Creating a New Class of Pharmaceutical Services Provider for Underserved Areas: The Tanzania Accredited Drug Dispensing Outlet Experience

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Abstract

The Problem: In developing countries, the most accessible source of treatment for common conditions is often an informal drug shop, where drug sellers are untrained and operations are unmonitored.

Purpose: We sought to describe a public–private initiative in Tanzania that created a new class of provider in government-accredited drug outlets, which improved the quality of medicines and pharmaceutical services in previously underserved areas.

Key Points: The accredited drug-dispensing outlet program combines changing behavior and expectations of community members who use, own, regulate, and work in drug shops. Success resulted from including community stakeholders from the beginning of the process.

Conclusions: Addressing shortages in qualified health care providers by training and accrediting private sector drug dispensers to recognize common conditions and provide quality pharmaceutical products and services is feasible in a developing country, when supported by an appropriate policy and regulatory environment. Scaling up and sustaining the program will be a challenge.

Keywords

Essential medicines, retail drug outlet, pharmaceutical services, public–private initiative, Tanzania, accreditation, regulation, stakeholder involvement

MOST PEOPLE IN DEVELOPING COUNTRIES GET THEIR MEDICINES FROM PRIVATE RETAIL DRUG SHOPS

Many people in developing countries buy medicines from the most convenient source, which is usually the local retail drug shop—called *duka la dawa baridi* in Tanzania. *Duka la dawa baridi* are authorized by the Tanzania Food and Drugs Authority (TFDA) to provide nonprescription medicines in the private sector; however, many sell prescription drugs illegally.[1,2] With an estimated 5,600-plus stores registered in 2003, and many more operating without registration,[3] *duka la dawa baridi* constitute the largest retail source of medicines in Tanzania, where licensed pharmacies are scarce; as of June 2007, Tanzania had 499 registered wholesale and retail pharmacies, with approximately 60% of them located in Dar es Salaam.[4]

Duka la dawa baridi are everywhere throughout the countryside, and for rural or periurban communities, they may be the only nearby place to buy medicines and get health advice on common illnesses, such as malaria.[5] For example, caretakers often treat children at home, and retail drug sellers may be their only contact regarding the child's health. A review of literature looking at the role of drug sellers in child health in Africa reported that the use of retail drug shops during

child illnesses ranged from 15% to 82% with a median around 50%, and that caretakers used retail outlets even when cheaper alternatives existed, such as village health workers.[6]

In 2001, the Strategies for Enhancing Access to Medicines (SEAM) Program* conducted an assessment to characterize the country's public and private pharmaceutical sectors and determine the population's access to essential medicines.[1] The assessment revealed access gaps in drug availability, primarily in the public sector, and issues related to quality and affordability of products and services, especially in the private retail sector. It also showed that few Tanzanians could obtain pharmaceutical services because of the lack of registered pharmacies, and instead frequently sought care from *duka la dawa baridi*, which often had medicines in stock when public facilities did not. Such drug outlets are potentially important partners in health care delivery, but the person behind the counter dispensing antimalarials or other medicines often has no health training or oversight, which can result in poor treatment and dispensing practices and the sale of substandard and unregistered drugs.[1,7,8]

CREATING A NEW CLASS OF HEALTH CARE PROVIDER—THE ACCREDITED DRUG DISPENSING OUTLET PROGRAM

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.[9] Throughout Africa, programs are testing innovative approaches to ease the health care personnel shortage.[10,11]

This article describes 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 focused singularly on training and other capacity-building activities and have often been limited to a particular intervention, such as malaria or child health.[12,13] The franchising concept for improving service quality in drug shops and clinics has also been applied in developing country settings[14,15]; however, the Tanzanian program is a comprehensive, public–private partnership that combines the creation of consumer demand with government oversight that ensures that shops meet standards for training, operations, and the sale of quality products.

