

Executive Summary

The goal of the accredited drug dispensing outlet (ADDO) program is to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas where there are few or no registered pharmacies. To achieve this goal, the ADDO model takes a holistic approach that combines developing the capacity of owners, dispensers, and institutions that regulate or work in retail drug shops. For shop owners and dispensing staff, this is achieved by combining training, incentives, consumer pressure, and regulatory enforcement with efforts to affect client demand for and expectations of quality products and services.

Major program strategies in creating the ADDO program include—

- Developing an accreditation scheme based on Ministry of Health-instituted standards and regulations
- Developing business skills of ADDO owners
- Enhancing capacity of dispensing staff through training, education, and supervision
- Providing ADDO owners with commercial incentives (e.g., access to loans, authorization to sell some prescription medicines)
- Using public education to improve customer awareness of product and service quality and the importance of treatment compliance
- Improving legal access to a limited list of basic, high-quality prescription and non-prescription essential medicines
- Focusing on regulation and inspection by improving local regulatory capacity

The Tanzania ADDO model is *scalable, sustainable, and transferable* to other country contexts. Funded by the government of Tanzania and multiple development partners¹ over a 10-year period, Tanzania's ADDO program achieved nationwide scale-up in June 2013; 60% of all existing drug shops (5,467 of 9,226) in all 21 regions have been accredited, and 13,301 dispensers and 3,262 local inspectors have been trained. From the proof-of-concept pilot in Ruvuma region in 2003 through scale-up, the ADDO program has evolved; for example, the implementation model was revised to shift responsibility from central to local authorities; the rollout time decreased from an estimated 18 months to less than 12 months per region; and the estimated implementation cost was decreased by 55% (from US\$126,000 to US\$57,000 per district). The cost reduction resulted from a shift in program costs to the owners and dispensers, who gradually paid all costs associated with shop branding and renovations, increased inventories, and training. Many of these costs had been covered by donors in the early years of implementation. Overall, the decision to shift implementation to the districts from the central level allowed for multiple regions to be scaled up simultaneously; for example, while it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, 10 more regions completed implementation within 3 years using the new decentralized approach.

To assess sustainability and service quality, in 2010 we assessed ADDOs in the first region of Ruvuma, which had been operating as ADDOs for eight years and compared results to the 2003 pre-implementation and 2004 post-implementation assessments. In general, the quality of pharmaceutical services delivered by ADDO dispensers in Ruvuma was maintained over the eight years, and for some indicators, even improved, despite the fact that dispensers had not received continuing education and little supervision. For instance, the percentage of encounters where the customer received malaria treatment according to standard treatment guidelines rose dramatically from 6% in 2003, to 24% in 2004, to 63% in 2010.

The extent to which the ADDO model can be transferred and replicated in other country's setting has been demonstrated by implementation of Accredited Drug Shops (ADS) and Accredited Medicine Stores (AMS) in Uganda and

¹ Bill & Melinda Gates Foundation, USAID, DANIDA, Rockefeller Foundation, Clinton Health Access Initiative, the Global Fund to Fight AIDS, Tuberculosis and Malaria

Liberia, respectively. Management Sciences for Health worked with national and local stakeholders to develop an accreditation model based on the Tanzanian experiences, but adapted to the two countries' different contexts. Liberia, especially, offered a unique opportunity to build a sustainable drug seller initiative in an emerging-state context and in an urban rather than rural area.. In Uganda, 520 ADS have been accredited in four districts, and its National Drug Authority (NDA) has developed a national scale-up strategy. In Liberia, 200 AMS have been accredited in the most densely populated county in Liberia. In both countries, evaluations have shown that ADS and AMS have increased the availability of good quality pharmaceutical products and improved dispensing and business skills.

Using the World Health Organization's health system building blocks as a framework, this case study demonstrates that a drug seller program that focused on creating and implementing public-private partnership using government accreditation to increase access to quality pharmaceutical products and services in underserved areas of Tanzania is *scalable, sustainable and transferable*.

Introduction

Prior to 2003, *duka la dawa baridi* (DLDB) constituted the largest network of licensed outlets for basic essential medicines in Tanzania. They were located in all districts in the country, and their combined inventory turnover value was estimated to be greater than Ministry of Health and Social Welfare (MOHSW) expenditures on essential medicines for primary health care (HERA 2006). Because pharmacies are located almost exclusively in major urban areas (60–70% percent in Dar es Salaam alone), while approximately 75% of Tanzanians live in rural and peri-urban communities, DLDB were often the most convenient drug outlet (CPM 2008).

