

Malaria Case Management After the Affordable Medicines Facility for Malaria (AMFm): Availability, Quality, and Market Share for ACTs in Kenya's Private Pharmacies

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Abstract

Between 2011 and 2016, the Affordable Medicines Facility-Malaria (AMFm) subsidy program substantially increased access to WHO prequalified artemisinin combination therapies (ACTs) through Africa's private sector pharmacies and drug-sellers. While the program was rigorously and extensively evaluated, little is known about private-sector case management of malaria in the period since its discontinuation. This paper leverages digital point-of-sale data from 250 pharmacies and private-sector clinics, combined with Indian export data for pharmaceuticals, to examine anti-malarial prescribing and importation practices in the Kenyan private sector after the AMFm. We find that the AMFm has driven an enduring shift to ACT usage even after the subsidy's discontinuation; however, non-WHO prequalified products have captured a growing portion of overall market share. As of 2019, the price of artemether lumefantrine (AL) in the Kenyan private sector had returned to the level seen at the close of AMFm. Rapid diagnostic tests remain underutilized in the private sector, which is consistent with prior literature and suggests room for intervention. The findings highlight the continued importance of the private sector in malaria case management in Kenya, and the value of technological innovation in providing unique insights on how to shape private sector malaria treatment.

JEL: I11, I18

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ACTs in Kenya's Private Pharmacies**

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The Center for Global Development is grateful for contributions from the Bill & Melinda Gates Foundation in support of this work.

Daniel Rosen, Jessica Vernon, Rachel Silverman, Elizabeth Juma, Maria Dieci, and Prashant Yadav, 2020. "Malaria Case Management After the Affordable Medicines Facility for Malaria (AMFm): Availability, Quality, and Market Share for ACTs in Kenya's Private Pharmacies." CGD Working Paper 561. Washington, DC: Center for Global Development. <https://www.cgdev.org/publication/malaria-case-management-after-affordable-medicines-facility-malaria-amfm-availability>

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Introduction

Even after decades of control efforts, malaria remains endemic across most of sub-Saharan Africa, with an estimated 228 million cases causing 405,000 deaths each year.¹ The economic impact of malaria is also significant, driving losses across the continent from healthcare costs, absenteeism, and lost productivity and investment. In the most affected countries, recent estimates suggest that the malaria burden depresses per-capita incomes by up to 16%.²

Africa's private sector pharmacies and drug shops play a prominent role in malaria case management. In Uganda, Kenya and Tanzania, over half of patients with suspected malaria seek malaria treatment via private pharmacies and drug shops.³ Though widespread access to treatment is welcome, the malaria community has had longstanding concerns about the quality of malaria case management in these private sector settings. These concerns can be broadly divided into three categories.

The first concern is whether malaria patients receive *appropriate* first-line treatment. Historically (before 2011), most patients seeking malaria treatment in private pharmacies would receive either sulfadoxine-pyrimethamine (SP) or non-recommended monotherapies as treatment instead of more efficacious (but more expensive) artemisinin combination therapies (ACTs). Use of SP or monotherapies is both less effective than ACTs and risks driving drug resistance.

A second concern is the *quality* of the drugs used for malaria treatment—including the quality of ACTs. International malaria key opinion leaders strongly encourage the use of WHO-prequalified ACTs, which have been subjected to rigorous quality standards. However, price-sensitive African pharmacies and patients may not be willing to pay a premium for WHO-prequalified drugs, which tend to be more expensive than non-prequalified competitors. Non-prequalified drugs are of *unknown* quality and may be substandard. Risks from substandard drugs include contamination and insufficient active ingredients, among others. Market penetration of poor-quality ACTs is a particular concern, as low-quality products are more likely to contribute to artemisinin resistance.

A third concern is whether febrile patients *with non-malarial illnesses* receive appropriate treatment. Such patients may receive *unnecessary* treatment due to presumptive (and incorrect) malaria diagnosis upon presentation with febrile illness. Ideally, ACTs should only be

¹ World Health Organization (2019). *World Malaria Report 2019*. Geneva: World Health Organization.

² Sarma N, Patouillard E, Cibulskis R, Archand JL (2019). The economic burden of malaria: revisiting the evidence. *Am J Trop Med Hyg* 101(6):1405-1415.