Guided by the results of the 2001 SEAM access assessment, the Ministry of Health and Social Welfare (MOHSW) and the TFDA worked with SEAM to develop and launch an accredited drug dispensing outlet (ADDO) program (also known as *duka la dawa muhimu*), which would replace *duka la dawa baridi*. The pilot program in the Ruvuma region took a multidimensional approach that combined changing the behavior and expectations of community members who use the drug shops and those who own, regulate, or work in the shops.

For shop owners and dispensing staff, these changes were achieved by combining training, incentives, and regulation with efforts to increase client demand for and expectations of quality products and services. At the ADDO, the intent is for the dispenser to fill a prescription, or when one is not available, to listen to the client's description of symptoms and advise him or her appropriately. Advice might include recommending and providing a proper medicine together with appropriate dispensing information; recommending home care if a medicine is not warranted; suggesting a prevention product or service connected to the client's complaint (such as an insecticide-treated bed net for those with presumptive malaria); or referring the client to the closest health facility for care beyond the scope of shop services.

The government's primary contribution to the ADDO strategy included developing an accreditation mechanism based on MOHSW/TFDA-instituted standards and regula-

Table 1. 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

* A Management Sciences for Health program funded by the Bill & Melinda Gates Foundation from 2000 to 2006.

tions and expanding legal access to a limited list of basic, prescription and nonprescription, essential medicines. To become accredited by the government, dispensers need to acquire and maintain the appropriate knowledge, skills, and competence and have a client-centered attitude that meets with the ethics and responsibilities of their new role. Currently, dispensers must be qualified as nurse assistants to enter training and become accredited (the country has too few pharmacy assistants to fill the need for dispensers); the government is debating reducing the educational requirement to deepen the pool of dispenser candidates.

Table 1 includes a list of ADDO core dispenser training topics in addition to topics added as the program expanded in scope to cover additional public health areas. The ADDO program has great potential to expand the human resource base for pharmaceutical services by creating a new, government-sanctioned class of health care provider that must meet certain education and training standards to serve communities that have little or no access to quality pharmaceutical services.

CHANGES TO THE POLICY FRAMEWORK

When the ADDO program was conceived, the Tanzania Food, Drugs and Cosmetics Act of 2003 provided the overall policy and regulatory framework governing retail drug sellers; however, certain regulations and policies had to be developed and instituted to apply the ADDO concept to improve access to essential medicines and quality services. Some of key results include the following:

Table 2. ADDO Program Stakeholders and Their Roles

Partner	Action/Role
Central Government: MOHSW and Ministry of Finance	• Develop and approve policies and regulations related to accessing essential medicines. • Mobilize and allocate resources. • Coordinate development partners' participation. • Oversee the ADDO program. • Responsible for its successful implementation.
TFDA	• Develop ADDO regulations, strategic planning, and program advocacy. • Coordinate partners at implementation level. • License and accredit ADDOs and dispensers. • Train and supervise local inspectors. • Monitor and evaluate program.
Local Governments (Regional and District)	• Inspect ADDOs and enforce regulations in collaboration with TFDA. • Supervise and monitor ADDO operations. • Incorporate ADDO activities into council comprehensive health plans. • Allocate resources (human, financial, facilities). • Produce standard reports.
Development Partners/Funding Agencies	• Provide financial and technical support to MOHSW/TFDA and other implementing organizations.
Academic and Governmental Training Institutions	• Help to develop dispenser training curricula and manuals. • Incorporate ADDO package into training program. • Train ADDO dispensers.
ADDO owners and dispensers	• Build/upgrade premises to meet ADDO standards. • Undergo standard training. • Purchase medicines from authorized sources. • Stock essential medicines. • Maintain ADDO standards. • Provide public health education.
Pharmaceutical Wholesalers	• Increase access to wholesale services by opening district subsidiaries to serve ADDOs.
Banks and Microfinancing Institutions	• Provide financial services (loans) and business training to ADDO owners
Nongovernmental Organizations	• Provide technical support to TFDA and districts in implementing the program. • Sensitize the community to the program. • Use ADDOs to carry out other public health interventions (e.g., delivery of treated nets)
Consumers (Patients and Caregivers)	• Patronize ADDOs to obtain services. • Report ADDO malpractice to relevant authorities.

