

Funded by the Bill & Melinda Gates Foundation through a three-year grant, the East African Drug Seller Initiative (EADSI) aimed to increase access to quality medicines and pharmaceutical services in underserved areas through involvement of the private sector. EADSI built on Management Sciences for Health's Strategies for Enhancing Access to Medicines Program, also funded by Gates, and which, in collaboration with the Tanzania Food and Drugs Authority (TFDA), launched the country's successful accredited drug dispensing outlet (ADDO) program. EADSI's goal was to create a sustainable accredited drug seller model that can be adapted, replicated, and scaled up in underserved regions of developing countries and that will ultimately operate independent of donor support.

Situation in Tanzania: The ADDO pilot showed improvements in access to quality medicines and pharmaceutical services in Ruvuma. However, successful pilot initiatives do not necessarily reflect what is needed to ensure successful national scale-up. Scaling up requires much more than simply adding staff and resources. The experience showed that greater efficiencies in implementation and some changes to the drug seller accreditation/regulation model were needed to enable Tanzania and other countries to institutionalize and sustain the initiative.

Strategy for Change: EADSI organized a stakeholder workshop in July 2008 to review ADDO implementation results and develop consensus on options for revising the existing model to help ensure successful ADDO scale up and financial sustainability. EADSI worked with Tanzanian stakeholders to revise the ADDO model and decentralize implementation, which allowed multiple regions to scale up concurrently while decreasing implementation costs and maintaining the quality and sustainability of the program.

Program Evaluation



Household interview in Mara

Decentralized implementation model. With changes to the ADDO model, EADSI needed to determine whether the new approach had reduced access to quality pharmaceutical products and services that had been originally demonstrated in the Ruvuma pilot. The decentralized ADDO implementation model was evaluated in 30 shops in Singida region, while 30 shops in Mara served as the control. Baseline and endline quantitative data collection on unaccredited drug shops and ADDOs in Singida and Mara used shop audits to assess availability and mystery shoppers to evaluate dispensing quality; 120 mystery shoppers in each region presented at unaccredited drug shops or ADDOs using the scenario of a child with simple malaria or nonbloody diarrhea. To gauge consumer satisfaction, EADSI conducted baseline and endline household surveys in Singida and Mara to assess medicine access and use behaviors and determine community health concerns. At baseline, we visited 308 households in Singida and 333 in Mara. Endline data represents 290 households in Singida and 328 in Mara.

EADSI also collected qualitative data to assess other differences between the centralized and decentralized rollout approaches. This data included interviews with drug shop owners, dispensers, and local authorities in Mtwara region, which implemented ADDOs using the centralized model, and in Singida region, which used the revised model. In addition, EADSI interviewed five central-level government representatives and seven national trainers.

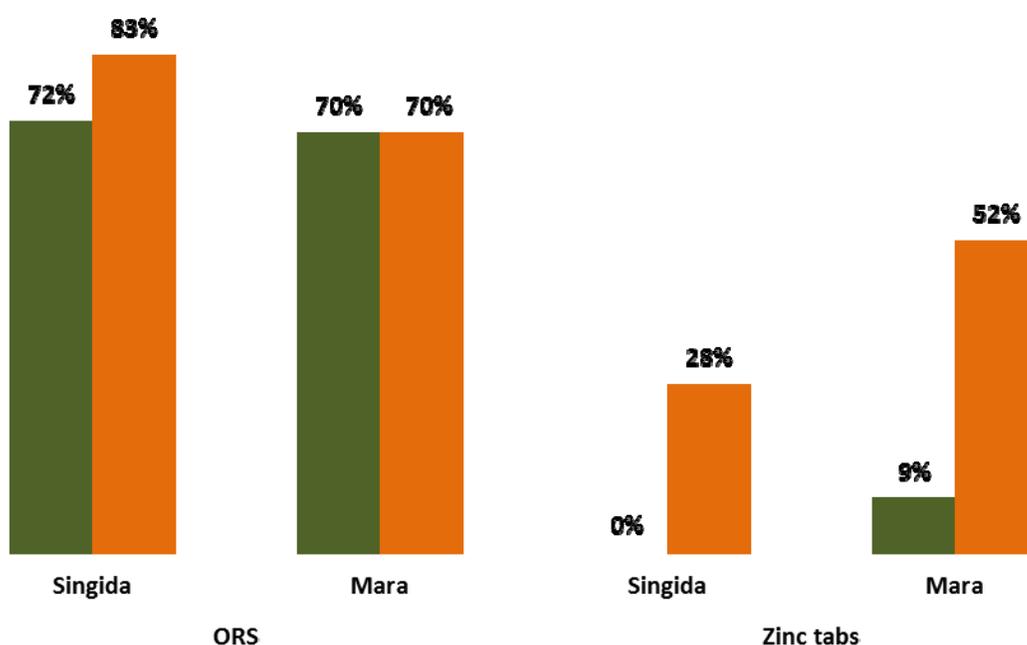
ADDO program sustainability. To assess sustainability of the ADDO initiative, EADSI looked at business indicators such as profitability in Ruvuma, Mtwara, and Singida. In addition, to determine whether medicine availability and quality