³ Cohen J, Dupas P, Schaner S (2015). Price subsidies, diagnostic tests, and targeting of malaria treatment: evidence from a randomized control trial. *American Economic Review* 105(2):609–45.

dispensed following diagnostic confirmation of malaria through use of a rapid diagnostic test (RDT) or laboratory-based diagnosis. Antimalarial misuse is an example of a market failure: individuals fail to account for the potential for resistance when deciding about treatment, leading to drug resistance and financial waste. “The use of presumptive treatment for malaria has the potential for facilitating resistance by greatly increasing the number of people who are treated unnecessarily but will still be exerting selective pressure on the circulating parasite population.”⁴

This carries a cost: artemisinin resistance could lead to 116,000 deaths annually as well as medical costs of \$32 million and productivity losses of \$385 million.⁵ Relatedly, both RDT-negative cases and cases incorrectly diagnosed with malaria may not receive appropriate referrals back to the public sector for diagnosis and treatment of their non-malarial illnesses. Referral rates of malaria-negative cases from private sector pharmacies to the public sector may be as low as 15% in practice, with even lower rates of referral completion.⁶

Between 2011 and 2016, the international malaria community piloted an innovative program—the Affordable Medicines Facility-Malaria (AMFm)—in an attempt to address some of these challenges with malaria case management in the private sector. The AMFm offered a factory-gate subsidy for pre-qualified ACTs in eight countries (later reduced to six)—including Kenya—with the goal of lowering their price to under \$1 for a course of treatment, thereby gaining market share from otherwise cheaper but less effective antimalarials (e.g. SP and monotherapies).⁷ The Global Fund Secretariat originally set a uniform 95% subsidy across all participating countries. Starting in 2013, after participating countries were given flexibility to set their own subsidy levels within an overall budget constraint, Kenya reduced its subsidy level to 70%.⁹

Evaluations of the AMFm have found that the program decreased ACT retail prices, increased the proportion of drug shops stocking ACTs, and led to more patients being

⁴ Boland P (2001) Drug resistance in malaria. World Health Organisation report.

⁵ Lubell Y, Dondorp A, Guerin PJ, et al. (2014). Artemisinin resistance—modelling the potential human and economic costs. *Malaria Journal* 13(452).

⁶ Thompson A, Khogali M, de Smet M, et al. (2011). Low referral completion of rapid diagnostic test-negative patients in community-based treatment of malaria in Sierra Leone. *Malaria Journal* 10(94).

⁷ Tougher S, Ye Y, Amuasi JH, et al. (2012). Effect of the Affordable Medicines Facility—malaria (AMFm) on the availability, price, and market share of quality-assured artemisinin-based combination therapies in seven countries: a before-and-after analysis of outlet survey data. *The Lancet* 380(9857):1916–1926.

⁸ Arrow, KJ (2012). Saving a program that saves lives. Op-Ed. *New York Times*. November 13, 2012.

⁹ ACTwatch Group, Tougher S, Hanson K, Goodman C. What happened to anti-malarial markets after the Affordable Medicines Facility-malaria pilot? Trends in ACT availability, price and market share from five African countries under continuation of the private sector co-payment mechanism. *Malaria Journal* 16(173).

treated with appropriate first-line therapy.¹⁰¹¹¹² Nonetheless, the program was scaled down starting in 2015 and fully discontinued by 2017. In this context, it is important for the malaria community to understand the extent to which the AMFm led to enduring change in private-sector case management of malaria even after the end of the subsidy--and to identify remaining challenges.

This paper examines the state of malaria case management in Kenya's private-sector pharmacies in the aftermath of the AMFm discontinuation. It leverages digital point-of-sale data from about 250 pharmacies and private-sector clinics, supplemented by Indian export data for pharmaceuticals, to understand importation and prescribing practices in the private sector. Specifically, it investigates the extent to which the three challenges described above—appropriate first-line prescribing, ACT quality assurance, and inappropriate treatment of non-malaria febrile illnesses—have either been addressed or remain outstanding following the end of the AMFm subsidy. It concludes with recommendations for countries and the international malaria community to further improve private-sector malaria case management and address outstanding challenges.

Data

The data used in this paper come from two primary sources:

1. **Maisha Meds Digital Point-of-Sale System:** Maisha Meds is a technology-enabled healthcare company aiming to improve access to affordable and quality medicines across the global south. The company offers point-of-sale software to small rural pharmacies and clinics with limited internet connectivity and electricity, allowing them to log individual patient transactions; track inventory/stock levels; produce real-time business analytics; and order stock directly from a selection of quality medicine suppliers. Maisha Meds has deployed its software across 300+ pharmacies and clinics in Kenya, Uganda, Tanzania, Ghana and Nigeria; these pharmacies and clinics, in turn, support over 130,000 patients each month. Each patient interaction in participating pharmacies is captured and uploaded, allowing Maisha Meds to view changes in malaria commodity consumption trends in near real-time (while anonymizing individual pharmacy-level data).

¹⁰ Tougher S, Ye Y, Amuasi JH, et al. (2012). Effect of the Affordable Medicines Facility—malaria (AMFm) on the availability, price, and market share of quality-assured artemisinin-based combination therapies in seven countries: a before-and-after analysis of outlet survey data. *The Lancet* 380(9857):1916–1926.