- Development of the Standards and Code of Ethics for ADDO Regulations, 2004.
- Decentralization of regulation and inspection to the local level with the creation of district- and community-level ward inspectors along with inspection protocols.
- Legal allowance of ADDOs to sell and dispense a limited list of prescription-only medicines.
- Creation of new operating standards required for accreditation, including premises upgrades, minimum entry-level education, and completion of a 4-week training curriculum for ADDO dispensers.

BUILDING COMMUNITY PARTNERSHIPS TO ESTABLISH THE ADDO PROGRAM

The complexity of the ADDO pilot program required an enormous amount of effort to establish relationships with and garner support from a wide variety of community stakeholders over the 3 years from program start to the launch of the first ADDO. In this initiative, the definition of community was very broad, from consumers who frequent drug shops to national-level government authorities; however, activities centered on partnerships among shop owners and community, district, and regional authorities—especially as the program matured. As part of the process to launch the pilot program, the SEAM Program's relationships with stakeholders ranged from giving preliminary briefings on the proposed ADDO strategy to working closely on all aspects of the program design and implementation (Table 2). During the program's development, the TFDA had the final responsibility for the work, with the SEAM Program providing technical and financial assistance as appropriate. Local government and other health sector stakeholders, such as the MOHSW, made technical and policy contributions.

To build support and promote advocacy for the ADDO program, SEAM held more than 20 workshops in the pilot region of Ruvuma to brief stakeholders and solicit their views on what important components to include in the program. In addition, qualitative information was collected on the community's behaviors and preferences regarding access to medicines and their expectations about how ADDOs should operate. To gather this information, SEAM held 28 focus group discussions with consumers, shop owners, dispensers, and community leaders, and conducted 15 in-depth interviews with key local government informants, the results of which fed into the ADDO implementation model. For example, community input resulted in the name for the new shops, *duka la dawa muhimu*, which means "essential drug shop" in Swahili.

Much of the outreach effort centered on generating interest among *duka la dawa baridi* owners in transforming their shops into ADDOs by engaging them in discussion and incorporating their concerns into the program. Incentives for owners included business management training, the establishment of a regional pharmaceutical wholesaler to serve ADDOs exclusively, and links with a microfinancing bank, which many owners used as a way to fund the premises renovations required by the ADDO program. The TFDA developed application procedures and selection criteria for new ADDOs with input from community groups, local government, the MOHSW, and others. A district technical advisory committee in consultation with local government made certain program decisions, including those related to the number of ADDOs located in each village/ward.

Close regulation and supervision of the ADDOs is important to ensure that established service and product standards are maintained after accreditation, but the TFDA lacked the capacity to carry out a widespread monitoring and supervision effort. The approach to regulating the ADDO program involved making local government responsible for performing routine inspections and reporting on ADDOs in their area of jurisdiction. This work is done in partnership with and on behalf of the TFDA, which retains overall regulatory responsibility. The role of local government was formulated to fit with its responsibilities under local government reform, which has decentralized funding and decision-making authority for various areas, including delivery of public health services.

> 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 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

THE LAUNCH AND EXPANSION OF THE ADDO PROGRAM

The TFDA accredited the first ADDO in August 2003. By August 2005, more than 150 shops were accredited across

the Ruvuma region and an evaluation of the pilot program showed significant improvements in accessing quality medicines and pharmacy services.[16] As a result of the successful pilot program, local, regional, and national government representatives determined that the ADDO program had significantly improved both access to and rational use of essential medicines in Ruvuma, and the MOHSW approved a strategy to roll out ADDOs throughout mainland Tanzania. The government of Tanzania is financing the rollout in Mtwara and Rukwa regions initially; the government has also received Round 7 funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria to support the ADDO expansion to increase access to artemisinin-based combination therapies for malaria to children under the age of 5. Also, through the President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development is funding a scale up in the Morogoro region. Initial rollout regions were chosen based on their low level of pharmaceutical access and socioeconomic status (Figure 1).