pharmaceutical services had been maintained over time, we evaluated the pilot region, Ruvuma, using shop audits and mystery shoppers. We visited 30 shops in Ruvuma and audited their products to assess availability. To evaluate dispensing quality, 120 mystery shoppers in Ruvuma visited ADDOs using the scenario of a child with simple malaria or nonbloody diarrhea. Household surveys in Ruvuma (301) determined consumer satisfaction and community health concerns and assessed medicine access and use behaviors.

Results: Decentralized Implementation Model

Product availability. The number of ADDOs with oral rehydration solution (ORS) available increased 15% (from 72% at baseline to 83% at endline) and ADDOs stocking zinc tablets increased to 28% from none at baseline. In Mara, the control region, ORS availability remained static, while zinc tablet availability jumped from 9% to 52% ($p < 0.05$), due to the start of another regional initiative targeting diarrhea (Figure 1).

Figure 1. Percentage of Unaccredited Drug Shops and ADDOs with Antidiarrheals Available at Baseline and Endline



Quality of pharmaceutical services. The use of ORS and zinc is the recommended treatment for diarrhea. Dispensers in Singida dispensed antibiotics for diarrhea 23% less after the conversion to ADDOs (98% baseline to 76% at endline), while Mara remained basically unchanged (84% baseline to 87% endline). ORS and zinc use in Singida increased from 20% to 33% and from 0 to 9%, respectively. ORS and zinc use in Mara was also low. At baseline, ORS use was 18% and rose to 22%, while zinc use went from 7% to 5%. Although not statistically significant, the results show that ADDO dispensers improved their practices. Clearly, however, management of uncomplicated diarrhea is an area that needs further emphasis in both training and onsite supervision.

Dispensing service indicators for uncomplicated malaria improved after the ADDO intervention in Singida; however, future training should also address room for improvement.

Did the drug seller—	Singida		Mara	
	Baseline %	Endline %	Baseline %	Endline %
Ask about symptoms?*	47	72	60	56
Ask about other medicines the child took?	25	40	42	30
Give instructions on how to take the medicine?*	51	81	62	60
Give information on looking for danger signs?*	6	7	2	0