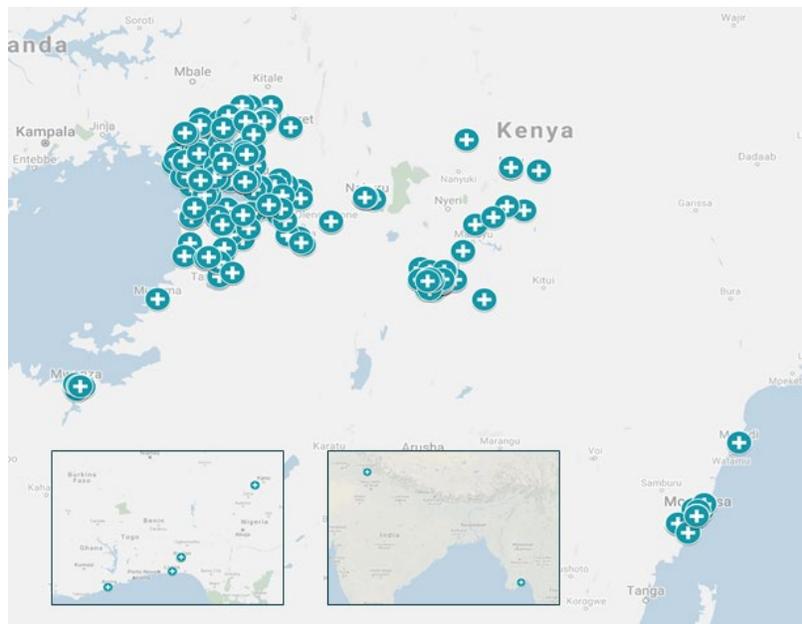
¹¹ Yadav P, Cohen JL, Alphs S, et al. (2012). Trends in availability and prices of subsidized ACT from the first year of the AMFm: evidence from remote regions of Tanzania. *Malaria Journal* 11(299).

¹² Cohen JL, Yadav P, Moucheraud C, et al. (2013). Do price subsidies on artemisinin combination therapy for malaria increase household use? Evidence from a repeated cross-sectional study in remote regions of Tanzania. *PLoS ONE* 8(7):e70713.

This paper uses data from about 250 Maisha Meds-supported pharmacies in Kenya captured between 2017 and 2019. (We omit data collected after November 2019 to avoid conflating COVID-19 related impacts with broader pre-existing trends). About 150 of these pharmacies are located in Western Kenya; 50 in Nairobi; 10 in the coastal region; and the remainder spread across the country (figure 1). About 60% of these pharmacies and clinics are medium-sized, with sales between \$800 and \$10,000 per month. Analysis was limited to only private sector pharmacies and clinics, of which most serve low- to middle-income customer segments.

For this analysis we focus on artemether lumefantrine (AL) tablet sales, which comprises 87% of ACT sales in Kenya. All volumes and prices are standardized to the 20mg/120mg dosage strength.

Figure 1. Maisha Meds Network of Supported Pharmacies, Kenya



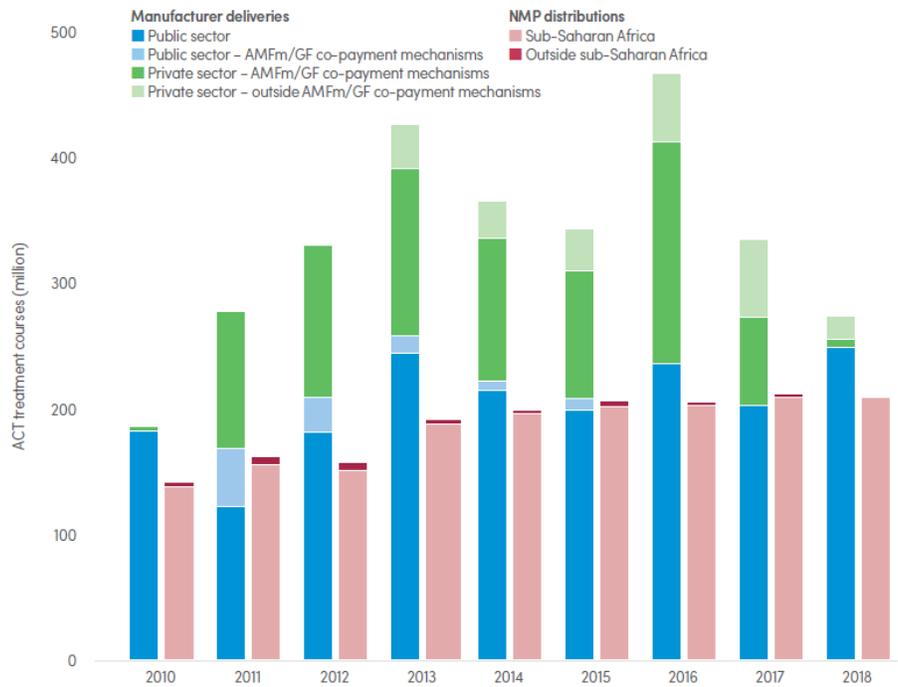
- 2. Indian export data:** Export data for Indian pharmaceuticals—comprising 37% of total market share in Kenya by value and 87% of finished AL imports—is used to corroborate findings from the Maisha Meds sample and ensure Maisha Meds pharmacies were reflective of Kenya’s broader national trends. Data was filtered for molecule names “artemether” and “lumefantrine,” as well as all known and registered brand names for AL combinations in Kenya. Data was first anonymized by known quality standard of the manufacturer and the destination sector (e.g. public, private, donor). We converted value to volume by taking the average price per standard unit/year based on the top 100 lines of export data where pack size, strength and form were available. (This approach to volume estimation is the best available due to frequent missing data on price-per unit within this data source.)