In addition to expanding the number of ADDOs and accredited dispensers, the government and donors are expanding the scope of services that ADDOs provide by using them as a platform for strengthening community-based health care interventions, such as providing a resource for HIV/AIDS prevention and care initiatives, building the capacity of ADDO dispensers to manage key childhood illnesses, and distributing subsidized, artemisinin-based combination therapies and insecticide-treated nets.[2,17] For example, partners are working with the government to integrate a child health component into the ADDO package of services based on supporting the Integrated Management of Childhood Illness strategy with the goal of improving child health and ultimately reducing child mortality. Child health interventions include training ADDO dispensers in rational medicines used for malaria, acute respiratory infection, and diarrhea; creating demand for services through community mobilization activities; and recognizing and referring seriously ill children to health facilities. In a 2006 review of ADDO records, among 391 cases of

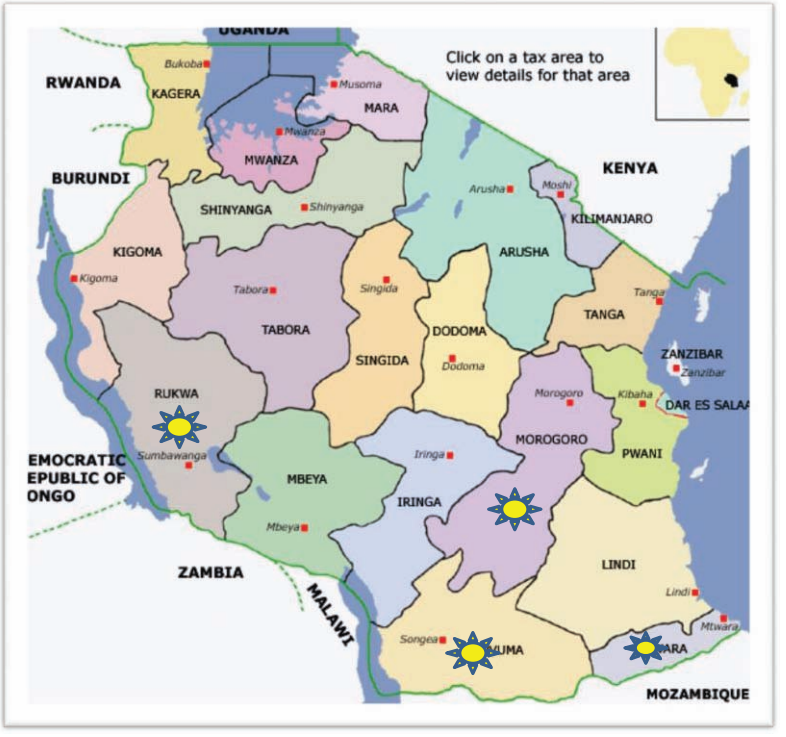

Figure 1. ADDO Program Regional Coverage, January 2008

malaria, over half (57%) of caretakers of a child suffering from fever went to the ADDO directly to seek treatment advices.[18] The same survey showed that 97% of the ADDO dispensers provided the recommended oral rehydration solution for children with nonbloody diarrhea.[18] Adding a child health component to ADDOs will help to fill the gap when government health facilities are out of medicines or far away and not easily accessible.

> Before the ADDO shop opened, people were reluctant to go to the health center if they felt sick because it was so far away. They would wait and hope that they started to feel better, but sometimes their situation would become serious, and someone would have to carry them to the Mission hospital. Now, people can come to the shop and get medicine immediately for simple malaria.
>
> —Frieda Komba, ADDO owner in Namtumbo

KEY LESSONS LEARNED

A comprehensive approach that includes training, marketing, incentives, accreditation, and regulation of private sector drug sellers can substantially improve pharmaceutical services in developing countries. Even grassroots drug outlets can appropriately dispense prescription medicines; however, they need a combination of supervision, monitoring, and regulatory inspections to support improvements (Figure 2). Supervising and mentoring ADDO owners and dispensers are complex, time consuming, and expensive because of the number of shops, the time needed for supervisory visits, and the lack of institutions and infrastructure available for providing such support. On the regulatory side, decentralizing regulatory authority to the districts has shown some promise in the ADDO program, but needs an adequate commitment of human and financial resources from the local government, which has been a challenge.

