at baseline to USD 1.17 at endline. The endline median price is 83% higher than the recommended retail price (RRP) of USD 0.58 for an adult dose. The median price of QAACTs with the AMFm logo in private for-profit outlets at endline was USD 1.17 per AETD. This is 1.5 times higher than the price of the most popular antimalarial which is not a QAACT in tablet form which in Zanzibar was amodiaquine (with a price of USD 0.79 per AETD). Zanzibar has therefore clearly met Benchmark 2, which states that the ratio of median prices should be less than 3. The median price of QAACTs with the logo was also much lower than the price of AMT tablets (USD 7.46), so Benchmark 3 was also met.

Market share: Zanzibar has seen a nearly six-fold increase in the market share of QAACTs from baseline to endline, from 10% of all antimalarial AETDs sold/dispensed at baseline to 58% at endline. Benchmark 5 of a 10% increase in QAACT market share has therefore been easily achieved. In public sector outlets, the QAACT share has increased by 15 percentage points, from 23% to 38%, with the main shift being away from non-quality-assured ACTs, from 21% at baseline to only 3% at endline. In private for-profit sector outlets, the increase in QAACT market share is even more dramatic, with a 59 percentage point increase, from 2% at baseline to 61% at endline. Benchmark 6 has also been achieved, with the market share of AMTs measured in all outlets falling by 12 percentage points, from 12% to nearly 0 at endline.

Context: Contextual factors included early adoption of ACTs as the first-line drug (in 2003); enforcement of AMT ban; allowing ACTs to be sold in drug stores with over-the-counter status; scale up of diagnostics; IRS and distribution of LLINs; and a dramatic reduction in the number of malaria cases.

Summary: Zanzibar has met all of the Success Benchmarks that could be assessed. These very substantial improvements in QAACT availability and market share; reductions in QAACT prices; and reductions in availability and market share of nATs, AMTs and non-quality-assured ACTs have occurred despite less than seven months of effective implementation of AMFm, and with a relatively limited flow of copaid antimalarials into the country (0.19 treatments per capita delivered as of the end of 2011). It seems appropriate to conclude, therefore, that in Zanzibar AMFm has met with a highly supportive and conducive environment. Key regulatory steps to support OTC sales of QAACTs and to intensify enforcement of the ban on AMT are likely to have played an important role in the achievement of the benchmarks, in addition to core AMFm interventions of the supply of copaid QAACTs and the strong communication campaign. Although information on appropriate use of ACTs was not collected as part of the IE, the relatively high availability of diagnostic testing in the public sector should contribute to rational use of QAACTs, providing another supporting contextual factor. In this light, the shift in market share toward the private for-profit sector, where diagnostic testing is not universally available, should be seen with some concern, and efforts to improve availability of RDTs especially in drug stores are needed.

Conclusions

A number of key findings can be distilled on the process and impact of AMFm:

1. **Achievement of success benchmarks** – Figure 24 provides an overview of the performance of each pilot against the AMFm success benchmarks. Of the 8 pilots, success benchmarks were clearly met in 5 pilots for availability, 5 pilots for QAACT price relative to the most popular antimalarial that is not a QAACT, and 4 pilots for QAACT market share (all shaded green). It is also possible that benchmarks were met in

a one additional pilot for availability and price, and in 3 additional pilots for market share, although the evidence is not as strong (shaded amber). The success benchmarks related to AMT price and market share were met in all pilots with sufficient AMTs in the market to make these benchmarks relevant.

2. **AMFm and the private for-profit sector** – AMFm has been a "game changer" in the private for-profit sector for all pilots except Niger and Madagascar, with a dramatic impact on the antimalarial market, through large increases in QAACT availability, decreases in QAACT prices, and increases in QAACT market share. These changes were substantial and achieved in only a few months, demonstrating the power of tapping into the distributional capacity of the private sector. The changes are very likely to be largely attributable to AMFm. The private for-profit sector response was similar in rural and urban areas, in some cases reducing or closing a rural-urban gap in availability and market share. There was considerable penetration of copaid QAACTs even in remote areas in Ghana and Kenya, where this was evaluated.