Section 1. ACT procurement and distribution through the private sector

Following the end of the AMFm, official data suggests a steep drop off in private-sector ACT prescribing. The 2019 World Malaria report states “...with declines in co-payments from the Global Fund, the number of ACTs procured for the private sector has decreased substantially since 2016.” The report estimates that the number of treatments disbursed by the private sector has fallen from about 225 million in 2016 to just 30 million in 2018 (figure 2).¹³

Figure 2. World Malaria Report (2019) Estimates of ACT Treatment Courses¹⁴

Number of ACT treatment courses delivered by manufacturers and distributed by NMPs to patients, 2010–2018^{a,b} Sources: Companies eligible for procurement by WHO/UNICEF and NMP reports.



ACT: artemisinin-based combination therapy; AMFm: Affordable Medicines Facility–malaria; GF: Global Fund to Fight AIDS, Tuberculosis and Malaria; NMP: national malaria programme; UNICEF: United Nations Children’s Fund; WHO: World Health Organization.

^a NMP deliveries to patients reflect consumption reported in the public health sector.

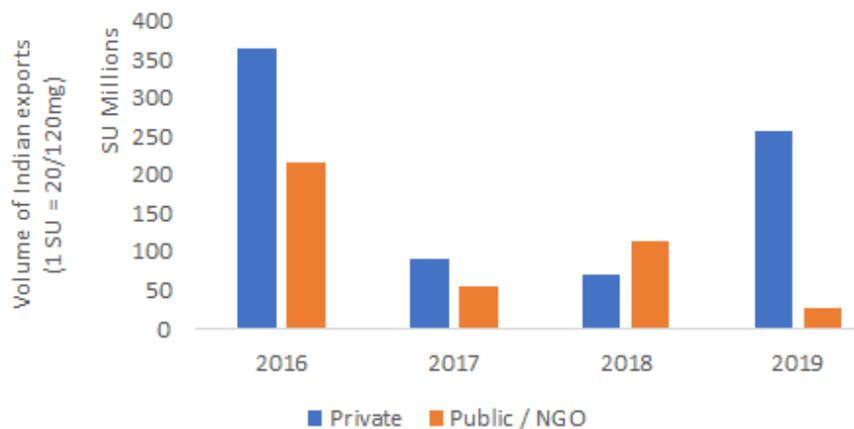
^b AMFm/GF indicates that the AMFm operated from 2010 to 2013, with the GF co-payment mechanism operating from 2014.

¹³ World Health Organization (2019). *World Malaria Report 2019*. Geneva: World Health Organization.

¹⁴ World Health Organization (2019). *World Malaria Report 2019*. Geneva: World Health Organization.

An examination of Indian export data, however, suggests a somewhat different story (Figure 3). Private sector AL imports to Kenya did indeed drop off substantially after 2016 but appear to have rebounded significantly by 2019.

Figure 3. Indian Exports of AL to Kenya by Year and Sector, Estimated by Volume (SU)