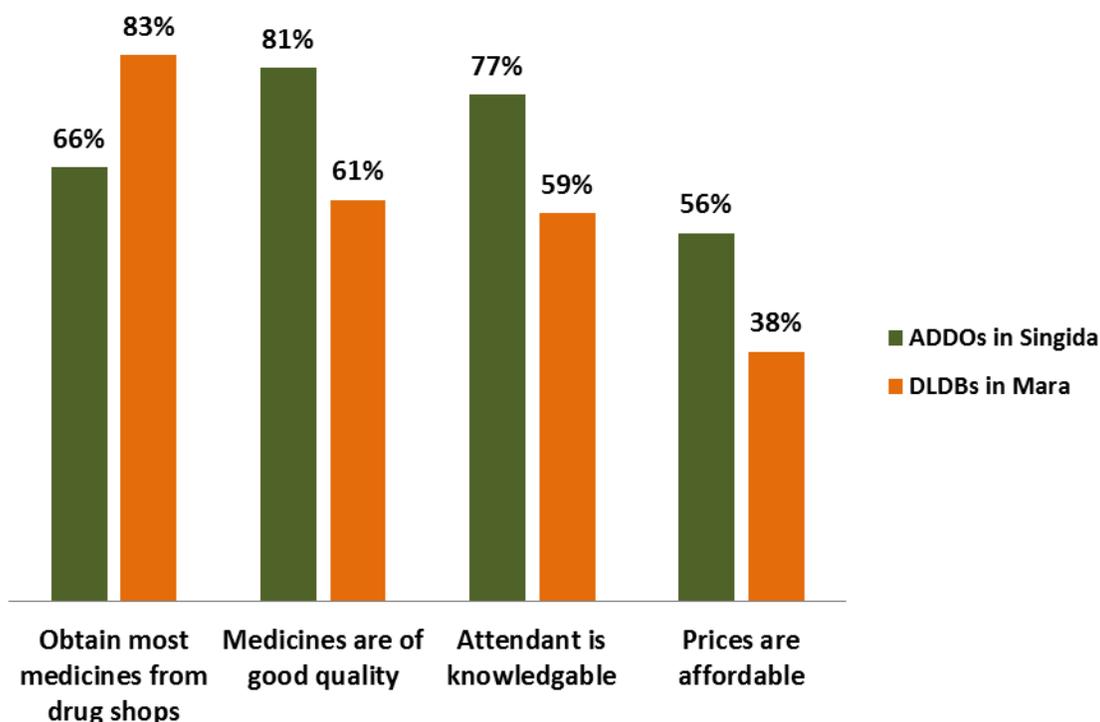
*p<0.05

In addition, the percentage of malaria scenario mystery shoppers who were referred to a health facility increased in Singida from 13% at baseline to 19% at endline. Because ADDO training should result in drug sellers feeling confident about handling uncomplicated malaria, the referral rate post-implementation should have been zero.

Consumer satisfaction. EADSI conducted household surveys in the pilot region of Singida and the control region of Mara. At baseline, we interviewed participants from households in Singida and in Mara about their preferences regarding where to seek health advice, buy medicines, and their opinions about ADDOs in Singida or *duka la dawa baridi* (DLDBs) in Mara (Figure 2). Respondents in both Singida and Mara preferred to go to a public health facility for health advice. The most common reason given for choosing a public health facility for treatment was diagnostic capability, followed by the qualifications of providers.

When asked where their first choice was to buy medicines, 48% in Singida reported ADDOs at baseline and 56% at endline, an increase of 17%, while about 80% in Mara reported DLDBs at both baseline and endline. When asked why they chose drug shops, the most common answers at endline were availability of medicines (28% and 62% in Singida and Mara, respectively) and distance (58% in Singida and 28% in Mara).

Figure 2. Household Opinions Regarding ADDOs or *Duka la Dawa Baridi* at Endline



Time required for implementation. While it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, an additional 10 regions completed implementation within 3 years using the new decentralized approach.

Cost of implementation. The decentralized implementation model resulted in a significant reduction in roll out costs per district. The TFDA determined that the savings were greater than 50%. For example, in a district with 100 outlets to be accredited and 120 dispensers to be trained, the decentralized implementation model cost 73 million Tanzanian shillings (TSH) (~49,000 US dollars [USD]) compared with a cost of 163 million TSH (~109,000 USD) under the centralized implementation model. Savings came primarily from a reorganized dispenser training schedule that was reduced from

45 to 26 days and a merge of mapping and preliminary inspection activities to identify which drug shops are eligible to enter the accreditation program. Owners also pay all costs associated with shop renovations and increased inventories.

The average cost of accreditation to ADDO owners in Mtwara (centralized approach) was about 21% higher than the average in Singida: 2,589,000 TSH (~1,599 USD) versus 2,145,000 TSH (~1,325 USD). In Singida, 93% of owners thought the money spent was worthwhile, compared with 95% of owners in Mtwara. Accreditation includes costs such as premises upgrades, increased medicine inventory, and training.

Stakeholder satisfaction. In Singida, over 60% of owners and dispensers in 7 of 9 districts reported good communication with TFDA and district authorities, while over 80% in the other two districts, did not get regular feedback. All of the respondents in Mtwara felt that the financial and technical support received from central level was adequate during implementation.