Although important as a source of medicines for a significant proportion of the population, data from a 2001 assessment (SEAM 2003) indicated that DLDB were associated with problems including—

- Authorization to sell only a limited list of over-the-counter medicines
- Illegal availability of prescription medicines
- Questionable medicine quality
- Inadequate storage for medicines
- Untrained staff
- Inadequate regulatory enforcement and supervision

The Tanzania Food and Drugs Authority (TFDA), as the program champion, and Management Sciences for Health, as the technical partner, designed the accredited drug dispensing outlet (ADDO) program to address these problems. The program's goal is ***to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas with few or no registered pharmacies.***

To achieve that goal, we took a holistic approach that combines changing the behavior and expectations of those who use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this was achieved by combining training, incentives, and regulatory enforcement with efforts to affect customer demand for and expectations of quality products and services. Major program activities that contributed to this strategy include—

- Developing accreditation based on ministry of health-instituted standards and regulations
- Creating a strong public sector-based regulatory and inspection system and strengthening local regulatory processes and capacity
- Developing drug shop owners' business skills and providing them mentoring
- Changing the behavior of drug shop owners by facilitating the availability of commercial incentives (e.g., access to loans)
- Providing legal access to a limited list of basic, high-quality prescription essential medicines for sale in accredited shops, which usually involves changes in existing regulations
- Changing behavior of dispensing staff through training, education, and supervision
- Improving awareness of customers regarding quality and the importance of treatment compliance through marketing and public education.

The ADDO experience deepened MOHSW's understanding of the nature and importance of the private sector, which contributed directly to government development of public-private partnerships (HERA 2006). The MOHSW and TFDA recognized that this is a challenging, complex, and costly program that required significant support from government and its partners. A fully regulated, comprehensive private sector pharmaceutical services system in Tanzania can have a substantial impact on the health of the population. Observing the wide-ranging impact of ADDOs, and recognizing the critical public health role of non-pharmacy retail shops, the MOHSW and TFDA were convinced that rolling out the ADDO program to all areas of the country was warranted. While acknowledging the significant costs and time needed for a full national implementation, the broad societal and health sector benefits were judged to justify the cost.

The ADDO model is based on the assumption that to effectively and sustainably address the problem of access² to quality medicines and pharmaceutical services in a resource-limited setting, all aspects of the drug shop enterprise—the physical premises, medicine inventory management, provider’s capacity and interactions with consumers, and appropriateness of recommended treatments according to national guidelines—have to be comprehensively and systematically addressed. In addition, the larger health system in which drug shops operate, which include product licensing and supply, training, and inspection and involve local and national authorities also need to be strengthened.

This case study addresses the key study question, “Is the Tanzania ADDO model scalable³, sustainable⁴, and transferable⁵?” Specifically, it asks—

- Was the decentralized ADDO implementation model effective in scaling up the ADDO program nationally? What broader efforts helped to ensure scalability?
- Can ADDO program improvements be sustained?
- Was Tanzania’s ADDO model effectively adapted for Ugandan and Liberian needs and replicated?

This case study draws data and information from an archive of published and unpublished reports and studies related to the ADDO program, which was piloted in the Ruvuma region starting in 2003 and had been rolled out to every region in mainland Tanzania by mid-2013. The study uses the World Health Organization’s health system building blocks as a framework to characterize the ADDO program and its contributions.

The ADDO Program: Taking a Health System Perspective

"One thing is certain, informal providers represent a growing and undeniable force within the health community, and despite the refusal of some governments and others to acknowledge/engage with them, it is in all our interests—particularly the patients—to begin working more effectively with these elusive actors."

—Tom Feeny, HANSHEP⁶

Private medicine retailers are key players in promoting access to medicines in low- and middle-income countries (Wafula et al., 2012). In recent years, drug shops and pharmacies have been recognized in many countries for their potential to improve health across a wide area of diseases and health issues (Brieger et al., 2004; Smith 2009). Despite their popularity and potential, pharmacies and drug shops are not generally considered part of the larger health system and are mostly missing from countries’ health strategies, policies, and monitoring.

The ADDO program is an interesting example of how to use regulation control knobs to influence and structure the performance of a retail private pharmaceutical sector (Roberts & Reich 2011). Because health systems vary widely depending on the context, a best-practices model needs to be adapted for local conditions. But health systems that function well have certain shared characteristics. They have procurement and distribution systems that actually deliver medicines to those in need. They are staffed with a sufficient number of skilled and motivated health workers. And they operate with financing systems that are sustainable, inclusive, and fair—the costs of health care should not force households into poverty (WHO 2007).

² The key access dimension as defined in the access framework are physical availability, affordability, geographic accessibility and acceptability (or satisfaction).

