

**Accredited Drug Dispensing Outlets in Tanzania
Strategies for Enhancing Access to Medicines Program
Final Report**

Strategies for Enhancing Access to Medicines Program
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About SEAM

The Strategies for Enhancing Access to Medicines (SEAM) Program is funded by the Bill & Melinda Gates Foundation under contract D3601, and works to improve access to essential medicines and vaccines in the developing world by fostering partnerships between the public and private sectors.

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SEAM PROGRAM BACKGROUND

In 2000, Management Sciences for Health (MSH) received a grant from the Bill & Melinda Gates Foundation to identify and test innovative approaches for improving access to essential medicines in developing countries through greater participation of the private sector. To fulfill this mandate, MSH set out to implement programs to promote access, design a method to measure the nature and extent of the lack of access to essential medicines, and monitor the impact of these programs.

The Strategies for Enhancing Access to Medicines (SEAM) Program has four components: (1) technical collaboration with other Gates-supported global drug/vaccine access initiatives, (2) implementation of country-level public-private initiatives to improve access to essential drugs and commodities in two or three countries, (3) determination of the feasibility of franchising as a mechanism to improve access, and (4) development and deployment of information and communications tools to support technical interventions.

SEAM Access Framework

The SEAM access framework was developed after a review of the published and unpublished literature on access to health care in general and to medicines in particular. This framework was later discussed at a consultative meeting jointly sponsored by MSH and the World Health Organization (WHO), in Ferney-Voltaire, France, held December 11–13, 2000. More than 40 experts from 15 countries participated in the discussions and concluded that, as with health services, the concept of access to essential medicines is a construct with several distinct dimensions that are distinguished by sets of specific relationships.

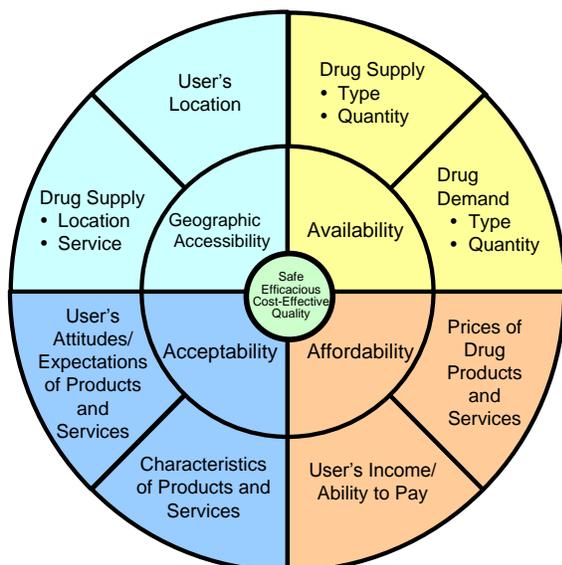


Figure 1. SEAM Access Framework

The following four dimensions of access emerged from the discussions—

Physical availability, defined by the relationship between the type and quantity of product and service needed and the type and quantity of product and service available

Affordability, defined by the relationship between the products and services and the user's ability to pay for them

Geographic accessibility, defined by the relationship between the location of the product or service and the location of the potential user of the product or service

Acceptability (or satisfaction), defined as the fit between the user's and provider's attitudes, and expectations about the products and services and the actual characteristics of these products and

services

In addition, quality of products and services was defined as an essential component that cuts across all dimensions. Participants developed a set of 17 key indicators to represent the four dimensions of access and one crosscutting characteristic (see Figure 1).

SEAM Country Assessments

After several rounds of internal discussions and consultations with experts from WHO and the World Bank as well as with contacts in developing countries, six countries—Ghana, Tanzania, Cambodia, India (state of Rajasthan), Brazil (state of Minas Gerais), and El Salvador—were identified as targets for assessments based on the conceptual framework, with the understanding that only two, or at most three, countries would eventually be selected for long-term projects under the SEAM Program. The initial selection criteria included perceived or known lack of access to essential medicines, perceived enabling environment for private sector initiatives, political and economic stability, and potential for collaboration with other MSH and Gates-funded local initiatives. The countries not selected for long-term assistance are expected to have benefited from the assessment exercise, in particular from a SEAM-supported analysis of potential public-private sector initiatives to enhance access to essential medicines. With such an analysis in hand, the country can approach donors and lenders to finance such work, as appropriate.

The assessments were carried out between February and May 2001. Local private, not-for-profit, and academic organizations collaborated in the adaptation of data collection instruments, sample selection, data collection, and analysis. The assessments included (1) determining the status of public and private sector access—in terms of geographical accessibility, availability, quality, affordability, acceptability—to essential public health medicines and health commodities; (2) identifying opportunities for private sector participation in improving access to public health commodities; and (3) determining the feasibility of implementing public/private sector strategies to improve access.

Using feedback from the 2001 SEAM conference and input from the SEAM Advisory Committee (see Annex 1 for member list), which held its first meeting on November 30, 2001, the MSH chief executive officer and Center for Pharmaceutical Management/SEAM Program managers elected to provide full support to country programs in Ghana and Tanzania and limited support for a country program in El Salvador. For both long-term and limited support, the results of the SEAM assessment surveys were critical in obtaining consensus among counterparts on the access problems that needed to be addressed, and in developing consensus around the interventions aimed at closing access gaps. The assessment results also served as a baseline, allowing both SEAM and country counterparts to measure change as progress was made in implementing the interventions.

TANZANIA COUNTRY BACKGROUND

The following section on health care in Tanzania was included as part of the 2001 SEAM assessment. This background provided part of the framework upon which the SEAM intervention in Tanzania was based. Though this information is dated, it presents the context to place SEAM's work in Tanzania.

Organization of Health Services

For a period of almost 30 years, health services delivery has been largely a prerogative of the state; a limited number of private, for-profit health services were available only in major towns of the country. After independence, socialism was the guiding principle in the country, and free-market practices dwindled. Health care facilities were redirected toward rural areas, and free medical health services were introduced. However, the government could not afford the funds necessary to carry out essential health care, so it sought external financial aid starting in the late 1970s. By the late 1980s, donor funds made up a larger percentage of the health budget than government funds¹.

