Closing the Affordability Gap
Ensuring affordable and effective malaria treatment for children in rural Uganda

Subsidized ACTs in the private sector: CAPSS¹ MoH-MMV Pilot

A caring mum is an ACT mum

Artemether 20 mg
Lumefantrine 120 mg
20/120

Recommended by The Ministry of Health - Uganda

This Coartem® pack is for children:
Age: 4 months to less than 3 years
or
Weight: 5 kilos to under 15 kilos

A complete 3 day treatment for malaria

Act fast, treat malaria with ACTs.
Be wise and caring.
When your child gets fever, don’t let a day pass by.
Start the ACT-with-a-leaf treatment within 24 hours.
Acknowledgements

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EXECUTIVE SUMMARY

Background:
Uganda has one of the highest rates of malaria infection in the world, with 11 million reported cases among its 31.6 million inhabitants in 2009. Children less than five years old are the most affected. The disease accounts for about 40,000 deaths each year and for 20-23 percent of in-patient deaths among under-fives. In 2006 Uganda’s Ministry of Health (MoH) adopted artemether-lumefantrine (AL) as its first-line treatment for uncomplicated malaria. Though AL is provided free of charge in public and faith-based facilities, frequent stock-outs severely limit its availability. Furthermore, ACTs are highly priced in the premium private sector, and drug shops carry little stocks. Consequently, ACTs are effectively out of reach for all but a small segment of Uganda’s population, leaving most with no option other than ineffective or unsafe treatment.

Methodology:
In 2007, Uganda’s MoH, the Medicines for Malaria Venture (MMV) and other stakeholders came together to develop the Consortium for ACTs Private Sector Subsidy (CAPSS) pilot. In five districts (four intervention and one control), CAPSS sought to provide subsidized ACTs through private sector outlets to complement public and community based ACT delivery, as has been recommended as part of the global initiative, Affordable Medicines Facility, malaria (AMFm). The aim of CAPSS was to bring ACTs within the reach of all those who need them – making them widely available to the caregivers of under-five children at a highly subsidized price through licensed drug shops. CAPSS was designed in line with the AMFm approach of providing subsidized medicines accompanied by a number of supporting interventions to ensure uptake and correct use. Most important of all, CAPSS sought to determine whether subsidizing ACTs in the private sector would be effective in ensuring that the subsidy reaches end users.

Findings:
Subsidizing ACTs has led to a rapid scale-up in the number of drug shops stocking the treatment, ensuring improved accessibility and uptake. Making ACTs affordable in the private sector greatly increased their availability, ensuring that more than three out of four licensed drug shops stocked them and this led to a concomitant increase in uptake by children under five in all socio-economic quintiles. The market share of ACTs purchased from licensed drug shops rose from less than 1 percent at baseline to 69 percent at the end-term evaluation. Supporting interventions ensured that over 70 percent of those who purchase an ACT complied with recommended treatment schedules. The increased uptake of ACTs also served to erode the market share of ineffective antimalarials such as chloroquine.

Interpretation:
CAPSS has validated the hypothesis that ensuring ACTs are affordable will drive availability and uptake, thereby displacing ineffective treatments. Given the importance and reach of the private sector, in particular drug shops, in Uganda and other African countries, its continued inclusion in healthcare provision, complementing that of public sector channels, is crucial to ensuring access to effective treatment within 24/48 hours of the onset of fever.

CAPSS successfully informed the AMFm, providing evidence in support of Phase 1. In addition, it provided the rationale for the use of a universal logo for all AMFm products. The CAPSS logo of “ACT with a leaf” has been chosen (with minor adaptation) as the global AMFm product logo (“ACTm with a leaf”).

BACKGROUND: THE NEED FOR AFFORDABILITY TREATMENT

Uganda’s antimalarial treatment policy since 2006 has been to deploy an Artemisinin Combination Treatment (ACT), artemether-lumefantrine (AL), as first-line treatment. However, this policy faced major challenges in implementation. First, although AL is provided free of charge through the country’s extensive network of public and not-for-profit health facilities, frequent stock-outs have severely limited its actual availability. Second, ACTs are sold at a high price in pharmacies, and there is poor availability in drug shops in rural areas. However, the private sector cannot be ignored, as it is the first point of access for about 60 percent of Ugandans seeking treatment for fever access all socio-economic groups.
THE CAPSS PILOT: TESTING THE FEASIBILITY OF CLOSING THE AFFORDABILITY GAP

A new initiative has been designed to close the “affordability gap” – the Affordable Medicines Facility, malaria (AMFM). The AMFM provides a subsidy for ACTs at the top of the supply chain and supports a core set of supporting interventions to ensure uptake and correct use. In 2007, the Ministry of Health (MoH) Uganda and MMV, in consultation with national and international stakeholders, developed the CAPSS pilot to test the viability of this approach and was one of two pilots to assess the overall feasibility of providing affordable treatment through the private sector.