Figure 2. Before (DLDB) and After (ADDO) Transformation

The main lesson learned in Tanzania was that the key to the ADDO program achievements was the broad-based support received from all public and private sector stakeholders, which was built by including their participation in the project's design and implementation.

ADDRESSING THE CHALLENGES OF SCALING UP

In all 21 regions of Tanzania, there are only 1,400 pharmacists in both the public and private sectors. By January 2008, in just four regions, 895 ADDOs had been accredited and 1,800 ADDO dispensers had been trained and accredited, which illustrates the enormous potential of ADDOs to improve access to pharmaceutical care in the community (Table 3). However, several major program challenges need to be addressed. For example, the program needs to develop more cost-efficient approaches to medicine dispenser training and continuing education on a large scale. Currently, all dispensing staff must be accredited through the government-approved, 4-week dispenser's course and then are supposed to receive additional education to maintain their accreditation.

Table 3. Number of Pharmacies and Retail Drug Outlets in Four Regions, January 2008

Region	District	Number of Pharmacies	Number of ADDOs
Morogoro*	Ulanga	0	55
	Kilombero	0	138
	Kilosa	0	158
	Mvomero	0	120
	Morogoro Rural	0	82
	Morogoro Urban	13	165*
	Subtotal	**13**	**553**
Ruvuma	Songea Rural	0	44
	Songea Municipal	1	58
	Namtumbo	0	24
	Tunduru	0	24
	Mbinga	0	59
	Subtotal	**1**	**210**
Mtwara*	Tandahimba	0	20
	Newala	1	20
	Mtwara Rural	0	4
	Mtwara Urban	2	8
	Masasi	1	11
	Nanyumbu	0	2
	Subtotal	**4**	**65**
Rukwa*	Nkasi	0	31
	Mpanda	0	0
	Sumbawanga Urban	1	0
	Sumbawanga Rural	0	36
	Subtotal	**1**	**67**
Total		**38**	**895**

Source: Tanzania Food and Drug Authority and Management Sciences for Health/Rational Pharmaceutical Management Plus.

* Accreditation in progress in few remaining districts and expected to be completed by late 2008.

In addition, local governments need to build capacity in carrying out monitoring and supervision; some districts have combined inspection and supervision activities to maximize efficiency, but that is not a preferable arrangement.

Defining the appropriate, country-specific mix of public- and private-sector responsibilities in a drug seller initiative is critical for timely scale up and sustainability: The private sector needs to assume more of the routine setup and implementation functions, such as training and marketing, while the government focuses on activities to protect public health, such as establishing regulations and standards, licensing, and providing enforcement through regular inspections.

Efforts that are under way to effectively scale up the ADDO program and ensure sustainability and public health focus include choosing appropriate public health interventions to integrate into ADDO dispenser training without overburdening dispensers or expecting ADDOs to provide more than they should; establishing a core base of national trainers and integrating the standardized training into the curriculum of national training institutions; developing mechanisms for supervision and monitoring to help ensure service quality; and addressing economic issues, such as reducing implementation and maintenance costs, increasing the cost share of private sector partners, and providing more links between ADDO owners and microfinancing institutions, which has been a successful mechanism to ensure sustainability.

CONCLUSIONS

The ADDO program in Tanzania provides proof of concept and lessons on how an innovative public–private initiative can address shortages in the number of qualified health care providers by training and accrediting retail drug dispensers to recognize and treat common conditions and provide quality pharmaceutical products and services. The success of the initiative has resulted at least in part from the focus on including community stakeholders from the very beginning and continually making communication and outreach a top priority.

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