In 1977, private, for-profit health services were banned under the Private Hospitals (Regulation) Act and the practice of medicine and dentistry prohibited as a commercial service. This act had negative implications for health services in the country. After a series of major economic and social changes, however, the government adopted a different approach to the role of the private sector. New policies were developed that looked favorably on the role of the private sector. The importance of the private sector in health care delivery was further recognized with an amendment to the 1977 Private Hospitals (Regulation) Act that resulted in the establishment of the Private Hospitals (Regulation) (Amendment) Act, 1991. Following this act, qualified individual medical practitioners and dentists could now manage private hospitals, with the approval of the Ministry of Health. Public-private partnerships are now actively encouraged as part of the Health Sector Reform policy pursued by the Ministry of Health (MOH).

According to government statistics, in 2000, Tanzania had almost 5,000 public and private health facilities, of which 80 percent were classified as dispensaries². Approximately 470 were health centers, which were primarily government run and served the rural areas of the country. Over 100 hospitals accounted for about two percent of all facilities. National government or parastatal organizations support most (66 percent) health facilities in Tanzania. Fifteen percent were run by mission-sector or other nongovernmental organizations (NGOs), and almost 20 percent were classified as private (Table 1). Thirteen NGO hospitals operated as Designated District Hospitals in the districts without public hospitals. The role of for-profit private providers is still limited but has been growing rapidly, particularly in the urban areas, since the relegalization of private practice in 1991. According to the government, the distribution of health facilities emphasizes rural areas where about 75 percent of the population lives.

¹ German Agency for Technical Cooperation (GTZ) and National Museum of Tanzania. 2001. *The History of Health Care in Tanzania*. Dar es Salaam: Tanzania Printers, Ltd.

² National Bureau of Statistics (NBS), United Republic of Tanzania. 2002. Household Budget Survey 2000/01.

Table 1. Distribution of Health Facilities in Tanzania, 2000

Health Facility	Government	Parastatal	NGO/ Mission	Private	Others	Total
Consultancy/referral hospitals	4	2	2	0	—	8
Regional hospitals	17	0	0	0	—	17
District hospitals	55	0	13	0	—	68
Other hospitals	2	6	56	20	2	86
Health centers	409	6	48	16	—	479
Dispensaries	2,450	202	612	663	28	3,955
Specialized clinics	75	0	4	22	—	101
Nursing homes	0	0	0	6	—	6
Laboratories	18	3	9	184	—	214
X-ray units	5	3	2	16	1	27
Total	3,035	222	746	927	31	4,961

Source: NBS 2002.

Note: — = not applicable

As seen in Table 1, NGOs own or run a significant proportion of health facilities that provide services on a nonprofit basis. The largest of this group is the Christian Social Service Commission, which is an umbrella organization of Protestant and Catholic churches that facilitates the provision of health and education services for its membership, primarily serving patients in rural areas of Tanzania. Other private faith-based groups whose members provide health services regardless of patient denomination include Aga Khan Health Services, Hindu Mandal, and Bakwata. In addition, some private corporations operate nonprofit health facilities for their employees and employee dependents.

The Pharmaceutical Sector

Pharmaceutical Policy, Laws, and Regulations

The Government of Tanzania's health reforms to improve health services through partnership between the public sector and private institutions have resulted in a number of legislative reforms and amendments. At the time of the 2001 assessment, pharmaceuticals were regulated through the Pharmaceuticals and Poisons Act No. 9 of 1978. The regulatory body overseeing pharmacy practice and medicine was the Pharmacy Board, under the Ministry of Health.

The Pharmaceutical and Poisons Act required that all pharmaceuticals be registered. However, enforcement of this provision was weak until 1999, when new management at the Pharmacy Board began to enforce registration requirements more vigorously. To carry out this work, the Pharmacy Board instituted a registration unit. Some of the pharmacists on staff had extensive experience in various areas of pharmacy, but limited experience in registration issues; however, some unit members attended training sessions. As of 2001, 4,800 products had been notified (the registration process had been started), and 1,408 human drugs and 64 veterinary drugs had been registered. Registration of human drugs increased by 123 percent in 2000 compared to 1999. Of the registered drugs, 60 percent were on the national essential drugs list. A lot of effort was put

into product registration and much has been achieved within a relatively short time. The government's commitment to support the essential drugs list concept is clear.

After the 2001 SEAM assessment, Parliament passed two acts that separated professional matters from the regulatory authority. The Pharmacy Act covers mainly professional norms and standards, educational standards, and registration of pharmacists, technicians, and assistants, and generally provides monitoring for good pharmacy practice. A Pharmacy Council oversees the implementation of the Pharmacy Act. The Tanzania Food, Drugs and Cosmetics Act established a food and medicine regulatory authority, the Tanzania Food and Drugs Authority (TFDA). In January 2003, Pharmacy Board responsibilities were assumed by the TFDA, and for the purpose of this report, TFDA will be referred to exclusively.

The TFDA approves the registration of drugs if it considers that availability of the drug is in the public interest and it may authorize the sale of unregistered drugs for specified purposes. The TFDA grants licenses for importing, exporting, manufacturing, and selling medicines under specified conditions. Manufacturing licenses are subject to compliance with Good Manufacturing Practice.

Ownership of pharmacies is reserved for pharmacists. The sale of pharmaceuticals is reserved for pharmacies in registered premises, conducted or supervised by a pharmacist. Exemptions are granted to dentists, veterinary surgeons, medical practitioners in the treatment of their patients, and staff members of a hospital, dispensary, or similar institution, or by exemption.

Pharmaceutical Distribution Structure

Manufacturers, wholesalers, sub-wholesalers, donors, and the medical stores department (MSD) are the main distributors of pharmaceuticals and medical supplies in Tanzania. The predominant single distributor of pharmaceuticals and medical supplies in Tanzania is the MSD. Since the government deposits funds for its health facilities with the MSD, it has a virtual monopoly for distributing pharmaceuticals and supplies to all public sector health facilities, including hospitals managed by church organizations. In addition to supplying government facilities, MSD has the country's preeminent drug distribution system. The distribution structure is described as follows—

- Foreign manufactures sell products to the MSD, local manufacturers, importers/wholesalers, donors, NGOs/mission agencies, and private hospitals.
- Local manufacturers sell products to the MSD, wholesalers, NGOs, and large private institutions (hospitals, retail pharmacies, etc.).
- Donors provide drugs to NGOs and voluntary agencies.
- The MSD distributes products to government health facilities, NGOs/mission facilities, and parastatals from seven zonal stores.

- Major importers/wholesalers sell primarily to sub-wholesalers/stockists, large private health facilities, and retail pharmacies. Sales to the public sector and NGO/mission agencies are generally minimal.
- Sub-wholesalers sell to smaller pharmacies, private health facilities, retail drug outlets (*duka la dawa baridi*), and smaller wholesalers.
- Consumers obtain their products from public sector health facilities, private sector facilities, NGOs, pharmacies, and retail drug outlets.