The pilot had a number of specific, quantifiable targets:

- Ensure that the subsidized ACT is available in at least 70 percent of all licensed pharmacies and drug shops (it is not sanctioned for sale in unlicensed outlets)
- Increase by 50 percent the number of children under five years of age who have access to effective treatment within 24 hours of the onset of fever
- Ensure that 85 percent of people who purchase the ACT comply with the recommended treatment schedules
- Achieve a 40 percent market share in antimalarials purchased at licensed drug shops in the pilot districts.

CHOOSING WHERE TO PILOT THE AMFM APPROACH

Four malaria-endemic districts (Kamuli, Kaliro, Pallisa, Budaka) were chosen to receive the pilot intervention supplies of the subsidized drugs. The fifth district (Soroti) was chosen as the control (Figure 1). All five districts are located in areas with perennial high malaria transmission (parasite prevalence is above 60 percent in school-age children).

The overall population of the intervention districts is estimated to be 1.4 million people (2007). The pilot districts have a total of 104 public health facilities and more than 400 drug shops, two-thirds of which are unlicensed.

Figure 1: The four intervention and the control districts
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METHODOLOGY: THE ELEMENTS OF A FULLY COMPREHENSIVE, MULTI-PRONGED APPROACH

The CAPSS Uganda pilot was designed in line with the AMFm approach of providing subsidized drugs in combination with supporting interventions including provider training, and demand generation. A series of consultative meetings was held in Uganda to design the intervention and build on existing best practice and the pilot was approved by all the relevant bodies of the Ministry of Health.5

Pilot management structure: ensuring proper governance
The topmost level of the CAPSS programme’s management structure was the project management team consisting of representatives of the key stakeholders (Uganda Ministry of Health, National Drug Authority and MMV). The implementation team, responsible for managing the day-to-day running of the pilot, included representatives from the lead CAPSS partners and the district health officers of each of the pilot districts.6

Aligning policy and regulation: getting the basics right
Prior to the pilot, Coartem was regulated as a prescription-only medicine. In order to facilitate the CAPSS intervention, the Uganda National Drugs Authority (NDA) rescheduled Coartem® (AL) so that it could be provided over the counter in the intervention districts and also authorized “van selling” (direct sale of the subsidized drug to licensed drug shops).

Repackaging and branding: making “ACT with a leaf” stand out
New packaging was designed for the subsidized AL (Coartem), to differentiate the product from the public sector offering, and was branded “ACT with a leaf” (Figure 2). The packaging was also designed to facilitate the correct use of the product, incorporating illustrated instructions.7 The distinctive branding of “ACT with a leaf” and associated communications campaign provided consumers with instant recognition that they were purchasing the high quality subsidized ACT.

Communications Programme: spreading the word about “ACT with a leaf”
The communications campaign developed by PACE (formerly known as PSI Uganda) was rooted in the caregivers’ knowledge, understanding and perception of recommended health behaviours. A comprehensive communication campaign was carried out, including: community mobilization, community events, radio spots and talk shows, posters, point of sales advertising, songs and community launch events. The wide array of activities quickly generated significant brand awareness and demand for the subsidized drug.

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5 The Senior Management Group, and the Basic Package and Essential Medicines body of the Technical Working group and the Health Policy Advisory Committee (HPAC).
6 National Drug Authority (guidance, training), PACE, formerly known as PSI Uganda (demand generation, design, repackaging, community mobilization), Surgipharm (quantification, importation, distribution, training), Malaria Consortium (training), i+ Solutions (training on drug management), the Steadman Group /Synovate (monitoring), Makere University (household surveys).
7 “ACT with a leaf” was packaged in colour-coded packs for the different age groups/ weight bands.
Distribution: getting the numbers right
The quantification of the amount of Coartem required for the pilot was based on estimates of the number of fever episodes per age group using epidemiological data, the likely source of treatment using the findings from the household survey, and a buffer for leakage. Surgipharm was responsible for the importation of the ACT and its storage, as well as for overseeing the repackaging, and the distribution of “ACT with a leaf” to licensed outlets within the intervention districts. In line with the AMFm model, the CAPSS pilot sought to replicate the existing supply chain. However, recognising that some of the districts are very rural and lack a wholesaler within their boundaries, the pilot improved the distribution chain by ensuring that licensed drugs shops directly received their supplies of “ACT with a leaf” from the distributor / sub-distributor. Two different compensation models to cover the additional costs of direct distribution were tested.