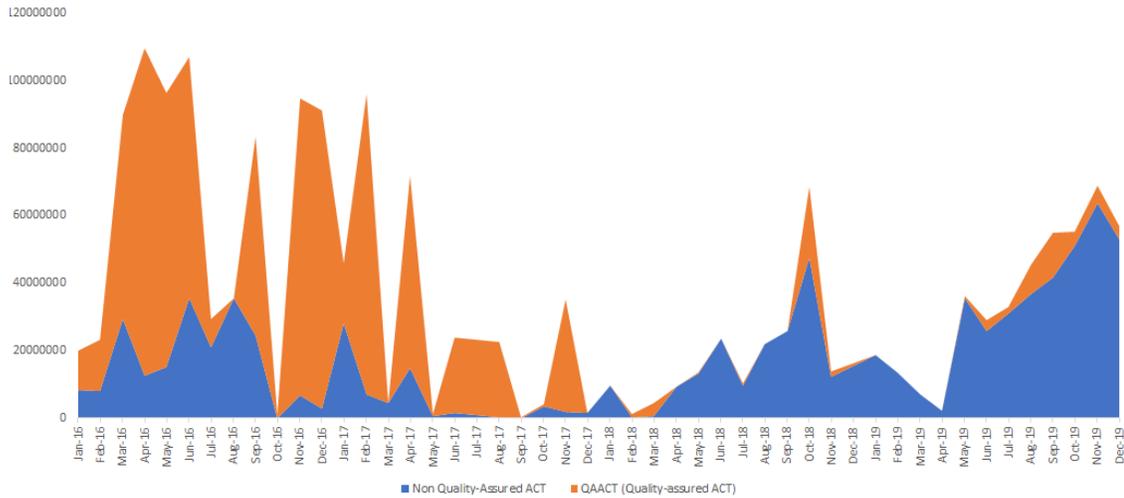


Source: Indian export data filtered for finished goods export of antimalarials to public sector and private sector wholesalers in Kenya 2016–2019. Average price per SU /year based on top 100 lines of export data where pack size, strength and form available. Data for lower cost non-WHO prequalified exports was less likely to include pack size, strength and form, meaning average price per unit and export volumes in 2018–2019 may be higher than depicted.

What explains this divergence? First, 2019 has not yet been added to the analysis in the global malaria report and may yet show a rebound. Second, the disparate findings may result from the fact that the World Malaria Report only collects data from national malaria programs and “companies eligible for procurement by WHO/UNICEF”—that is, companies that have received WHO prequalification. As a result, the official data may not be capturing a rise in private sector procurement of non-WHO prequalified antimalarials, potentially presenting a misleading picture to national governments and the global malaria community.

A deeper examination of Indian export and Maisha Meds point-of-sale data appear to support this second hypothesis. At the national level (as observed in Indian export data), non-WHO prequalified ACTs have gradually gained market share among Kenya’s private-sector wholesalers (figure 4). In 2016, WHO prequalified ACTs comprised 74.4% of private-sector imports, falling to just 9.7% by 2019 in value terms.

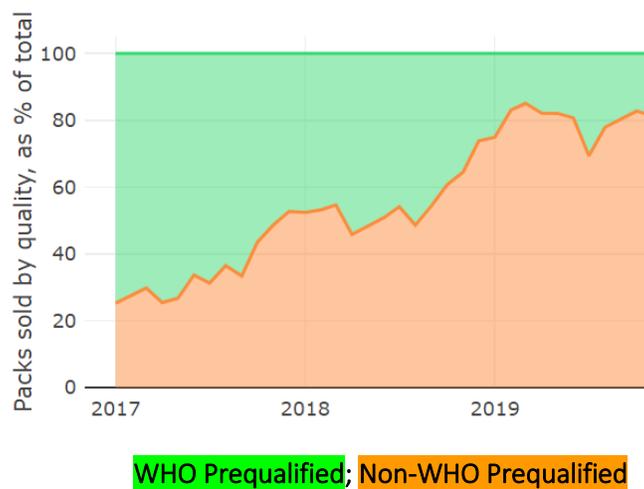
Figure 4. Indian Exports of WHO-Prequalified and Unknown Quality ACTs to Kenyan Private Sector Wholesalers, 2016–2019



Source: Indian export data filtered for finished goods export of antimalarials to private sector wholesalers in Kenya 2016–2019. Value presented in Indian rupees.

Similar trends are observed in pharmacies that are part of the Maisha Meds network (figure 5), though analysis necessarily excludes the roughly 50 percent of transactions that do not capture brand name. In early 2017, WHO pre-qualified ACTs comprised about three quarters of all ACT sales in Maisha Meds pharmacies (among transactions with known brands). By November 2019, four in five ACT sales with known brands were of non-prequalified products, while average AL sales per pharmacy remained relatively constant.

Figure 5. Proportion of Maisha Meds ACT Sales by Quality Standard, Among Transactions with Known Brand, 2017 to November 2019