Duka la Dawa Baridi

The 1978 Pharmaceutical and Poisons Act governs the retail activities of *duka la dawa baridi* (DLDBs), which literally means “cold drug shops”—where “cold” drugs are nonprescription (over-the-counter). In general, the act allows DLDBs to sell only nonprescription drugs (legally described as Part II poisons), and thus these retail outlets, also known as Part II poison shops, are not legally required to be supervised by a pharmacist.

According to Guidelines for Dealing with Part II Poisons, the Regional Commissioner approves DLDBs for a TFDA permit after consultation with the Regional Technical Advisory Committee. After the Regional Commissioner approves the permit and the Regional Trading Officer issues a business license, the owners are able to apply for a permit from the Regional Pharmacist, acting on behalf of the TFDA, to sell Part II poisons. However, in some areas, Part II poison shops operate without a TFDA permit. Also, the responsibility for inspection of DLDBs lies with the TFDA; however, even after planned increases in personnel are taken into account, the financial and human resources available to the board were insufficient for anything other than a limited number of inspections each year. From January 2000 to May 2001, for example, 159 Part II shops were inspected, which represents a small percentage of the shops in operation. Essentially, DLDBs are able to operate outside of the government’s regulatory framework.

The 39 DLDBs surveyed during the 2001 SEAM assessment reported that 32 percent of dispensing staff were nurse/midwives, clinical officers, or pharmaceutical assistants, while also reporting that 18 percent had no medical training. The remaining staff were predominantly nurse assistants (42 percent) or nurse auxiliaries (8 percent). Among those actually interviewed, and who provided this information, 41 percent had a nonmedical background. Therefore, it appears that over 60 percent of DLDB staff, many of whom are nurse assistants or auxiliaries, do not have formal training in drug dispensing. Furthermore, although the 1978 act permits DLDBs to dispense only over-the-counter drugs, 72 percent of those surveyed admitted to dispensing prescription drugs.

DLDBs constitute the largest network of formally licensed outlets for basic essential drugs in Tanzania. DLDBs are found in all districts in the country. However, they are not evenly spread throughout each district and even in rural areas are usually found in population and market centers. Although exact numbers are not available, it is estimated that there are more than 4,600 DLDBs in the country, about one for every 7,400 people. This is more than 80 percent higher than the equivalent figure for all public health facilities (Table 2).

Table 2. Number of Drug Outlets per Capita

Type of Facility	Number of Facilities	Facilities Per Capita
Duka la Dawa Baridi*	4,627	7,343
Public facilities**	2,907	11,687
Voluntary/religious**	772	44,009
Private**	934	36,375
Parastatal**	211	161,017
Other**	31	1,095,957
Private Pharmacies***	333	102,026

* MOH Health Statistics Abstract 1999, Volume I

** Estimate based upon figures from 13 districts visited by SEAM in Feb/Mar 2002 (4.3 million population and 587 DLDBs)

*** TFDA

DLDBs buy the drugs they sell from pharmacy shops, wholesalers, or unofficial supply sources. For those located in or close to a major urban center, finding these sources pose few problems compared with those located in rural areas. The latter group represents a significant proportion of DLDBs, and their operators often have to travel hundreds of miles to purchase stock from TFDA-registered suppliers. Sourcing is made more complicated because it is illegal for DLDBs to buy and sell Part I drugs. All of these factors may contribute to the high cost and uncertain quality of the drugs on sale.

DEFINING THE NEED IN TANZANIA

The 2001 SEAM 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 serving rural areas. The assessment made the following key findings: (1) geographical access to drugs does not appear to be a problem and is not perceived as a problem by the public; (2) availability of drugs is a problem at MSD, especially, but not exclusively, at zonal stores outside of Dar es Salaam Zone; (3) availability issues exist in public sector primary health care facilities and also in many hospitals;³ (4) availability does not seem to be a significant problem at mission health facilities; and (5) with respect to quality of drugs and services, SEAM data from districts surveyed revealed that the public cannot be assured of drug quality for a significant proportion of drugs in the Tanzanian market.⁴

These findings posed major challenges to the MOH, namely to seek ways and means of improving the availability of drugs in the public sector, especially in hospitals and primary health care facilities, and the quality of products and services in the private sector. To address these

³ Districts surveyed included Dar es Salaam-Temeke, Kinondoni, Masasi, Njombe, Karagwe, Kilimanjaro Rural, Tanga Urban, and Dodoma Urban.

⁴ Results obtained from pharmacies and *duka la dawa baridi* in study districts revealed that between 42 percent and 50 percent of drugs lacked TFDA registration or notification. In addition, 21–23 percent of drugs were classified as TFDA-notified drugs and thus quality was unknown.

challenges, SEAM developed strategies that the MOH approved for implementation. The strategies included (1) establishing a network of accredited drug dispensing outlets (ADDOs) in rural and periurban areas of the country to provide an increased range of products similar to those approved for primary health care facilities; (2) establishing a tiered pharmaceutical product quality assurance program; and (3) establishing an alternative, private sector supply system to augment the MSD supply system for the NGO sector, other MSD clients, and possibly rural retail drug outlets by providing quality, competitively priced health commodities.

To address problems of availability, affordability, and quality of drug products and pharmaceutical services in Tanzania, SEAM implemented strategies to—

- Provide a range of high-quality essential medicines and pharmaceutical services at reasonable prices through the creation of the ADDO program, which would be based on converting existing DLDBs. The outlets are made up of independent entities that are not part of a centrally controlled franchise or organization that serves to ensure quality. Instead, quality of both products and services are ensured through a combination of government accreditation (with the threat of losing licenses to sell drugs) and regulation mediated through routine monitoring by district and subdistrict local government and community structures.
- Help improve drug product quality by developing a national quality testing program that uses tiered testing to ensure pharmaceutical product quality and that can also serve as a model for other resource-constrained countries.
- Foster improved access to affordable, high-quality pharmaceutical products for the public and mission health care sectors through the development of a system of alternative pharmaceutical suppliers from the commercial sector that can supplement the supply services provided by the autonomous medical stores department.

The SEAM Program has produced separate reports detailing the activities of the quality assurance program and the alternative distribution program for the mission sector. Those reports can be accessed at www.msh.org/SEAM.