Pricing: the critical lever
In line with the AMFm model, MMV subsidized the AL product by 95 percent. The final price was calculated in relation to the market prices for other antimalarials and took into consideration standard commercial margins. The maximum recommended retail price (MRRP) for each age-pack was printed on the product. The price per tablet was identical across all packs, thereby removing any potential commercial interest in cutting up the packs. The final price per age-pack ranged from UGX 200 to UGX 800 (USD 0.10 to USD 0.40).

Training: ensuring dispensers have the required knowledge
The training of dispensers was critical to ensure the correct dispensing and use of ACTs. At least two dispensers from each licensed outlet participated in a comprehensive training covering malaria case management, product-specific knowledge, safety monitoring and supply logistics prior to the launch of the pilot. Refresher training was provided during the regular drug distribution circuits.

Monitoring progress: getting at the truth
An independent Kenyan-based market research organization, Synovate (formerly known as the Steadman Group), was contracted to track stocking and purchasing behaviour of “ACT with a leaf” using retail and public sector audits as well as exit interviews. In addition, Makerere University Institute of Social Research (MISR) was contracted to conduct the baseline and follow-up round of household surveys to assess what progress the pilot had made at the community level. The surveys involved over 3,000 interviews in each round.

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8 The costs of weekly distribution to Pallisa and Budaka were covered directly by MMV, whereas those for Kamuli and Kaliro came out of the distributor’s margins.
9 Import prices for the subsidized product for each weight band was USD 0.05, 0.10, 0.15, 0.20, respectively.
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ANALYSIS OF IMPACT: BETTER THAN HOPED

It is clear from the data that the pilot has achieved virtually all its major goals. It has produced a dramatic increase in the use of ACTs (AL), improved access to effective treatment, reduced its price to levels comparable with other antimalarials (such as chloroquine) and has ensured most caregivers purchase the correct dosage.

Private sector ACT availability provides a safety net

ACT availability in health facilities (public sector and not-for-profit sector) has been highly variable over the intervention period. The stock situation has deteriorated in all the intervention districts, with the exception of Kamuli. In May 2010, more than half the health facilities in Pallisa and Kaliro had no ACT packs in stock at the time of the survey; the situation in Budaka was acutely inadequate, with three quarters of facilities having no ACTs in stock (Figure 3).

Figure 3: Poor availability of ACTs in the public and not-for-profit sector across districts

ACT availability in health facilities, Sept 08, May 10

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Source: Synovate, Health facility audits, Sept 2008 and May 2010

In contrast, ACT availability in the control area (Soroti) has improved dramatically from only 40 percent of health facilities with at least one ACT pack in stock at the outset to about 75 percent in May 2010 (Figure 4). The contextual information that we collected demonstrates that this is largely because of improvements that had been made in the distribution system (using a push instead of a pull approach to the lower-level units). Private sector availability of ACTs in the intervention areas has improved significantly. 77 percent of all licensed drug shops in the intervention areas stock ACTs (primarily the subsidized ACT) compared with about 1 percent at the start of the pilot. ACT availability in the control areas has also increased from 13 percent to 32 percent of outlets.

Figure 4: Dramatic improvement in ACT availability in licensed drug shops

ACT availability in the public and private sector, various years

Source: Synovate, Public and private sector audits, various years
Availability of the subsidized ACT is significantly higher in licensed drug shops compared to unlicensed ones: 75 percent of licensed outlets in the intervention areas had stocks of the subsidized product compared to 15 percent in unlicensed outlets in May 2010. The latter are not permitted to operate as they do not meet the licensing criteria set by the National Drug Authority and thus do not receive direct supplies of the subsidized product. However as less than a third of all drug shops are licensed, overall access to subsidized ACTs is limited.

Figure 5: Good availability of subsidized ACT in licensed outlets in intervention districts

The private sector has played a complementary and/or substitutional role in ensuring access to effective treatment based primarily by the level of availability of ACTs in the public sector. Which of these two roles the private sector has played has varied greatly during the different data collection periods. In Kaliro, Pallisa and Budaka, access to ACTs has been largely assured through the availability of a subsidized ACT in private sector (Figure 6). In Kamuli, private sector availability complemented existing public sector availability. Although ACTs are stocked by the private sector in Soroti, access to ACTs there has been assured largely through the public sector.