3. **AMFm and the public sector** – AMFm led to fewer fundamental changes to public sector antimalarial supply, where QAACT supply continued to be hindered by problems with procurement and grant requirements, leading to substantial delays in ordering. Increases in QAACT market share were seen in the public sector in four pilots (Ghana, Nigeria, Uganda and Zanzibar), although in Nigeria most QAACTs distributed through the public sector were not copaid. QAACTs were available in less than 80% of all public facilities at endline in five pilots, and there was generally no change in public sector QAACT prices as most countries already provided QAACTs for free at baseline (except Ghana where public sector QAACT prices fell).

4. **Limited impact in Madagascar and Niger** – The impact of AMFm on the private for-profit sector was limited in Madagascar and Niger, where orders of copaid ACTs were very low. Explanations may include (i) the lack of full-scale mass media campaigns; (ii) the structure of the private for-profit antimalarial sector, which had a much higher proportion of general stores, and in Niger itinerant vendors, who are not allowed to stock QAACTs; and (iii) an unfavourable context of political and/or economic instability and severe weather conditions.
5. **Effect of duration of implementation –** Longer duration of implementation appears to be positively correlated with performance, if the combined presence of copaid ACTs and the operation of a large-scale sustained IEC/BCC campaign is considered a proxy for full AMFm implementation. With the exception of Zanzibar, pilots with earlier start dates achieved more success benchmarks. No large-scale sustained IEC/BCC campaign was in place by the end of 2011 in Madagascar, Niger or Uganda, and these pilots achieved fewer benchmarks. However, it is possible that delayed start dates reflect weaker implementation capacity in general, and therefore one should be cautious in attributing performance to duration of implementation alone.

6. **Prices and markups in the private for-profit sector** – The price of copaid QAACTs in the private for-profit sector at endline was very variable across pilots, ranging from USD 0.51 in Madagascar to USD 1.96 in Uganda. Reasons for this variability are unclear but may include (i) variations in the RRP and its promotion through national IEC/BCC campaigns; (ii) guidelines on markups (in Madagascar); (iii) differences in cost structure including tax components; and (iv) time since copaid ACTs first arrived in each country. The median retail gross markup on copaid QAACTs was less than 70% in all pilots (which can be considered reasonable for the retail sector), except Uganda (133%) and Zanzibar (100%).

7. **Crowding out oral artemisinin monotherapy** – Even at baseline, market share for oral AMT was less than 4% in Ghana and less than 1% in Kenya, Madagascar, Niger, Tanzania Mainland and Uganda. In Nigeria and Zanzibar where oral AMT market share was somewhat higher at baseline, large and significant falls were observed, likely reflecting a combination of the AMFm subsidy and complementary regulatory measures with particularly strong enforcement of the latter in Zanzibar.

8. **Availability and market share of non-artemisinin therapies** – nAT availability fell in some countries, but remained very high in most countries. However, the increases in QAACT market share were accompanied by decreases in nAT market share.

9. **Market structure** – The private sector was a major player in the antimalarial market in all pilots, accounting for between 40% and 97% of antimalarial sales volumes at baseline, and between 49% and 92% at endline. There was no clear pattern across pilots in the change in private for-profit market share between baseline and endline.

10. **Availability of malaria diagnosis** – Diagnostic availability (RDT or microscopy) varied substantially in the public sector, from 29% in Nigeria to 98% in Zanzibar at endline. However, in private for-profit outlets, only three pilots had substantial availability at endline (Kenya - 14%, Uganda – 21%, Zanzibar - 32%). In this sector, health facilities/ pharmacies have higher availability of diagnostics than drug and general stores.

11. **Results of operational research** – Results from studies of interventions to enhance the implementation of antimalarial subsidies by improving targeting and/or drug use show that implementation of such interventions is feasible on a small scale, but more evidence on effectiveness and cost-effectiveness of large-scale programs is needed to inform policy.