RATIONALE AND OBJECTIVES FOR THE ADDO PROGRAM

Duka la dawa baridi constitute the largest network of licensed outlets for basic essential medicines in Tanzania. They are found in all districts in the country, and their combined inventory turnover value is estimated to be greater than MOH expenditures on essential medicines for primary health care.

For many common medical problems, such as malaria and diarrhea, a variety of factors encourage people to self-diagnose and medicate before visiting a government health facility. These factors include distance to the health facility, seriousness of the illness, drug availability in the public facility, cash availability, and perceptions of privacy and quality of the health care providers, health facilities, and drugs. Since pharmacies are located almost exclusively in major urban areas (60 percent in Dar es Salaam alone), while approximately 75 percent of the

population lives in rural and periurban communities, DLDBs are often the most convenient retail outlet from which to buy drugs. Moreover, with out-of-stock rates of 20 to 30 percent in public primary health care facilities, as seen in the 2001 SEAM assessment, patients often turn to DLDBs to obtain medicines and supplies prescribed by the government health worker. Given the absence of pharmacy services in rural areas and the extreme shortage in poor urban areas, it is evident that DLDBs play an important role in providing access to essential drugs for a significant proportion of the population.

Although DLDBs are important to providing access to essential drugs for a significant proportion of the population, data from the 2001 SEAM country assessment indicated that they are characterized by a number of problems including—

- Authorization to sell only a limited list of medicines, not including basic essential prescription medicines
- Illegal availability of prescription medicines that are prohibited for sale in DLDBs by the TFDA
- Quality of medicines that cannot be assured
- Difficulty in finding reliable and legal sources of medicines and other health care commodities to sell
- Lack of adequate facilities for storing medicines properly
- Dispensing staff that lack basic qualifications and training, and shop owners that lack business skills
- High prices charged to consumers
- Inadequate regulation and supervision

The ADDO program was designed to address each of these problems. The goal of the ADDO program is *to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or periurban areas where there are few or no registered pharmacies.*

In the context of the ADDO program, *affordable* means that the price of medicines and services are within the means of the population that is served, whether that be through direct payment (e.g., cash, in-kind, credit) or through local health financing schemes. *Quality medicines* are those that are registered with the Tanzania Food and Drugs Authority and are therefore subject to national quality assurance programs and regulation. Quality pharmaceutical services are to be provided by certified, trained personnel according to national TFDA standards.

The objectives of the ADDO program are to—

- Improve the *quality of drugs* that people in the pilot region were buying
- Increase the *availability* of those products throughout the region
- Improve the *quality of dispensing services* from both technical and consumer perspectives
- Make drugs and pharmaceutical services *affordable* to people in the region

To achieve the goal and objectives, it was necessary to approach the problems of DLDBs in a systematic fashion. All aspects of the DLDB enterprise—including the physical premises, stock

maintained by the owner, consumer choices, interactions with dispensers, and recommended treatments—had to be improved. In addition, the larger systems in which DLDBs are embedded, which include licensing, supply, training, and inspection that involve ward, district, regional, and national authorities also had to be changed and strengthened.

The new ADDO shops are called *Duka la Dawa Muhimu*—or essential drugs shop.

ADDO STAKEHOLDERS AND PARTNERS AND THEIR ROLES

The complexity of the ADDO intervention required an enormous amount of effort to establish relationships with and garner support from stakeholders at all levels. The degree of SEAM’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.

The table below summarizes the cast of major stakeholders from different health care-related sectors. Also listed are examples of actions and responsibilities that are covered at those levels; however, not all stakeholders are involved in the listed activities. Some stakeholders had no responsibilities beyond support and advocacy of the program concept.

Table 3. ADDO Stakeholders and Their Roles

STAKEHOLDERS	ACTIONS AND RESPONSIBILITIES
National Government Level	
<ul style="list-style-type: none"> • Prime Minister’s Office for Regional and Local Government • Tanzania Food and Drugs Administration (TFDA) (previously Pharmacy Board) • Ministry of Health 	<ul style="list-style-type: none"> • Planning and resource mobilization • Coordination of partnerships • Establish and communicate policies, standards, guidelines • Licensing and accreditation • Inspection and enforcement • Training • Supervision, monitoring, and improvement • Information systems
Regional Government Level	
<p>Appointed, Elected officials</p> <ul style="list-style-type: none"> • Regional Commissioner <p>Sectors</p> <ul style="list-style-type: none"> • Regional Administrative Secretary • Regional Medical Officer • Regional Technical Advisory Committee • Regional Pharmacist 	<ul style="list-style-type: none"> • Planning and budgeting • Inspection and enforcement (appeals process) • Supervision and monitoring • Information systems
District, Ward Government Level	
<p>Appointed, Elected Officials</p> <ul style="list-style-type: none"> • District Commissioner • District Executive Directors • Ward Executive Officers • Ward Counselors • Community Development Officers 	<ul style="list-style-type: none"> • Coordination

STAKEHOLDERS	ACTIONS AND RESPONSIBILITIES
<ul style="list-style-type: none"> • Village Executive Officer <p>Health, Trade Sectors</p> <ul style="list-style-type: none"> • District Drug Technical Advisory Committees • District Health Services Board • District Medical Officer • Council Health Management Team • District Planning Officer, District Trading Officer • TFDA-trained inspectors • Health providers • Pharmacists • Technicians 	<ul style="list-style-type: none"> • Promotion and marketing • Licensing and accreditation • Inspection and enforcement • Training • Supervision • Monitoring and reporting to regional and national levels • Information systems • Referral systems
Private-Sector Level	
<ul style="list-style-type: none"> • Pharmaceutical wholesalers • Health providers • Medicine sellers • NGOs • Professional associations (Pharmacy Society of Tanzania; Medical Society of Tanzania) • Microcredit banks 	<ul style="list-style-type: none"> • Supply medicines and health services • Business practice support • Provide loans
ADDO-Level	
<ul style="list-style-type: none"> • Consumers • Owners of record • Dispensers of record 	<ul style="list-style-type: none"> • Care-seeking and drug purchasing • Investment • Maintenance of standards and ethics • Counseling of consumers • Rationally dispensing medicines

The ADDO program required not only buy-in from numerous stakeholders, but also working partnerships with key organizations described below.

TFDA is the national drug regulatory authority, previously called the Pharmacy Board. It is a legal body directly accountable to the Minister of Health. Its mandate is to ensure that pharmaceutical products conform to acceptable standards of quality, safety and efficacy, and that premises for manufacturing, storing, and distributing drugs and commodities comply with requirements. The TFDA is responsible for all aspects of the program, including policy/procedure setting, development and use of inspection tools, capacity building, data analysis, product testing, and enforcement of the quality assurance standards.