Figure 6: The private sector reaches areas not covered by the public sector
Take-up: “ACT with a Leaf” is now number one

Based on exit interviews conducted with caregivers at drug shops, “ACT with a leaf” now accounts for 69 percent of all antimalarials purchased from licensed drug shops for treating malaria in the under-five year old age group in the four intervention districts (Figure 7). In line with national regulations, “ACT with a leaf” was not sold to unlicensed drug shops; however, the product leaked to some of these outlets, resulting in 14 percent of children receiving ACTs. The market share of subsidized ACT dropped in September 2009 as demand outstripped supplies, resulting in stock-outs. This was largely due to the knock-on effects of protracted public sector ACT stock-outs, resulting in virtually all purchases of ACTs in the intervention areas and neighbouring districts having to be made through the private sector. This also increased the share of quinine sales from licensed drug shops and chloroquine sales in unlicensed ones.

Figure 7: “ACT with a leaf” - path to domination in antimalarial purchases for under-fives

Caregivers for children under five living in the intervention areas have better access to ACTs in the private sector than those living in the control areas, with a third purchasing ACTs (across licensed and unlicensed outlets), compared to only five percent in the control district (Figure 8). Quinine remains the most popular antimalarial in the control area.

Figure 8: Caregivers in the intervention areas can better afford to purchase ACTs

Source: Synovate, Exit interviews, various years
Improved access to treatment at the community level – but still long way to go

The household surveys look at what treatment is provided to all children who had fever up to 14 days before the interview. The findings reveal lower rates of treatment in the intervention districts compared to the control district: only 43 percent of children under five with fever get an antimalarial within 48 hours, compared to 61 percent in the control area, Soroti (Figure 9). However, a greater proportion of those who get an antimalarial in the intervention districts get an ACT (67 percent in Kamuli/Kaliro and 57 percent in Pallisa/Budaka, compared to 42 percent in Soroti).

Figure 9: Low overall rates of access to any treatment within 48 hours

Nonetheless, there has been a dramatic increase in access to effective treatment across all areas since 2007 in light of the improved ACT availability. Between 16 and 20 percent of children under five years gain access to ACTs within 24 hours; this figure increases to 29.5 percent within 48 hours (Figure 10). Access to treatment rates is highest in Kamuli/Kaliro, where there is better availability across both public and private sectors.

Figure 10: Dramatically improved rates of access to ACTs

If one compares parishes with licensed drug shops (and thus receive supplies of the subsidized drug), to those without licensed drug shops (and thus have no direct supplies), rates for access to treatment differed significantly during the first 24 hours. Over 20 percent of children under five assessed an ACT within 24 hours in supplied areas, compared to 11 to 13 percent in areas not supplied. The rates of access to treatment were also significantly higher at 48 hours when comparing areas with licensed drug shops to the control district (Figure 11).
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Figure 11: Access to treatment is significantly higher in areas with licensed drug shops

Access to treatment by areas receiving/not receiving supplies of ACT-leaf

Source: Makerere University, Household surveys, May 2010

Access to effective treatment based on the exit interviews conducted at drug shops has been significantly higher across all socio-economic groups (SES) in the intervention areas compared to the control area. In the lowest SES group, 24 percent purchased an ACT for the treatment of children under five in the intervention area compared to 6 percent in the control area. This figure rose to 39 percent in SES group 5 in the intervention area and stayed the same in the control area. Overall, 33 percent of all SES groups purchased ACTs in the intervention area (primarily “ACT with a Leaf”) and only 5 percent in the control area (Figure 12).

Figure 12: All socio-economic groups see similar purchase levels for “ACT with a Leaf” for children under five

Antimalarials purchased for under-fives by socio-economic groups (SES) from all outlets, Intervention area, May 2010

Source: Synovate, Exit interviews, May 2010

Antimalarials purchased for under-fives by SES group, Control area, May 2010

Source: Synovate, Exit interviews, May 2010
Low price makes “ACT with a leaf” the drug of choice

The subsidy has brought the price of ACTs in line with that of chloroquine and a full course of a child’s treatment costs less than that for quinine (Figure 13). The subsidy has been successful in ensuring that the maximum recommended retail price (MRRP per tablet: UGX 33.33) has been largely respected, particularly in licensed outlets, with the mean price varying within a 10 percent band (Figure 14).

Figure 13: Price of a full course of subsidized ACT is comparable to that of chloroquine

Figure 14: Price of subsidized ACT largely respected, rendering it affordable

The source of antimalarial treatment, whether public or private, varies considerably between localities. To a large extent this is determined by whether (affordable) ACTs are present on the shelf, in the public or private sector, at the time they are needed. The household surveys show that in the control area, two thirds of caregivers obtain ACTs for children under five from the public sector. In the intervention areas, only a quarter obtain ACTs for children under five from the public sector; most get their ACTs from the private sector (Figure 15). A third of ACTs obtained in Kamuli and Kaliro are from drug shops, compared to around one tenth in Pallisa and Budaka. Other drugs are sourced primarily from the private sector.