³ Defined as the ability to expand an intervention to support larger system without affecting performance.

⁴ Defined as persistence of the intervention’s effect over time.

⁵ Defined as extent to which an intervention can be replicated and implemented in a new country.

⁶ The Private Sector in Health Symposium. *Harnessing the informal providers for health systems improvement: Lessons from India*. <http://www.pshealth.org/site/privatesectorhealth/2013-symposium/webinar-series/130205-harnessing-informal-providers>

Service Delivery

As the ADDO program has taken off, many have recognized the potential of these shops to not only increase access to essential medicines, but also to serve as a platform for community-based public health interventions; for example, a child health training module for dispensers includes danger signs of pneumonia in children and the appropriate action (co-trimoxazole treatment or referral), depending on the situation presented (BASICS/RPM Plus 2008). Other programs currently being integrated include tuberculosis case identification and referrals and reproductive health commodities and services (MOHSW 2010).

As a result of the increasing interest in the concept, numerous organizations and programs have played a role in expanding both the services that ADDOs provide and their geographic reach—over 9,000 ADDOs are currently serving the 25 regions of mainland Tanzania. And improvements have been sustained: In 2010, 63% of malaria encounters in Ruvuma were treated according to the treatment guidelines, compared to 24% in 2004 (end of Ruvuma pilot), and 6% before the ADDO program started—a 950% improvement (Liana et al., 2011).

Health Workforce

Increased efforts to fight HIV/AIDS, malaria, and tuberculosis in sub-Saharan Africa have accentuated the critical shortage of health care workers, including physicians, nurses, and pharmacists. According to the World Health Organization, Tanzania had about one pharmacy professional (pharmacist or pharmacy technician/assistant) for every 100,000 people at the time of the ADDO program launch (WHO 2008). Throughout Africa, programs are testing innovative approaches to ease the health care personnel shortage (WHO 2006; SEAM 2007).

In their article, Rutta and colleagues (2009) describe how the government of Tanzania addressed a lack of access to quality medicines and services by creating a new cadre of pharmaceutical service provider based in retail drug shops. Although many interventions targeting retail drug sellers have been carried out in Africa and Asia, they usually have

ADDO Dispenser Curriculum Topics

- Laws, regulations, and dispensers ethics
- Good dispensing practices and rational medicines use
- Common medical conditions in the community
- Reproductive health and HIV/AIDS
- Communication skills and counseling
- Child health
- Record-keeping

focused singularly on training and other capacity-building activities and have often been limited to a particular intervention, such as malaria or child health (Goodman et al., 2007a; Tawfik et al., 2002). The Tanzanian ADDO program is a comprehensive, public–private partnership that combines the creation of consumer demand with government oversight that ensures that personnel and shops meet standards for training, operations, and the sale of quality products.

As part of the ADDO program’s business training, shop owners learn how to monitor product sales, what types of products to stock to improve business, and keep track of products’ expiry dates. A focus of the business training that ADDO owners receive is the importance of

recordkeeping. In a survey of owners, almost all reported keeping financial records (94%) and monitoring daily sales (98%); in addition, 69% tracked monthly profits (EADSI 2008)

By the time the last region was rolled out in mid-2013, 13,301 dispensers (90% women), 2,600 owners (39% women)⁷, and 3,262 local inspectors had been trained as part of the initiative. In surveys of stakeholders, including owners and dispensers, training has repeatedly been mentioned as the most highly valued benefit of the program.

“This program complements the government efforts to ensure that the communities get access to medicine. It is more valid here in Namtumbo where public health facilities are few in number and the district is facing a real crisis of shortage

⁷ The discrepancy between the number of shops and owners can be explained by some owners having multiple shops and may owners also being trained as dispensers.

of skilled health workers. I do not know what would have been the situation without the ADDOs. Our people depend on them”—District Executive Director, Namtumbo District, Ruvuma Region.

Health Information Systems

As mentioned, ADDO owners and dispensers are trained in keeping records of various types related to business and sales. Dispensers track who buys medicines (including select demographic information) and what conditions the medicines were purchased for. They also keep a log of adverse drug events as reported by their customers. The availability of such records at ADDOs has allowed supervision and inspection teams to review and assess ADDO dispensers' performance and the shops' compliance with regulations.

The records provide a wealth of information that could not only help health officials quickly identify problems, such as epidemics, but could also provide surveillance information on common conditions in the community. However, these data are not easily communicated and are therefore not reported to district, regional, or central health authorities. In addition, the ADDO regulatory authority (the Pharmacy Council⁸) needs more efficient ways to track activities related ADDOs and pharmacies, such as inspection dates, license renewal, and accreditation status.