The Mennonite Economic Development Associates (MEDA) is a Canadian-based nonprofit organization that works to address poverty by promoting entrepreneurship and business development through access to microloans, investment, and technological and marketing assistance. As part of the ADDO evaluation process, MEDA assessed the impact on the business support and training on ADDOs' function and sustainability. MEDA's role has consisted of providing business training for ADDO owners; managing a microloan program; and providing regular technical assistance as part of monthly monitoring visits to the ADDO shops.

The Summa Foundation provides financing and technical assistance to the private and commercial health sector in developing countries. As a partner to the SEAM Program, it assessed the financing and business skills training needs of drug shops that might participate in the ADDO program, identified potential partners for MSH in the microfinance and business training industries, and made recommendations to SEAM regarding the provision of grants, loans, and business skills training in order to strengthen the impact of the ADDO program.

The Muhimbili University School of Pharmacy faculty worked with the SEAM Program to develop the curriculum for ADDO dispenser training.

Scanad is a local advertising and promotion agency that served as marketing consultants to the SEAM Program.

HealthScope is a local research company that helped the SEAM Program with data collection, mapping, and recruiting.

In addition, the SEAM Program used a number of expert consultants with a broad range of expertise, including marketing, business, and finance.

CREATING AN ACCREDITED DRUG DISPENSING OUTLET PROGRAM

Conceptual Overview of the ADDO Program

The SEAM Program took a holistic approach that combined changing the behavior and expectations of individuals and groups who use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this was achieved by combining training, incentives, consumer pressure, and regulatory pressure with efforts to affect client demand for and expectations of quality products and services. The ADDO accreditation program was designed to include the following elements—

- Development and enforcement of practice standards and licensing requirements for ADDO shops, endorsed by the TFDA and MOH
- Training program for outlet managers and attendants in appropriate dispensing and stock management
- Enhanced supervision and reporting for performance monitoring and adherence

Figure 2 depicts the components of the ADDO system in Tanzania. The core of the system begins with clients with illness who make decisions to seek care. As mentioned previously, these decisions are based on a number of factors including cultural beliefs about what type of treatment is needed for a particular illness or condition (traditional, spiritual, conventional, etc.),

distance to care providers, drug availability, perceived quality of local care providers, and provider referrals.⁵

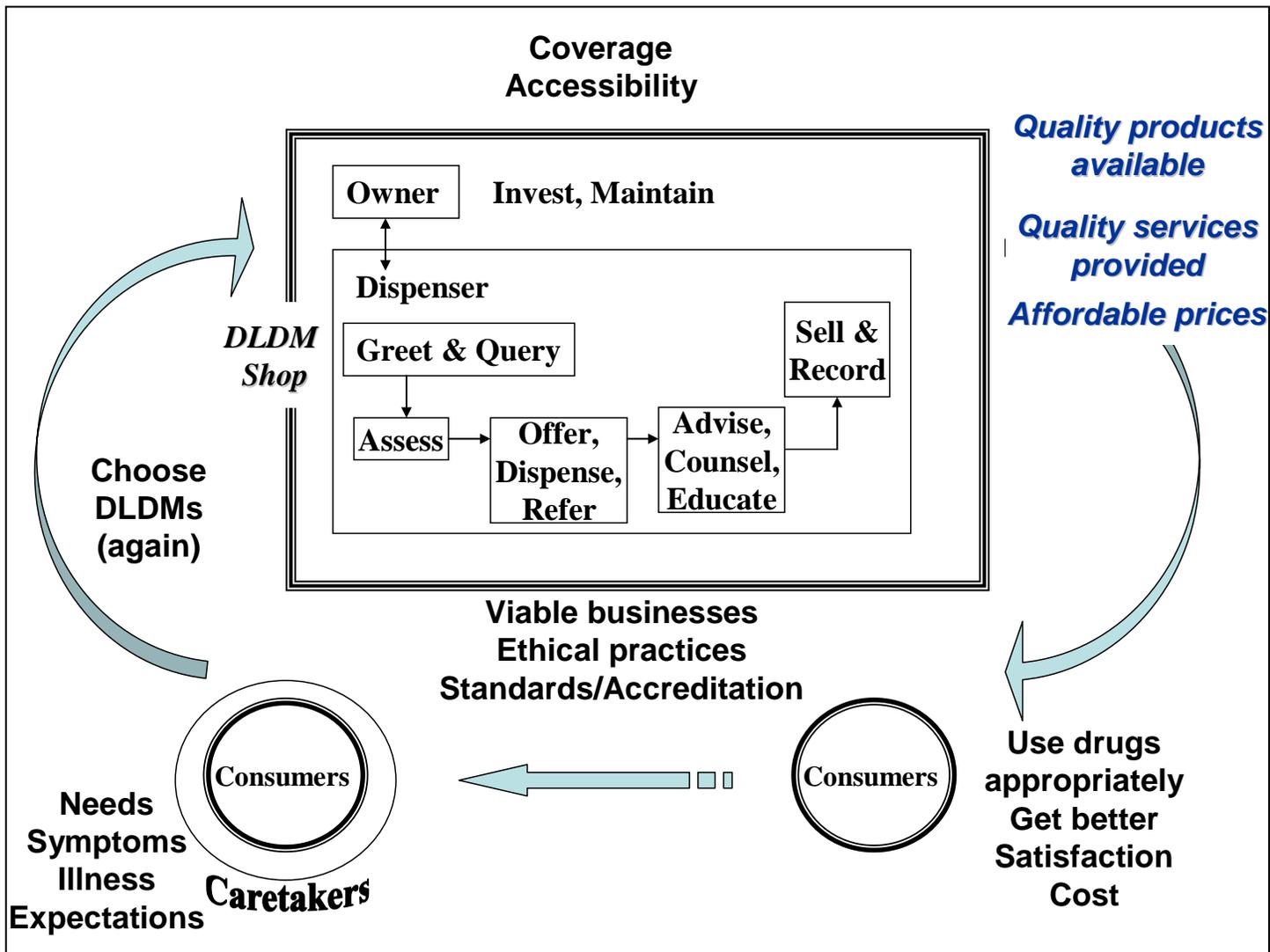


Figure 2. ADD0 System Framework

When consumers choose to go to an ADD0 shop, an interaction with the dispenser begins. The intent is for the dispenser to listen to the client’s request or description of symptoms and advise him or her appropriately. Advice might include recommending and providing a drug or drugs together with appropriate dispensing information, recommending home care if a drug is not warranted, promoting an associated product or service connected to the client’s complaint (such as an insecticide-treated bed net for those with presumptive malaria), or referring to an alternate