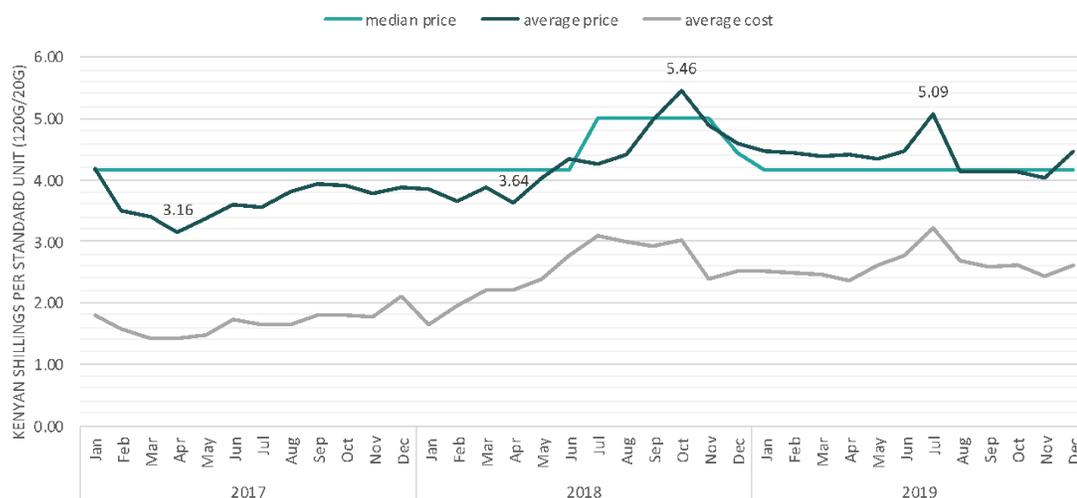


Source: Maisha Meds point-of-sale data 2017–2019 by AL manufacturer WHO PQ status. Excludes case = Manufacturer Unknown.

Section 2. Price sensitivity, product selection, and quality standards

Maisha Meds point-of-sales data suggests that private sector prices for ACTs increased dramatically in the aftermath of AMFm subsidies—in some cases by as much as 75% (figure 6). Anecdotal reports attribute this initial price increase to private sector shortages caused by a slowdown in wholesaler procurement, which was itself attributed to uncertainty of demand following removal of the subsidy. Following this temporary increase in treatment cost there was a drop in the average AL price back to the previous median price level of roughly KES 100 (\$1) per treatment course (24 tablets 20mg/120mg.)

Figure 6. Price to Patient and Cost to Pharmacy (KES) Per SU/Tablet AL



Source: Maisha Meds point-of-sale data 2017–2019. Cost refers to the pharmacy purchase price for a standard unit of AL. Standard Unit = AL 20mg/120mg.

Further analysis of the underlying data suggests the decreased price to patient—back to the \$1 per treatment course level targeted by the AMFm—was facilitated by an increase in sales of non-WHO prequalified ACTs, as described in the previous section. Specifically, the brand Lonart, manufactured by Bliss Pharmaceuticals in India, has now become the leading ACT brand sold by Maisha Meds pharmacies. While we cannot determine the quality of Lonart specifically, past evidence has shown that non-WHO prequalified ACTs have a significantly higher risk of poor quality (substandard, degraded, falsified) as compared to WHO prequalified ACTs (odds ratio 1:0.08).¹⁵

¹⁵ Kaur H (2015). Findings from the ACT Consortium Drug Quality Studies in 6 Countries. London School of Hygiene and Tropical Medicine. Available online at http://www.actconsortium.org/data/files/9_Harprakash_Kaur_Field_work_final.pdf

The relationship between market price and drug quality is difficult to pin down, but some cross-country evidence suggests that better-quality drugs are sold at higher prices than substandard counterparts.¹⁶

The cost of reaching WHO prequalification was estimated in 2015 as less than \$300,000 for an already compliant manufacturer; between \$650,000–\$3,000,000 for a manufacturer with established development and production processes; and even more for a manufacturer without the established protocols and capital equipment.¹⁷ These costs are then passed onto the final product price, which is why medicines produced by WHO prequalified manufacturers tend to be more expensive than non-prequalified competitors.

Section 3. Diagnosis and rational ACT use

The AMFm program subsidized ACTs but not RDTs; the economic logic that ensued created an incentive to presumptively treat all febrile patients with ACTs in lieu of testing. This, in turn, sparked some concerns about overuse and inappropriate use of ACTs in the private sector in patients with non-malaria febrile illness.¹⁸

Maisha Meds data confirms that underuse of RDTs remains a major problem in private sector pharmacies and clinics. In 2019, Maisha Meds sold a total of 116,097 ACTs but just 14,703 RDTs—a ratio of 1:7.9 RDTs for each ACT. Though there is no internationally accepted standard for the “ideal” ratio of RDTs to ACTs, and the ratio indicating universal RDT coverage would necessarily vary as a function of underlying epidemiology, a logical bare minimum would be over 1:1—that is, at least one test for every ACT distributed, as some RDTs should be negative meaning an ACT is not indicated.

The private sector average compares unfavorably against the national average for RDT usage in the Kenyan public sector. For comparison, the Kenyan public sector according to the National Malaria Control Program (NMCP) procured 11,425,842 rapid diagnostic tests (RDTs) and 5,234,693 courses of ACT. This ratio of 2.18:1 is much higher than seen in the private sector and represents a possible benchmark for appropriate clinical practice.