“We now have good communication with TFDA people, they visit us to see how we are doing, and when we have expired drugs, we report it to the pharmacist who takes measures.” (Dispenser, Singida Rural district)

“The training gave me skills on how to acquire and pay loans, and now I am able to calculate what profit and loss I get in my shops. Also through this shop, I pay school fees for my children.” (Owner, Singida Urban district)

“The shop is now like a small pharmacy and many people see me as a professional dispenser.” (Dispenser, Mtwara)

Challenges with decentralized model. Challenges reported included districts without the resources to provide supportive supervision and the transfer of district officials who are familiar with the ADDO program, resulting in new staff members who need orientation. Some districts did not plan or budget for ADDO activities, while some who did plan, had not received approval yet. Stakeholders thought that communication between district government and the central level was inadequate.

Results: ADDO Program Sustainability

Where possible, we compared the indicators in Ruvuma across three different years to measure how well the ADDOs were maintaining their service quality: 2002 which was before the ADDO implementation; 2004, which was post implementation; and 2010, after the shops had been operating for up to seven years.

Product availability. As part of the initiative, ADDOs were allowed to legally start selling a select list of prescription-only medicines, including a number of antibiotics. In 2004, the average availability of antibiotics in ADDOs was 77%, while in 2010, the average was 70%. In 2002, the average availability of antibiotics before the drug shops were allowed to sell them was 54%.

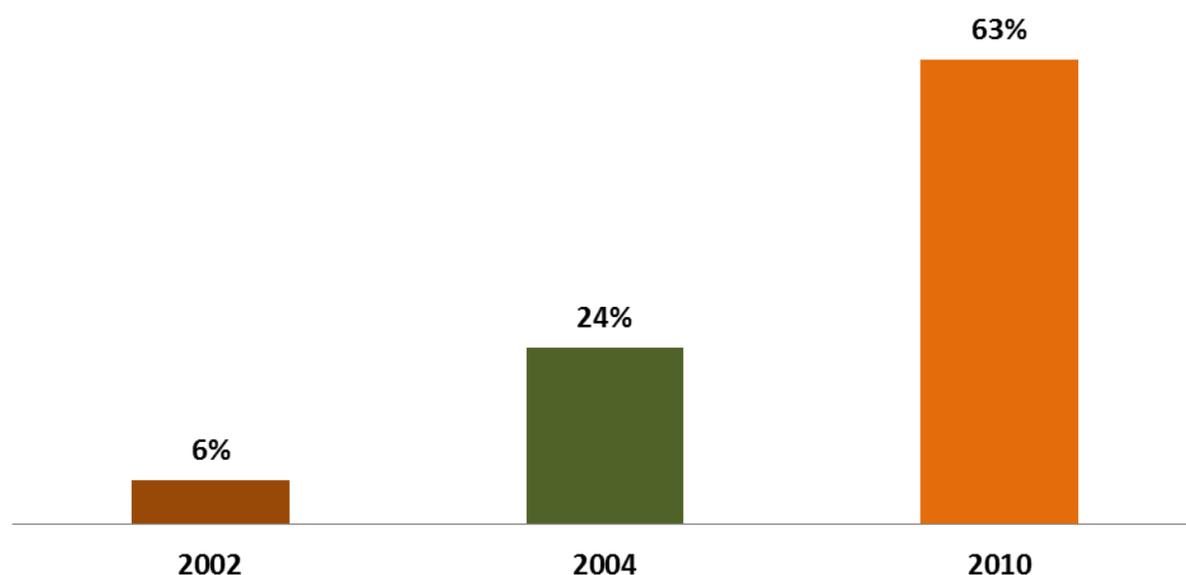
Over 90% of ADDOs in Ruvuma and Mtwara bought their medicines from wholesale pharmacies and 18% in Ruvuma used an ADDO-restricted wholesaler. (Mtwara has no ADDO-restricted wholesaler.) About 42% of ADDOs in Ruvuma and Mtwara were within a 2-hour drive of a wholesale pharmacy and 23% in Ruvuma were within a 2-hour drive from an ADDO-restricted wholesaler.