⁵ Robles, A., R. M. Shirima, R. T. Kimary, M. Mapunda, D. Masimba, N. H. Mlay, L. M. Mongo, I. Mpingirwa, M. Mushi, and M. Sadalah. 1998. *Community Acceptability of the CHF and Its Potential for Improving the Health Services and Health Situation in Madamigha Village, Singida District, Tanzania*. Dar es Salaam: Ministry of Health;

provider for care beyond the scope of shop services. Dispensers would need to begin with adequate qualification; acquire and maintain the knowledge, skills, and competence needed; and have a client-centered attitude that meets with the ethics and responsibilities of their new role. Training and refresher training of dispensers to upgrade skills will be offered at the outset and options for sustaining it will be explored.

These interactions would occur in the context of an ADDO shop that might also provide other products and services and may be owned by someone other than the dispenser. Owners of shops are business people who need to be willing to invest in raising the standards of drug-related services and products. This requirement identifies what will serve as incentives and potential returns on these investments. Owner's attitudes toward dispensers and clients also have to meet ethical standards of client service.

In light of these needs, mechanisms needed to be found to augment the resources available to the TFDA for routinely inspecting and reporting on the activities of ADDOs and other retail drug outlets. Therefore, a new system of inspection was instituted that is run by the TFDA but engages local government bodies. This system draws upon human and financial resources already available and fits with the major local government reforms that are taking place in Tanzania in which financing and responsibility are being decentralized.

Selection of ADDO Pilot Program Districts

To select districts where ADDOs might be initially established, a committee composed of TFDA personnel and SEAM staff used a set of criteria to prepare a short list of districts where it was felt that cooperation from regional and local government and health officials was expected and where obstacles to successful implementation would be minimized. Pre-selection criteria included—

- *Community health fund activity:* Community health fund activity was considered to be advantageous but not critical to selection. The committee recognized that where the community health fund was established, considerable advocacy and training at regional, district, and community levels had taken place and similar processes necessary for establishment of ADDOs would be easier compared to locales where activity was minimal or not existent.
- *Health sector reform/local government reform:* Formation of district health boards and village/ward health committees was seen as necessary forums for inspection, regulation, and advocacy. Evidence of local officials accepting responsibility for health affairs was also seen as an important factor.
- *Leadership:* While the committee recognized that staff changes could take place, strong leaders in permanent key positions at the regional and district levels were considered very important.
- *Number of Part II shops:* The districts selected would need to have a good number of licensed shops. The target for the first phase of ADDO implementation was to have 50–70 ADDOs operating within two to three districts. Since not all existing DLDB shops were

likely to meet initial application criteria or wish to participate, an estimated 80–100 DLDBs located in the districts were considered minimal.

- *Number of pharmacies:* Since avoiding conflict between ADDOs and pharmacies was essential, the committee looked for very few or no pharmacies located in the test districts.
- *Donor activity:* Districts where donor activity was low or nonexistent would assure leadership attention for the ADDO program.
- *Urban/rural composition:* The districts should reflect populations residing in both urban/periurban and rural areas.
- *Financial consideration:* Per capita income in the districts needed to support revenue requirements for a sustainable ADDO operation.

The following regions/districts were considered: Mbeya—Urban/Rural and Rungwe; Shinyanga—Urban/Rural, Kahama, Bukombe; Nzega; Igunga; Hanang, Singida—Rural and Urban, Iramba and; Ruvuma—Songea Urban and Rural and Mbinga.

After applying the selection criteria to this group of regions/districts and discussing the rationale for final selection with key government stakeholders, the committee recommended Mbeya, Shinyanga, Songea, and Ruvuma for site surveys.

The results of the site surveys were rated using a system where weights were assigned to each selection criterion based upon the following—

- A. Critical: essential for program success
- B. Important: valuable for program success
- C. Helpful: supportive of the program, but not essential to success

In the end, the process of first short-listing districts for site surveys and then applying criteria to the team survey findings resulted in the unanimous recommendation to initiate the ADDO program in Ruvuma region/Songea Urban and Rural and Mbinga districts. During the project, Songea Rural was split into two: Songea Rural and Namtumbo. In addition, Ruvuma also has a region called Tunduru, which was left out of the original plans because it is remote and difficult to reach during the rainy season; however, Tunduru was added at the end of the project because local officials and shop owners were eager to be involved.

Singida was ruled out due to lack of interest from regional/district health leadership. Shinyanga Urban and Rural scored high ratings; however, security issues in the rural districts were so significant that the team visiting this region felt it would not be safe for SEAM personnel to work in the districts. The Mbeya Region was attractive, but the number of pharmacies located in Mbeya Urban would present an obstacle. A final consideration was selecting districts that combined regional town and rural districts. In this way, experience could be gained in different social and economic environments.

To select a control district, the working committee tried to find districts that closely matched the most important features of the Ruvuma region's districts. No urban districts had implemented a community health financing program; however, Singida Urban and Rural with Iramba were

found to be similar to Songea Urban and Rural and Mbinga for most of the important control region features. Singida was recommended as the control region.

Major Program Elements

Program Development

During the preparatory phase of program development, final responsibility for the work rested with the TFDA with SEAM providing technical and financial assistance as appropriate. Local government and other health sector stakeholders, such as the MOH, provided technical and policy contributions as necessary.

SEAM made considerable efforts to build support and promote advocacy for the ADDO program among stakeholders who included DLDB owners, the community at large, local government and district/region health care personnel. The goal was to stimulate interest and acceptance of the system. SEAM held over 20 workshops to brief stakeholders in the Ruvuma region and solicit their views on what aspects should be included in the program (Box 1).

Much of the SEAM outreach effort centered on generating interest among DLDB owners in transforming their shops into ADDOs by engaging them in discussion and incorporating their concerns into the program. Application procedures and selection criteria for new ADDOs were developed by the TFDA with input from community groups, local government, MOH, 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 and whether existing DLDBs would be permitted to operate once ADDOs were in place.