Though some patients may visit pharmacies to fill prescriptions following diagnosis elsewhere, the very limited use of RDTs in the private sector likely indicates presumptive use of ACTs. However, this topline finding overlooks substantial facility-level heterogeneity. Maisha Meds pharmacy-level data shows 5 pharmacies where the ratio of RDTs to ACTs exceeded 1:1; and another 11 where the ratio was between 1:1 and 1:2. No incentives were in

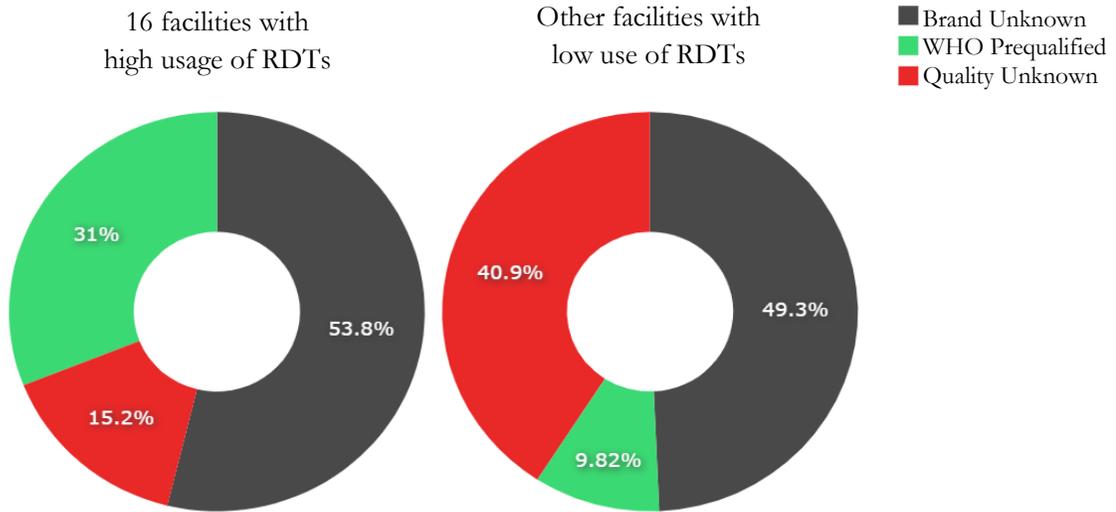
¹⁶ Bate R, Jin GZ, Mathur A (2011). Does price reveal poor-quality drugs? Evidence from 17 countries. *Journal of Health Economics* 30(6):1150–1163.

¹⁷ World Health Organization (2015). Investing in WHO Prequalification of Finished Pharmaceutical Products: Information for Manufacturers.

¹⁸ Cohen J, Dupas P, Schaner S (2015). Price subsidies, diagnostic tests, and targeting of malaria treatment: evidence from a randomized controlled trial. *American Economic Review* 105(2):609–645.

place to guide this behavior. Further investigation of this subset of pharmacies also revealed a strong preference for WHO prequalified AL brands over non-prequalified products where brand was known (figure 7).

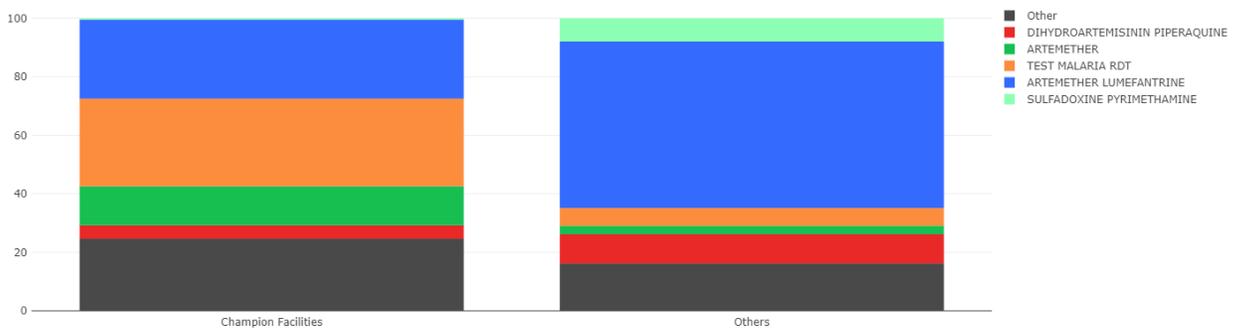
Figure 7. Brand Preferences for facilities with High RDT Usage versus All Others



Source: Maisha Meds point-of-sale data 2017–2019.

These “exemplar” pharmacies were not based in particularly high-income areas. This would suggest that pharmacists’ use of RDTs and brand preferences can be influenced by training and patient advice, not just as a function of affordability. However, the 16 facilities were more likely to be a clinic and more likely to be a large facility (defined as having sales greater than \$800 per month) than the overall Maisha Meds sample of pharmacies. Relative to other facilities, as well as being more likely to use RDTs, they were also more likely to sell injectable artemether monotherapy and less likely to sell DHAP and S/P (figure 8).