Quality of pharmaceutical services. In large part, the quality of pharmaceutical services delivered by ADDOs in Ruvuma was maintained and for some indicators increased. For example, Figure 3 shows that the percentage of encounters where the customer received malaria treatment according to standard treatment guidelines has risen dramatically since the post implementation evaluation. This is very encouraging and shows that improvements can be maintained over the long term.



Retired nurses in ADDO dispenser training

Figure 3. Percentage of Encounters Receiving Malaria Treatment According to Standard Treatment Guidelines in Ruvuma



On the other hand, dispensing service indicators for uncomplicated malaria were unpredictable. A significant improvement (decrease) in referrals for uncomplicated malaria in 2010 was encouraging; however, dispensers should not be referring any cases of simple malaria to a health provider.

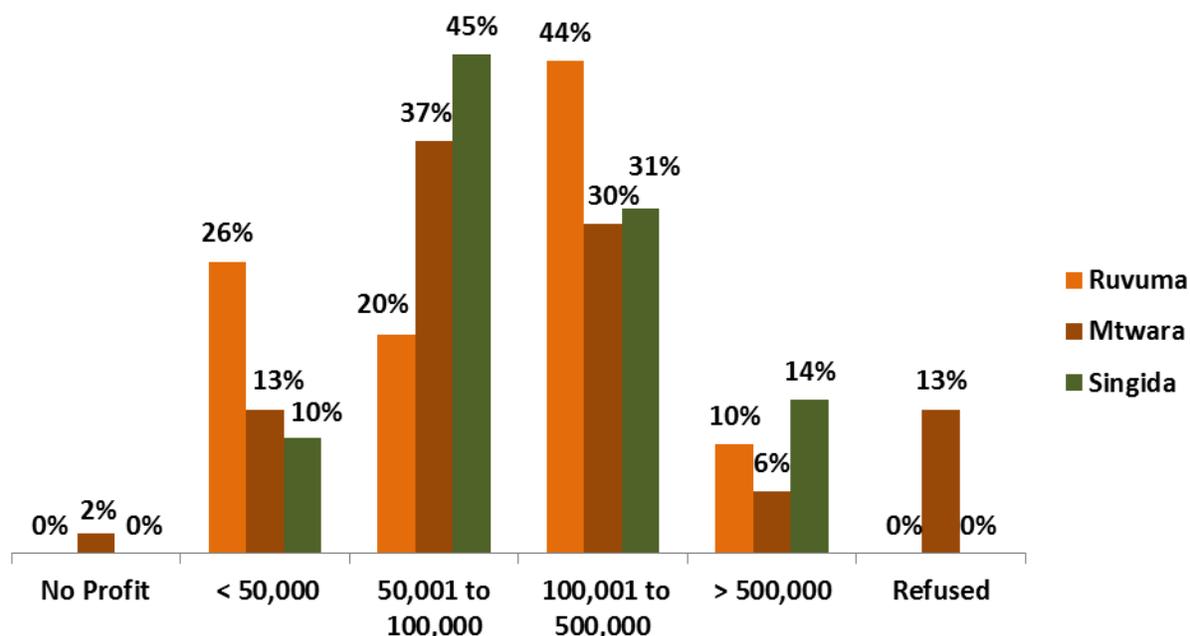
Did the drug seller—	2002 (%)	2004 (%)	2010 (%)
Ask about symptoms?	60	48	53
Ask about other medicines the child took?	37	54	43
Give instructions on how to take the medicine?	81	60	77
Recommend referral to a doctor or clinic?	32	52	17

Consumer satisfaction. In Ruvuma, 86% of respondents to the household survey reported that they routinely obtained most of their medicines from ADDOs—95% of those treating an acute illness turn to ADDOs for medicines. The primary reason Ruvuma residents chose ADDOs was because of the availability of medicines there (59%). In addition, 79% felt that the dispensers at ADDOs are knowledgeable.

Financial success of ADDOs. At the time of the survey, 84% of ADDOs in Ruvuma (176/210) and 98% of shops in Mtwara (129/132) had been operating for more than two years. Shop closures in Ruvuma were due to a lack of accredited dispensers, which ADDOs need to operate legally. However, TFDA collaborated with a private training institution to train 206 dispensers in Ruvuma to fill the gap, and as of March 2011, Ruvuma had 239 ADDOs in operation.