To help rectify these problems with information access, MSH is working with the Pharmacy Council and a local contractor to put a system in place that will allow bi-directional communication, including giving ADDOs the ability to transmit health information to the Pharmacy Council and potentially the MOHSW. This system will incorporate geographic information systems (GIS) to map locations of ADDOs and other health facilities, which the Pharmacy Council can use to enforce licensing restrictions based on shop location and contribute to the development of an incentive program to encourage new shop openings in underserved areas. The system will also incorporate mobile technology that makes it possible to report ADDO data (e.g., basic shop information, drug availability, and prices). The mobile application will facilitate an easy, safe, and accurate transfer of data by synching with a web-based database at the Pharmacy Council. Pharmacy Council will also be able to use text messaging to send information to shop staff, including alerts related to drug recalls, for example. The local contractor is designing the applications using open-source software (Motech Suite) which will be available to other drug seller initiatives.

Access to Essential Medicines

For many common medical problems, such as malaria and diarrhea, a variety of factors lead people to self-diagnose and medicate before visiting a government health facility: distance to the health facility; lack of drug availability in the public facility; cash availability; and customer perceptions of privacy and quality of the health care providers, health facilities, and medicines (Tawfik et al., 2002; Brieger et al., 2005; Goodman et al., 2007b; EADSI unpublished data;). A review of literature looking at the role of drug sellers in child health in Africa reported that the use of retail drug outlets during child illnesses ranged from 15–82% with a median around 50%, and that caretakers used retail outlets even when cheaper alternatives existed, such as village health workers (Brieger 2003).

People were accessing medicines from drug shops in Tanzania long before ADDOs were developed. What is different now is that whereas prescription drugs, such as antibiotics, previously were sold illicitly by untrained shop staff, accreditation standards have broadened the list of medicines ADDOs can legally dispense to include basic high-quality essential medicines—both prescription and nonprescription. Coupled with a dispenser training program on appropriate medicine use and referral, quality of care in ADDOs has improved. In addition, consumers who buy medicines in ADDOs can be assured that the quality is better; for example, during the pilot evaluation in Ruvuma, registration status of medicines was an indicator of the quality of drugs being sold in stores. After ADDOs were introduced, the proportion of unregistered medicines in Ruvuma was reduced by a factor of 13, from 26% to 2% (SEAM 2007). In evaluations since

⁸ Until 2011, TFDA was the regulatory authority responsible for ADDOs; however, a regulatory change placed the responsibility with the Pharmacy Council.

then in other regions, no unregistered products have been found in ADDOs. ADDO dispensers also receive training on the importance of not selling drugs that have expired, and expiry has not been identified as a problem.

The ADDO program acted as a catalyst and drove the creation of new policies related to improving access to medicines in the private sector, including the 2009 MOHSW notice to phase out all unaccredited drug shops by 2011, the establishment of the Medicine Access Steering Committee under MOHSW stewardship to coordinate access initiatives in the private sector, and the National Malaria Control Programme's 2006 adoption of the ADDO platform as part of its national strategy to increase access to malaria treatment in the private sector, paving the way for distribution of subsidized artemisinin-based combination therapy through ADDOs. Other significant new policies include the incorporation of child health services into the ADDOs (2006) and the National Health Insurance Fund decision to allow members to fill prescriptions at ADDOs (2007). These new policies relating to public-private partnership in the pharmaceutical sector have placed Tanzania in a stronger position to meet the health needs of both rural and urban communities.

Financing

Developing and implementing an accredited drug seller initiative and bringing it to scale requires committed resources, individuals, and institutions. The initial funding for the ADDO pilot program in Ruvuma came from the Gates Foundation, but multiple stakeholders contributed to the program roll-out and enhancement (see Table 2). When the implementation model was revised to shift responsibility from central to local authorities, the rollout time decreased from an estimated 18 months to less than 12 months per region, and TFDA records indicated that the estimated implementation cost was decreased by 55% (US\$ 126,000 per district compared with US\$ 57,000 per district). Additional savings resulted from a shift in program costs to the owners and dispensers, who now pay all costs associated with shop branding and renovations, increased inventories, and training. Many of these costs were covered by donors in the early years of implementation.

Once the program was established, the primary financing issue shifted to shop profitability—shops need to stay in business to continue to provide access to medicines in the community. In addition, the local governments must include the ADDO program in their budgets, which the government has mandated. In 2007, the National Health Insurance Fund incorporated ADDOs into its scheme, which allows members to access drugs at no cost and ADDOs to receive reimbursement. ADDO owners feel that this arrangement boosts their sales (EADSI 2011). The fund continues to accredit ADDOs to serve its members, and as of 2011, it had accredited 241 ADDOs; this number will likely increase with the completion of ADDO rollout.