Figure 15: The private sector is the main source of ACTs in the intervention districts for children under five
Most children receive the right dose

Above 80 percent of caregivers of children under five (except in Pallisa) purchased the correct number of tablets at the right price (Figure 16). Knowledge of the correct dosing varied: about 70 percent of caregivers know the correct number of tablets per dose and over 80 percent know that the dose should be given twice a day for three days. The knowledge in Budaka was higher than the other districts. The composite indicator across all intervention districts for the appropriateness of treatment administered was 71 percent.

Figure 16: Good levels of knowledge

Appropriateness of treatment for under fives with subsidized ACT, May 2010

Source: Synovate, Exit interviews, May 2010

Discussion of current challenges

Although the CAPSS pilot has been successful in achieving its aims, there are still a few challenges in ensuring adequate availability in poor, rural areas.

Further licensing of drug shops is critical to improved access

In the more developed areas where private businesses flourish, there is a sufficiently large number of drug shops able to achieve the required licensing standards. However, in other less developed areas where there are currently no licensed outlets, this situation results in insufficient coverage for the population. Many of the smaller drug shops rely on the immediate cash flow from sales to pay for their next orders. Such cash flow constraints mean that the smaller outlets inevitably place very small orders with the distributors, since they cannot afford to tie up significant amounts of money in stock. Prices in the more remote rural areas tend to be higher than in urban or suburban centres, largely due to the additional costs of distribution. Further enhancement in access to ACTs will require overcoming these distribution challenges in poorer, more remote areas.

Ongoing currency devaluation prevents continuation of the maximum retail price

It is highly unlikely that it will be possible to maintain the maximum recommended retail price due to the ongoing devaluation of the Ugandan Shilling. When CAPSS was developed the UGX traded at about UGX 1650 to a US dollar. Today the currency trades at about 2,375 to a dollar. Continued devaluation of the Ugandan Shilling results in the importers of “ACT with a leaf” facing higher landed costs. These costs are normally passed on to the consumers in terms of higher prices.\(^10\) This continuing rise in the UGX landed costs will undermine any attempt to maintain a maximum recommended retail price. Moreover, national drug regulatory agencies in many countries (particularly in East Africa) do not attempt to control market prices in view of price liberalization policies. Rather than imposing a maximum price, therefore, a more pragmatic approach would be to issue a “recommended retail price” (RRP). This would be effective in setting price expectations.

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10. MMV covered these increased costs to maintain the MRRP.
Ensuring adequate ACT supplies in both the public and private sector is critical to improved access

Ensuring uninterrupted availability of ACTs in both the public and private sector is critical to guaranteeing access to effective treatment. In this regard, the two sectors can play a complementary role that produces a synergistic effect in jointly improving access to treatment. A concerted effort needs to be made to ensure that more caregivers of children under five seek treatment within 48 hours of the onset of fever. The introduction of rapid diagnostic tests in the public sector (and subsequently in the private sector) could help ensure that patients quickly get access to the correct treatment.

CONCLUSION: AMFM’S “ACT WITH A LEAF” IS A WINNER

CAPSS has fully achieved its original objectives:

- Achieved: “ACT with a leaf” is stocked by 77 percent of all licensed outlets (target: 70 percent)
- Exceeded: six-fold (600 percent) increase in the number of children under five who have access to effective treatment within 24 hours of the onset of fever (target: 50 percent)
- Almost there: 71 percent who purchase an ACT comply with recommended treatment schedules (target: 85 percent)
- Achieved: “ACT with a leaf” has a 69 percent market share in antimalarials in the pilot districts (target: 40 percent).

Providing subsidized ACTs through the private sector in line with AMFM has led to dramatic improvements in the availability of effective malaria treatment. Given the importance and reach of the private sector, its continued inclusion in healthcare provision in Uganda will be crucial to ensuring that children under five have access to effective treatment. As highlighted in the discussion, further improving access to effective treatment in remote areas will require a number of specific actions and policy change to increase the number of licensed drugshops. CAPSS has also validated the hypothesis that an affordable treatment drives availability and uptake, thereby displacing ineffective treatments, and has provided evidence to garner support for Phase 1 of AMFM. In addition, CAPSS provided the rationale for the use of a universal logo for all AMFM products – the CAPSS logo of “ACT with a leaf” has been chosen and adapted to become as the AMFM product logo (“ACTm with a leaf”).
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MMV's vision is a world in which innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and help to ultimately eradicate this terrible disease.

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