12. **Issues not covered by the Independent E**valuation – A number of important issues related to AMFm policy decisions were beyond the scope of the Independent Evaluation, including the impact on targeting copaid ACTs to persons with parasitemia; advice provided to patients; adherence to dosing regimens; global artemisinin supply and prevalence of counterfeit products.

13. **Possible hindering factors for AMFm in some countries include**:
    - Delays in the public sector procurement process for copaid ACTs
    - Issues with Global Fund grants and delays in procurement of supporting interventions, meaning that implementation of most SIs lagged behind the arrival of copaid ACTs by several months
    - Suspension of Global Fund disbursements or grants interrupting implementation of supporting interventions
    - Application of Global Fund demand levers to ration orders
    - Political and/or economic instability
    - An antimalarial provider market dominated by highly informal outlets operating outside of regulated distribution channels (in Madagascar and Niger)
14. **Possible facilitating factors for AMFm in some countries include**:
    - Strong AMFm governance structures (including steering committees), involvement of the private sector and technical assistance from the Clinton Health Access Initiative
    - Generally smooth operation of the registration process for first-line buyers and ordering through the copayment mechanism
    - Strong, large-scale mass media campaigns, including promotion of the AMFm logo
    - Longer duration of implementation
    - Establishment and promotion of an RRP set at an appropriate level
    - Complementary regulatory changes, such as giving ACTs over-the-counter status, and implementation of the AMT ban
    - AMFm training in some countries (although only Ghana and Zanzibar had over 20% training coverage)

Figure 24: Overview of the achievement of the AMFm Success Benchmarks by county, indicating benchmarks achieved (in green), nearly or possibly achieved (in amber) and not achieved (in red), (point estimate, and p-value for statistical test of whether the level stated in the benchmark was achieved)

Benchmark	Ghana	Kenya	Madagascar	Niger	Nigeria	Tanzania mainland	Uganda	Zanzibar*
1. 20 percentage point increase in QAACT availability	52 ($p<0.01$)	35 ($p<0.01$)	4.6 ($p=0.99$)	10 ($p=0.99$)	26 ($p=0.14$)	44 ($p<0.01$)	46 ($p<0.01$)	39
2. Median price of QAACTs with AMFm logo is <3 times the median price of the most popular antimalarial in tablet form that is not a QAACT (ratio)	3.0 ($p=0.81$)	1.0 ($p<0.01$)	1.6 ($p<0.01$)	2.5 ($p<0.01$)	3.1 ($p=0.99$)	1.0 ($p<0.01$)	3.3 ($p=0.99$)	1.5
3. Median price of QAACTs with AMFm logo is less than the median price of AMT tablets (difference, QAACT – AMT)	-0.94 ($p<0.01$)				-1.17 ($p<0.01$)			-6.3
4. 5 percentage point increase in percentage of children with fever who received ACT treatment	na	na	na	na	na	na	na	na
5. 10 percentage point increase in market share of QAACTs	40 ($p<0.01$)	31 ($p=0.01$)	8.6 ($p=0.61$)	-8.8 ($p=0.99$)	18 ($p<0.01$)	16 ($p=0.23$)	17 ($p=0.08$)	48
6. Decrease in market share of oral AMTs (percentage point change)					-3.9 ($p=0.03$)			-12

Notes: Green shading = the benchmark was achieved, with strong statistical evidence (generally $p<0.01$); Amber shading = either the benchmark was nearly, but not fully, met, or the evidence that the change seen was unlikely to be due to chance is weak ($p\geq0.05$). However, the power to detect a 10 percentage point increase in market share was only 35% in Tanzania, 66% in Uganda and 70% in Madagascar, compared with the usual minimum standard of 80%; therefore, p-values should be interpreted with caution. Red shading = the benchmark was not met; Grey shading for Benchmarks 3 and 6 = not relevant because the number of AMT products was very low at baseline. * p-values not shown for Zanzibar because a complete census of antimalarial stocking outlets was undertaken; na = not available; ACT= artemisinin-based combination therapy; AMT= artemisinin montherapy; QAACT= quality-assured artemisinin-based combination therapy