Our research has shown that shops are profitable (EADSI 2011). Although the pilot program in Ruvuma linked the majority of owners with microfinance institutions to help them become accredited, few owners in other regions used that option to finance their shop operations (2%). The majority of owners (79%) reinvested their ADDO business profits, while 11% reported tapping personal savings for business financial needs; 8% used a combination of options (EADSI 2008).

Overall, median drug prices increased more in ADDO intervention regions compared to control regions; however, in unaccredited drug shops and in ADDOs, individual prices increased, decreased, and stayed the same. The price increases following ADDO implementation seem to support the assertion that after incurring significant expenses in renovations, training, and inventory, ADDO owners recoup some of their expenses by raising prices. How this affected consumers' ability to buy essential medicines is unknown. In addition, ADDO owners may reduce prices after they earn back their initial investment. To assess if the price increase is a temporary or permanent phenomena, we compared 2010 prices of select tracer items in Ruvuma to the 2004 prices by normalizing them with international prices. The average median price for a market basket of antibiotics compared with the *International Drug Price Indicator Guide* showed virtually no difference between 2004 and 2010 (+15% compared with +16%). Median prices in Ruvuma compared to the international price guide increased 1% between 2004 and 2010 after adjusting for inflation.

Leadership and Governance

Developing the accreditation standards was a critical part of the model design and led to the overhaul of regulations governing DLDB operations. Draft standards were reviewed and approved by TFDA technical committees before being approved by MOHSW and signed into law by the Minister of Health. The development of the ADDO standards and code of ethics resulted from a comprehensive, wide-ranging stakeholder consultation process; nearly 400 people participated, including regional and district medical officers, members of Parliament, councilors, and DLDB owners. The law⁹ requires all ADDO owners and dispensers to have a thorough understanding of these standards and ethics. It was amended in 2009 to accommodate the revision of the model to reflect decentralized implementation and operations—most notably, inspections.¹⁰ As the program expanded, it quickly became clear that a centralized TFDA did not have the capacity to conduct regular inspections. Therefore, an important aspect of revising the model was to decentralize the monitoring and inspection responsibility to the local level, with TFDA conducting the training. Table 1 summarizes the standards for accreditation, which covers areas such as inspection.

Table 1: ADDO Program Standards for Accreditation

Component	Process or requirements
Accreditation application process	A Council Food and Drug Committee is responsible for a four-part application process for shops: an application form, initial inspection of the existing facility, re-inspection after any premise upgrades required for accreditation, and ongoing inspection after accreditation.
Incentives for owners	Owner incentives focus on improved shop profitability and approval to sell a range of prescription medications. Incentives for owners who commit to standards include access to micro-financing for stock purchases, a marketing campaign encouraging consumers to buy medicines at ADDO, and more reliable sources of affordable, quality wholesale goods.
Premises infrastructure	The standards provide instructions for building size, layout, identification, dispensing and services areas, storage, and security.
Staff qualification	The grade levels of ADDO dispensers include nurses, nurse-midwives, clinical officers, assistant medical officers, pharmaceutical assistants, and pharmaceutical technicians. The most common qualification of ADDO dispensers prior to ADDO training is nurse assistant.
Training	All dispensers must be accredited by the TFDA, display their accreditation certificate, and have their photo identification on their coats when working. Accreditation involves completing a TFDA-approved dispensers' course. Course topics include in-depth information on ADDO drugs in their generic and brand forms; illness indications and contraindications; drug dosages, side effects, and patient information; laws governing dispensers' work; basic management, record-keeping, and business ethics; and communications skills. ADDO training for shop owners focuses on ethics, regulations, and improvement of business management skills.
Drug quality and availability	The ADDO list of approved pharmaceuticals includes a full range of over-the-counter drugs and a limited list of prescription drugs, including common antibiotics and oral contraceptives. ADDOs may sell only those drugs registered with and approved by the TFDA. ADDO-restricted wholesalers can receive a license to sell nonprescription and ADDO-restricted approved prescription drugs under the supervision of a full-time pharmaceutical wholesaler's technician.
Record keeping	ADDOs must keep records of all prescription drugs sold and their selling prices, financial and sales information, customer complaints, and expired medications. These records may be used for supervision purposes and must be available for review by inspectors.
Regulation, inspection, and sanctions	Local government officials receive a basic inspection training course from the TFDA and are certified as local inspectors. They work with the TFDA to conduct a minimum of two inspections of each shop annually. The program also carries out inspections of remaining unaccredited shops, and can issue sanctions against those that illegally sell prescription drugs. A channel exists for registering any

⁹ The Tanzania Food, Drug and Cosmetics Act (standard and code of Ethics for Duka la Dawa Muhimu Regulation 2004.