Figure 4 below shows that very few shop owners reported not making any profit at all. About 35% of all ADDOs in Singida, Mtwara, and Ruvuma made an average net profit of between 50,000–500,000 TZS per month with mature ADDOs in Ruvuma making the highest amount per month.

Figure 4. Average Net Profit per Month Reported by ADDO Owners in 2010 (TZS)



Institutionalization of ADDOs. One of the critical signs of institutionalization is local government acceptance of ADDOs through the budget process. In five regions, Mbeya, Mtwara, Morogoro, Ruvuma, and Singida, 23 of 25 districts (92%) included ADDO activities in their 2008–2011 health budgets. At the central level, Tanzania strengthened ADDOs' place in the country's health system through a number of policy and regulatory changes. For example—

- The National Malaria Control Programme identified ADDOs as a mechanism to supplement public-sector delivery of subsidized artemisinin-based combination therapy (ACT) to increase access in rural and underserved areas.
- TFDA added ACTs to the existing limited list of prescription-only medicines ADDOs are legally authorized to dispense.
- Child health interventions using the Integrated Management of Childhood Illness strategy were integrated into the ADDO program.
- The National Health Insurance Fund accredits ADDOs to provide products and services to its members.
- TFDA authorized ADDO scale-up in urban areas with underserved populations.

Challenges to sustainability. Although the Ruvuma ADDO program has been maintained and enhanced since the launch in 2003, challenges to the program's long-term sustainability nationwide remain. For example—

- Dispenser's training has not been institutionalized, despite the readiness of some private training institutions to conduct training and the willingness of owners and dispensers to pay for training.
- Many district councils are including ADDO activities in their health plans and budgets; however, the amount set aside for ADDO activities can be small because of competing priorities.
- Legislative changes have shifted government responsibility for the ADDO program from TFDA to the Pharmacy Council; however, the Pharmacy Council's limited capacity may result in a rough transition.

- Despite improvement overall, some ADDO services still have room for improvement; for example, too many dispensers sell the antibiotic metronidazole for simple diarrhea instead of the recommended treatment, ORS.
- Regulatory enforcement varies greatly between districts because of a lack of inspectors, competing priorities for funding and personnel, and a limited number of central-level staff to support districts.
- ADDO rollout has not included consumer education about or promotion of ADDO services and appropriate use of medicines.
- ADDO owners' lack of access to new capital limits their ability to stock all the medicines they need. For example, NHIF has refused to accredit ADDOs that cannot sufficiently stock all the medicines on its list.



ADDO supervision visit

Disease Burden

To assess whether ADDOs appropriately address the needs of the communities they serve, EADSI measured the household prevalence of both acute and chronic diseases in Singida, Mara, and Ruvuma. An average of 50% of respondents reported that someone in the household in the previous two weeks had an acute illness and an average of 18% reported chronic illness. The three regions also had similar patterns for specific conditions. For acute conditions, an average of 59% reported fever; an average of 36% cough or other upper respiratory infections; and 8% with vomiting or diarrhea. An average of 98% took medicines for the acute illness. For chronic disease, the top four reported by someone in the household were: hypertension and cardiovascular disease at 27%; asthma, 14%; arthritis, 13%, and ulcers, 12%. An average of only 78% of those with a chronic condition took some sort of medication for it in the previous two weeks.

The Future of ADDOs

The map below shows the status of the program rollout in Tanzania as of November 2011. In 2009, the Ministry of Health and Social Welfare issued a notice to phase out all unaccredited drug shops by 2011—all 21 regions have at least started activities to introduce the ADDO initiative.

A new Gates Foundation-funded program, Sustainable Drug Seller Initiatives (SDSI), builds on EADSI. One of SDSI's objectives is to enhance the ADDO program's long-term maintenance and sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and health system context.

ADDO Status as of November 2011



Regions completed out of 21	14
Regions in initial stages	7
Functioning ADDOs	3,484
Potential ADDOs	5,853
Dispensers trained	7,126

- ADDO regions
- Regions in initial stages of ADDO implementation