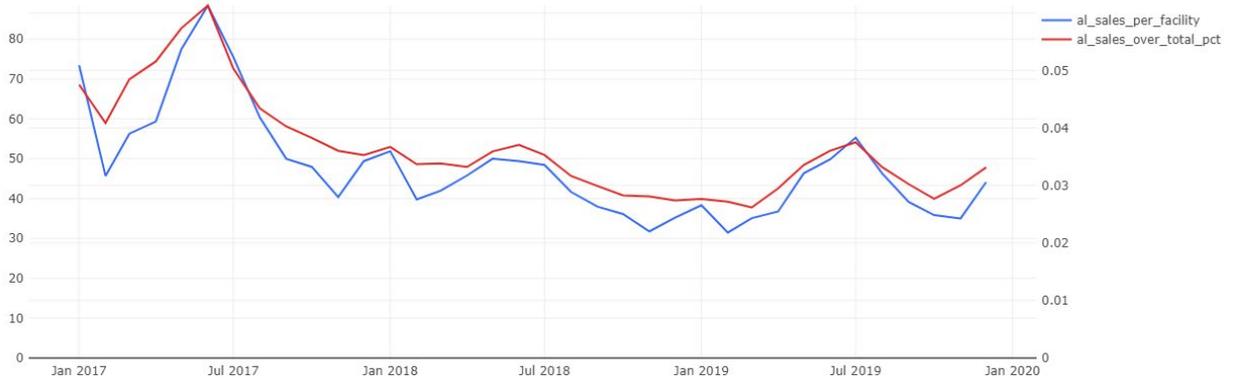
Figure 8. API Preferences for facilities with High RDT Usage versus All Others



Source: Maisha Meds point-of-sale data 2017–2019.

At the private-sector facility level, the removal of the AMFm subsidy does not appear to have substantially slowed prescription of AL in the private sector from 2017–2019, with antimalarial sales making up a lower but still similar proportion of total pharmacy/clinic sales in 2019 as in 2017 (figure 9).

Figure 9. AL Antimalarial Sales in Maisha Meds Private Facilities, 2017–2019



Source: Maisha Meds point-of-sale data 2017–2019.

Discussion and conclusions

Our findings suggest that the challenges facing malaria case management in the Kenyan private sector have reduced slightly but remain significant following the discontinuation of the AMFm. Examination of Maisha Meds and Indian export data suggest the drop-off in private-sector ACT prescribing has not been as high as indicated by earlier reports; indeed, the AMFm appears to have produced an enduring move to ACTs from SP and other non-recommended monotherapies that has survived the end of ACT subsidies.

However, known quality standards for ACTs have quickly eroded in the absence of subsidy for WHO prequalified products. Other studies have reported that the shift from WHO prequalified to non-prequalified products started as early as 2011 to 2014.¹⁹ The drive to maintain a constant \$1 treatment price following the AMFm discontinuation—and consumer expectations of a \$1 price tag—may have led private wholesalers to purchase less expensive but non WHO prequalified brands, potentially resulting in a compromised quality of medicine entering the private sector supply chain. Official WHO reports, which collect data only from national malaria programs and prequalified suppliers, are likely to miss this

¹⁹ Akulayi, L., Alum, A., Andrada, A. et al (2017). What happened to anti-malarial markets after the Affordable Medicines Facility-malaria pilot? Trends in ACT availability, price and market share from five African countries under continuation of the private sector co-payment mechanism. *Malar J* 16(173).

important substitution and understate the overall supply of ACTs delivered through the private sector.

While non-prequalified products face higher risks of quality issues than prequalified products, unknown quality does not necessarily imply poor quality. Based on the observed trends, we can offer two possible explanations to explain the described changes in brand preference, price and quality. Either the AMFm resulted in subsidizing higher price AL medicines that had been through WHO prequalification but were of similar quality to cheaper alternatives, or the removal of subsidies has resulted in a decrease in the quality of AL in the Kenyan private market. This highlights the need to continue to monitor the private sector market not just in Kenya but across the region for changes in brand preferences and to increase understanding of the quality of non-WHO prequalified suppliers. Ideally these same suppliers could be encouraged to reach WHO prequalification status over time.

Finally, this study demonstrates the potential value of integrated, real-time analytics to provide an up-to-date picture of market trends and inform policy responses. During the AMFm, retail availability, price and other characteristics were only captured periodically (and labor-intensively) through surveys/retail audits, mystery shoppers and household surveys. As a result, data on availability, market share, and price were only available at infrequent intervals. Maisha Meds's digital POS, in contrast, offers high frequency data that can be leveraged by individual shop owners and national/international policymakers alike. This new capability—and the findings it has generated—have the potential to inform renewed global policy efforts to tackle the persistent challenges of malaria case management in private-sector pharmacies, clinics and drug shops in sub-Saharan Africa. The capture of brand information is expected to improve over time. The Center for Global Development and Maisha Meds are currently exploring the potential of programs to improve private sector malaria case management by leveraging digital platforms which allow better targeting and provide real-time analytics to track product flow, pricing, and improve the ratio of ACT/RDT dispensing.