¹⁰ The Tanzania Food, Drug and Cosmetics Act (standard and code of Ethics for Duka la Dawa Muhimu (Amendments) Regulation 2009.

	customers' complaints against ADDOs or any shops' complaints about harassment by inspectors or other problems.
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In addition to the government's role in overseeing ADDO operations, MSH has been working to strengthen existing ADDO owner/dispenser professional associations and facilitate the formation of new provider associations to serve as a governance resource and a professional "voice." This work has resulted in an association toolkit that was developed through a consultative stakeholder workshop (MSH 2010). It includes operational and management tools, which are available in English and Kiswahili related to how to form and register an association, mobilize financial resources, and monitor and evaluate activities.

As part of the research for this work, owners and dispensers were interviewed regarding their perceptions of how membership in an association can help them individually. For example, ADDO owners expect the associations to—

- Give them a strong unified voice on matters relating to their businesses
- Help them access loans to improve their businesses
- Enable them to have joint procurement of drugs and other pharmaceutical products and enjoy the economies of scale resulting from bulk purchases
- Provide them with a platform to engage with various authorities such as the Tanzania Food and Drugs Authority (TFDA), Tanzania Revenue Authority, and local government authorities
- Create a forum for them to share experiences and resolve conflicts among members
- Enable them to pool resources to start their own savings and credit cooperative societies
- and advance loans to members
- Provide them with a mechanism for self-regulation to minimize noncompliance with pharmaceutical sector regulations and standards

Likewise, dispensers mentioned that the associations will—

- Provide them with a platform to deliberate on issues of interest
- Give them a common voice to air grievances to owner
- Help them demand better salaries and work conditions, including standard working hours, overtime payment, and annual leave
- Provide them with a forum to exchange ideas and experiences in line with their training and enable them to improve their skills and promote self-compliance to regulations
- Enable them to pool resources and invest in other income-generating activities toward a goal of individual development and self-improvement.

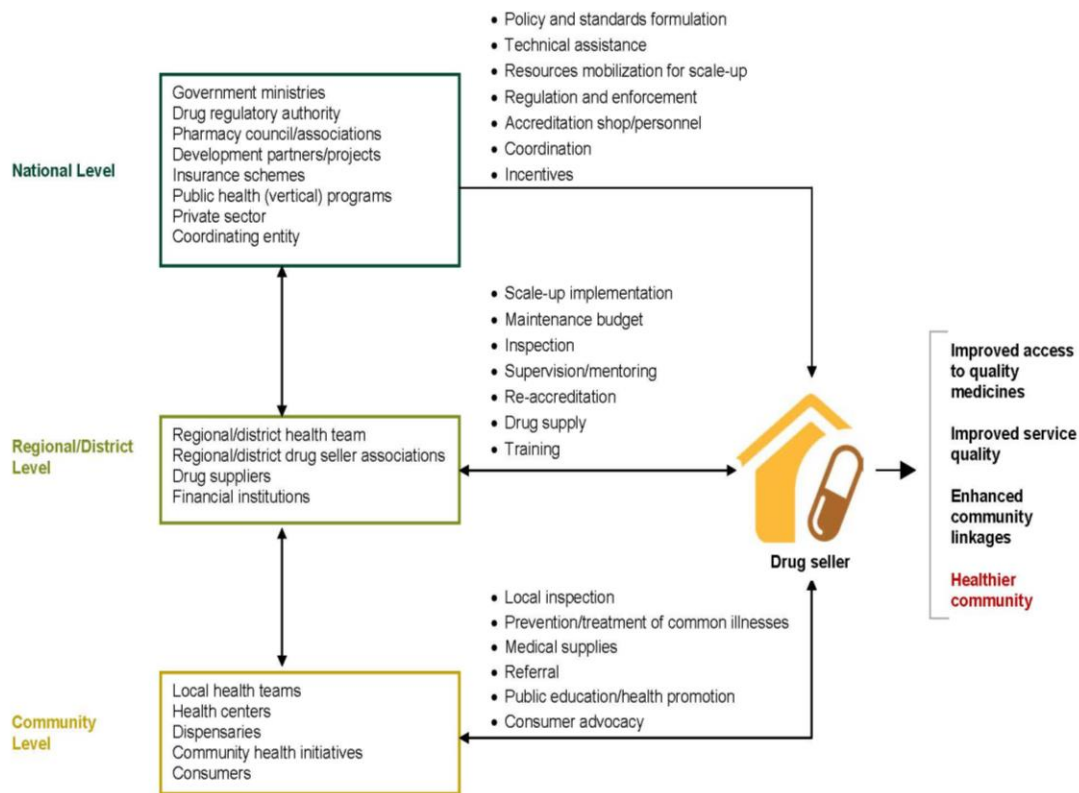
Although inspection is a critical aspect of the program, it was clear that the level of supportive supervision to owners and dispensers needed to increase. Having inspectors who have the power to close down shops for legal infractions serve as supportive supervisors is obviously not ideal, but a lack of government personnel who could take over that role left a gap. Through an ongoing program, MSH is now exploring how associations can provide that support through a peer supervision model that is under development and will be tested in Uganda and adapted for use in Tanzanian ADDO associations.