Box 1. Stakeholder Expectations of ADDOs based on 2002 Workshop Discussions

What Stakeholders Agree about ADDOs

- Trained dispensers with identification and uniforms
- Expanded list of medicines
- More blister packaging
- More efficient, cheaper licensing process
- Affordable prices of drugs and services
- Supervision and inspection
- Loans to owners and bonuses to dispensers as incentives to move ADDOs forward
- Dispensers communicating well with clients about drugs and services (polite, thorough)
- Reliable source of drugs nearby
- All groups contributing and working together

Differences in Stakeholder Expectations about ADDOs

- Inspection mechanisms; who will do it and how will it be done?
- Injections and other clinical service provision at ADDOs; will they be allowed?
- Extent and source of incentives; what is the balance between ensuring commitment and providing needed support?

Development and Approval of ADDO Standards for Accreditation

Minimum but enforceable standards were developed and approved to cover the following areas—buildings, drug list, drug quality, personnel, record keeping, and shop location. In developing these standards, care was taken to strike a balance between achieving program objectives and avoiding setting objectives so high or making them so prescriptive that they become unreasonable, thereby deterring DLDB owners from participating in the program.

ADDO owners and dispensers should recognize that ADDOs are providing a valuable health service to their community and that the trust placed in them by members of the community must continue to be earned by ADDOs’ providing quality drugs and services to the greatest extent possible. The code of ethics was incorporated into the daily business practices of owners and sellers.

Box 2. ADDO Program Components for Standards for Accreditation

Component	Process or requirements
Accreditation application process	A District Drug Technical Committee is responsible for a four-part application process for shops: an application form, initial inspection of the existing facility, re-inspection after any structural changes 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 microfinancing for stock purchases, a marketing campaign encouraging consumers to buy ADDO pharmaceuticals, and more reliable sources of affordable, quality wholesale goods.
Building/ infrastructure	The standards provide instructions for building size, layout, identification, dispensing and services areas, storage, and security.
Staff qualifications	The grade levels of ADDO dispensers include nurses, nurse-midwives, clinical officers, assistant medical officers, pharmaceutical assistants, and pharmaceutical technicians. The most common grade of ADDO dispensers prior to ADDO training is nurse assistant.
Drug quality	The ADDO list of approved pharmaceuticals includes a full range of over-the-counter drugs and specific prescription drugs, including common antibiotics and oral contraceptives. ADDOs may sell only those drugs registered with and approved by the TFDA.
Training and continuing education	All dispensers must be accredited by the TFDA, display their accreditation certificate, and have their photo identification on their clothing 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. Continuing education is part of maintaining dispenser certification. ADDO training for shop owners focuses on ethics, regulations, and improvement of business management skills.
Record keeping	ADDOs must record all prescription drugs sold and their selling prices, financial and sales records, customer complaints, and a list of 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 TFDA 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 customers' complaints against ADDOs and other DLDBs and any shops' complaints about harassment by inspectors or other problems.
ADDO-restricted wholesalers	Approved wholesalers can receive a license to sell nonprescription and ADDO-approved prescription drugs under the supervision of a full-time pharmaceutical technician.

Training and Continuing Education

All ADDO dispensing staff had to be accredited through a TFDA-approved dispenser's course developed by the Muhimbili University College of Health Sciences School of Pharmacy and conducted jointly by the TFDA and SEAM. The course provides basic dispenser training on ADDO-approved drugs, common indications and contraindications, common dosages, side effects, patient information, and effective communication skills. Training for owners also provides an understanding of the laws governing dispensing practices, teaches skills in management and record keeping, and discusses pharmacy practice ethics.

The Mennonite Economic Development Associates, which administered the microfinance component of the ADDO program, conducted the business skills and management training.

Recertification is required at intervals through continuing education programs.

Advocacy and Development of Ownership

Incentives were needed if owners of DLDBs and others interested in operating an ADDO were expected to participate in an accreditation scheme. The most powerful incentives are those that stimulate the growth and development of their business. Discussions with groups of DLDB owners suggested that the following would be the key incentives—

- Instituting a broader, legally approved drug list
- Marketing and advocacy
- Linking ADDOs to health financing initiatives such as the community health fund
- Improving access to wholesale suppliers
- Reducing the burden of taxes and license fees

To encourage DLDB owners and others to open ADDOs and maintain required standards, the TDFA and SEAM Tanzania, with help from DLDB owners and other stakeholders, designed an array of incentives to stimulate business growth. The attractiveness of incentives helped stimulate transformation of existing DLDB into commercially successful ADDOs, and in turn, led other DLDB owners to improve their shops in order to compete (Box 3).

Box 3. ADDO Program Owner Incentives

Prescription Drugs

- The approved list includes drugs used in primary health care and a small number of lifesaving drugs.
- It is illegal for any other retail drug outlet, except pharmacies, to sell prescription drugs; therefore, selling prescription drugs gave ADDOs a significant economic advantage over DLDBs.

Prescription Drugs Approved for Sale at ADDOs*

Aminophylline injection	Erythromycin tablets	Nystatin tablets
Amoxicillin capsules	Ethinylestradiol + levonorgestrel	Oxytetracycline hydrochloride eye ointment
Amoxicillin oral suspension	Ethinylestradiol + norethisterone	Phenoxymethyl penicillin suspension
Bendrofluazide	Hydrocortisone ointment/cream 1%	Phenoxymethyl penicillin tablets
Benzylpenicillin powder for injection	Indomethacin capsules	Phenytoin
Co-trimoxazole suspension	Lignocaine injection	Procaine penicillin fortified
Co-trimoxazole tablets	Metronidazole suspension	Promethazine injection
Dextrose 5%	Metronidazole tablets	Propranolol
Diclofenac sodium tablets	Nitrofurantoin tablets	Quinine injection
Doxycycline capsules/tablets	Normal saline injection	Quinine tablets
Ergometrine injection	Nystatin oral suspension	Silver sulfadiazine cream
Erythromycin oral suspension	Nystatin pessaries	Water for injection
	Nystatin skin ointment	

*Approved drugs include primary health care drugs frequently out of stock at public facilities as well as selected lifesaving drugs.

Marketing Campaign

- A well-designed marketing and communications strategy helped motivate shop owners and dispensers as well as local government and community leaders to participate in the ADDO program.
- An effective marketing campaign helped convince consumers to purchase their drugs from ADDO shops.

Skills Training

- Owners received training in business skills and pharmacy practice as well as legal requirements.
- Dispensers received training in pharmacy principles and practice and completed a pharmacy internship.