Stakeholder Engagement: The Linchpin of Success and Sustainability

The one critical element that has been essential to the ADDO program's success is stakeholder engagement—the successful buy-in and sustained commitment came directly from the effort, time, and resources spent to fully connect with all vital stakeholders at all levels. Involvement ranged from publicly stating support for the concept to working

closely on all aspects of the program design and implementation. At the end of the pilot in Ruvuma, regional and district stakeholders reported the following program strengths: use of a participatory approach that involved all stakeholders from the beginning: owners, dispensers, consumers, political leaders; a fair and transparent process for permit application and approvals; the dispenser training component; and respecting and valuing community-level inputs. One major result of full stakeholder engagement was the decentralization of the implementation model; in 2008, the MOHSW mandated that local governments incorporate ADDO implementation and maintenance in their regular planning and budgeting. Another result was the development of a 2009 strategy to introduce ADDOs to urban areas

The figure below illustrates the drug seller initiative conceptual framework. The framework is based on developing public-private sector links at the national, district, and community levels—the public sector developing and enforcing standards, while providing economic incentives through authorization of an expanded list of drugs that can be dispensed, and the private sector responsible for supply, shop renovations, and training.



Accredited Drug Seller Initiative Conceptual Framework

During the program’s critical early period, TFDA in collaboration with MOHSW, organized a study visit of members of Parliament’s Social Welfare Committee to ADDO shops in Ruvuma. Their enthusiastic reaction paved the way for the allocation of additional funding for roll-out from the government. In her budget presentation to the Parliament in 2004, the Minister of Health, Hon. Anna Abdallah, reported that \$1.06 million had been allocated to support the expansion of the ADDO program following very promising results from the pilot in Ruvuma. Such a high-level commitment of the government’s own budget provided an incentive for continued donor interest and support, which is illustrated in the list of program milestones (Table 2). Another sign of government ownership was the various government strategic documents that started addressing the ADDO program as a “key MOHSW program” and not a “donor-funded project.” For example in the Ministry’s Health Sector Strategic Plan III July 2009–June 2015 “Partnership for Delivering the MDGs,” the ADDO program was cited as fundamental in the private sector provision of essential medicines to vulnerable groups (MOHSW 2004; 2008).

Table 2: ADDO Program Milestones: 2003–2013

ADDO Program Phase	Year	Description		
Assessment, program design, conceptualization and planning	2001-2003	The Strategies for Enhancing Access to Medicines (SEAM) Program, MOHSW, TFDA, and several stakeholders from the government, local government, academic institution, and private sector collaborated on a pharmaceutical sector and access to essential medicines assessment, recommended a public-private sector approach to improving access, and designed and reached a consensus on the ADDO model with Ruvuma as a pilot region. Program funding provided by the Gates Foundation .		
Pilot program development and implementation—Ruvuma region	2003-2005	SEAM Program and TFDA design and launch the ADDO program in the Ruvuma region—210 outlets accredited. (Gates Foundation). Private sector contribution (210 owners’ investment for premises construction or upgrade to meet accreditation standards).		
Pilot program M&E	2003-2005	SEAM commissioned monitoring and evaluation of the ADDO program in Ruvuma (Gates Foundation).		
	2006	Danida sponsored an independent evaluation of the ADDO program in Ruvuma by HERA.		
Program scale-up (centralized approach)	2006-2008	Government of Tanzania, through the MOHSW, approves TFDA plan to rollout ADDOs to Tanzanian mainland. U.S. Agency for International Development (USAID) , through MSH’s Rational Pharmaceutical Management Plus Program, funds ADDO rollout in Morogoro region using resources from the President’s Emergency Plan for AIDS Relief—553 ADDOs. Government of Tanzania funds rollout in Mtwara and Rukwa regions—122 ADDOs. Private sector contribution (675 owners costs investment for premises construction or upgrade to meet accreditation standards) in Morogoro, Rukwa, and Mtwara.		
		2007–2008	Danida supports TFDA to conduct training of trainers and district inspectors, develop and print training materials used for scale-up, and carry out national sensitization seminars with local governments.	
		2007-2011	Gates Foundation funds the East African Drug Seller Initiative (EADSI) to work with TFDA to review and revise the existing ADDO model to make nationwide scale-up more cost-efficient and to help ensure the long-term sustainability of ADDOs and to evaluate effect of changes made on access to medicines and quality of products and services provided.	
			2008	Tanzanian stakeholders agreed to decentralize implementation model to improve efficiency of scale-up and sustainability of program at consensus meetings in Dodoma and Morogoro.
			2008	Global Fund to Fight AIDS, Tuberculosis and Malaria agrees to fund ADDO rollout in six to eight high-impact malaria regions to improve access to antimalarials for children under five; Danida and government of Tanzania also contribute funding for rollout.
2009	Clinton Foundation funds initial implementation activities in Shinyanga and Dodoma			
	2008-2009	Local governments in Shinyanga, Tabora, Iringa, Arusha, Kagera, and Kilimanjaro took initiative on their own to mobilize funds to introduce ADDOs.		

	2011	Cost of training in Dar es Salaam for the urban ADDO model funded by ADDO dispenser and owner contributions (~1,300 dispensers and ~1,700 owners).
	2013	Last region, Mwanza, launches the ADDO program in June 2013. Officially, ADDO program coverage is nationwide.
Program maintenance and sustainability; public health intervention integration into the ADDO program	2006	National Malaria Control Programme adopts the ADDO concept as part of its national strategy to increase access to malaria treatment.
	2006	MSH's Rational Pharmaceutical Management Plus Program collaborates with the Basic Support for Institutionalizing Child Survival Project to add a child health component to ADDO services (USAID funded FY07, FY08, FY09).
	2007	Tanzania's National Health Insurance Fund initiates plan that allows members to fill prescriptions at ADDOs.
	2007	MSH's Strengthening Pharmaceutical Services Program uses President's Malaria Initiative funds to provide subsidized artemisinin-based combination therapy through ADDOs (FY06, FY07, FY08).
	2008	The Prime Minister's Office for Regional Administration and Local Government mandates local governments to incorporate ADDO program implementation into their planning and budgets.
	2009	Rockefeller Foundation funds MSH to develop a strategy to promote program sustainability and quality through the establishment of ADDO owner and dispenser associations.
	2009	Government of Tanzania regulation is revised to phase out unaccredited drug shops (<i>duka la dawa baridi</i>) by 2011.
	2011	Legislative change mandates the transition of program oversight from TFDA to Pharmacy Council.
	2010-2012	As a pilot, MSH's Systems for Improved Access to Pharmaceuticals and Services Program collaborates with National TB and Leprosy Control Program to integrate interventions to engage 550 ADDOs in Morogoro to improve early detection of people with TB symptoms (USAID).
	2011-2014	Gates Foundation funds the Sustainable Drug Seller Initiative (SDSI). The SDSI program builds on MSH's SEAM and EADSI programs. Both SEAM and EADSI programs focused on creating and implementing public-private partnerships using government accreditation to increase access to quality pharmaceutical products and services in underserved areas of Tanzania and Uganda. SDSI's goal is to ensure the maintenance and sustainability of these public-private drug seller initiatives in Tanzania and Uganda and to introduce and roll out the initiative in Liberia .

Beyond improving the quality of medicines and dispensing services, availability of essential medicines, and the regulatory system, the impact of a nationwide ADDO approach on the pharmaceutical sector—and consequently on society as a whole—promises to provide a model framework for private-sector pharmaceutical delivery in the developing world.

To replicate the Tanzania ADDO model, MSH worked with national and local stakeholders in Uganda and Liberia to develop an accreditation model based on the Tanzanian experiences, but adapted to Ugandan and Liberian contexts. For example, Uganda's professional pharmaceutical society embraced the model and played a much bigger role than Tanzania's professional society did. Liberia on the other hand offered a unique opportunity for building a sustainable drug seller initiative in an emerging state and in a densely populated versus rural area.

In Uganda, 520 drug shops have been accredited in four districts and NDA has developed a national scale-up strategy. Liberia has 200 AMS in the country's most populated county. Like Tanzania, ADS in Uganda and AMS in Liberia have led to increased availability of good quality pharmaceutical products and improved dispensing and business skills. With the Uganda and Liberia experiences, MSH hopes to solidify the global view that initiatives to strengthen the quality of pharmaceutical products and services provided by private sector drug sellers are feasible, effective, and sustainable in multiple settings.

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