Microfinance Program

- A loan fund was established by the Summa Foundation, administered by MEDA.
- MEDA administered loans to ADDOs for two years only.
- MEDA created a long-term, sustainable source of credit for drug shops by building relationships with microfinance institutions to cover both rural and urban areas.
- At the end of the two-year period, MEDA will transfer the ADDO owners' accounts to microfinance institutions.
- Tax and licensing fee liabilities were simplified.

Links to Health-Financing Initiatives: community health funds and the National Health Insurance Fund

- Community health funds are attractive potential clients for ADDOs, because they have large cash balances, despite their limited membership. Ideally, community fund district committees would purchase drugs and supplies from ADDO outlets rather than from the government supply organization only.
- Ultimately, the link between community health funds and ADDOs was not made because the fund in Ruvuma was not functioning well. In other places, this relationship could still be beneficial.
- The National Health Insurance Fund requires alternate essential drug suppliers to meet its membership needs and could provide ADDOs with additional clients, but only if improved reimbursement mechanisms are implemented, which proved untenable in Ruvuma.

Regulation and Monitoring

Close regulation and monitoring of the ADDOs is important to ensure that established service and product standards are maintained following accreditation. The approach to regulation for the ADDO program involved making local government responsible for performing routine inspections and reporting on ADDOs and DLDBs in their area of jurisdiction. This work is done in partnership with and on behalf of the TFDA, which retains overall responsibility for regulation. 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.

To guard against abuse of their position, inspectors do not have decision-making powers. Rather, they report to an appropriate local committee, such as the village/ward health committees and ward development committees, who, in turn, were answerable to district bodies. Sanctions are taken against errant ADDOs and DLDBs. Local, district, and national authorities take appropriate action and levy penalties in accordance with regulations to be promulgated by the TFDA. The regulatory system has an appeals procedure to allow owners to seek redress against overly severe or otherwise unusual punishments.

Box 4. ADDO Operations Monitoring and Reporting Structure

- ADDO inspectors report to ward authorities.
- Ward authorities report to District Drug Technical Advisory Committee (DDTAC).
- DDTAC decides on what actions, if any, are needed based on each report.
- DDTAC provides summary reports quarterly to TFDA with copies to regional authority.
- DDTAC requests TFDA assistance to deal with serious breaches of law and regulations.
- All ADDO owners have right of appeal to regional authority and TFDA.

Marketing and Promotion

For the ADDO program to succeed, an effective communications and marketing strategy must convince consumers, shop owners and dispensers, local government, and community leaders to participate in the program in their respective capacities. SEAM conducted formative research for a behavior change communication strategy using focus group discussions. Box 5 contains a summary of the behavior change communication research results.

Box 5. Use of Formative Research to Develop Behavior Change Communications

Duka la dawa baridi are formally licensed businesses that are intended to sell drugs and other commercial products. The challenge is to change the behavior of consumers, shop owners and dispensers, local government and community leaders so that quality drugs and services are delivered—without having direct organizational control over stakeholders. To transform DLDBs into ADDOs, a marketing approach was used to change the behavior of target groups through communications, training, and support. The goal of the baseline studies was to understand—

- **The behaviors and preferences of consumers or clients, shop owners, dispensers, local government and community leaders regarding DLDB services.**

- **Consumer, owner, dispenser, and leader opinions and recommendations for how the ADDO program should function.**

The qualitative study of behaviors was conducted from April to June 2002 and covered the three intervention districts of Songea Urban, Songea Rural, and Mbinga. During this study, qualitative data were collected by conducting focus group discussions and in-depth interviews. Focus group discussions were conducted with consumers, *duka la dawa baridi* owners, dispensers, and community leaders, and in-depth interviews were conducted with key governmental informants. A total of 28 focus groups were conducted in the districts and a total of 15 interviews were conducted in the districts and at regional level.

The results indicated almost unanimous concern about the quality and origin of drugs sold by the DLDBs. All stakeholders wanted trained dispensers who could provide quality medications at reasonable prices. However, the owners preferred very limited government regulation.

SEAM sponsored formal and informal discussions and consultations to foster broad support for the ADDO program's elements as well as ownership and partnership in the change process. Based on the the research and discussions, the final ADDO components balanced program objectives with measures to encourage DLDB owners' participation.

Based on the results of this research, SEAM contracted with a social marketing expert who led the development of a marketing and advocacy plan. As part of the marketing plan, SEAM contracted with a professional advertising firm to develop logo and radio spots, help with name selection, and billboard creation, all centered on the theme of *Trust*. (See Box 6.)

Box 6. ADDO Marketing and Promotion Activities

Radio spots

- 5,475 in 2004, about 1,800 in 2003
- One branded, one generic—changed once since campaign started in August 2003
- Broadcast on Radio Songea and Radio Maria
- Reduced to 36 spots per month on Radio Songea for 2005 (funding constraints)
- Themes included “Take Timely Action,” “Take the Full Dose,” “Quality Medicines from Duka la Dawa Muhimu,” and “Quality Dispensing from *Duka la Dawa Muhimu*”
- *Radio spots were the most powerful means of marketing and promotion.*

Newspaper ads

- Until December 2004, 24 half-page ads placed each month
- Three different ads
- Placed in two newspapers
- Reduced to one half-page per month in one paper for 2005
- *Newspaper ads had a limited impact.*

Billboards

- 25 billboards height two meters by width of three meters.
- 2 billboards height three meters by width of six meters.
- *Billboards were a successful means of advertising.*

Launches

- One for each district (except Namtumbo and Songea Rural done as one)
- Speeches, advocacy by senior political and government leaders

- Theater and music by well known, popular theater group—on day of launch and then touring around district for several days after

Evaluation

The ADDO program works to improve access to affordable, quality medicines and pharmaceutical services, and therefore, it was necessary to define parameters for evaluating the results and outcomes in terms of access. To this end, baseline and endline evaluations were conducted to assess the various factors that influence access to medicines.

The main access gaps immediately addressed by the ADDO program and reviewed in the course of the evaluation were the **quality of services and products** and **availability of essential medicines**. In addition, the program addressed the **appropriateness of dispensing** important products provided by the ADDOs. Consumer and ADDO owner **acceptability/satisfaction** were reviewed to ascertain customer acceptance of the new approach and to identify reasons for conversion to the ADDO system among owners. In the absence of any mechanism to discourage increased prices charged to patients, stakeholders thought it might be possible that ADDOs would negatively impact **affordability**, although competition, financing for working capital, and improved, locally based, wholesaling services were expected to mitigate any such effect.

ADDO PROGRAM ACTIVITIES AND TOOLS

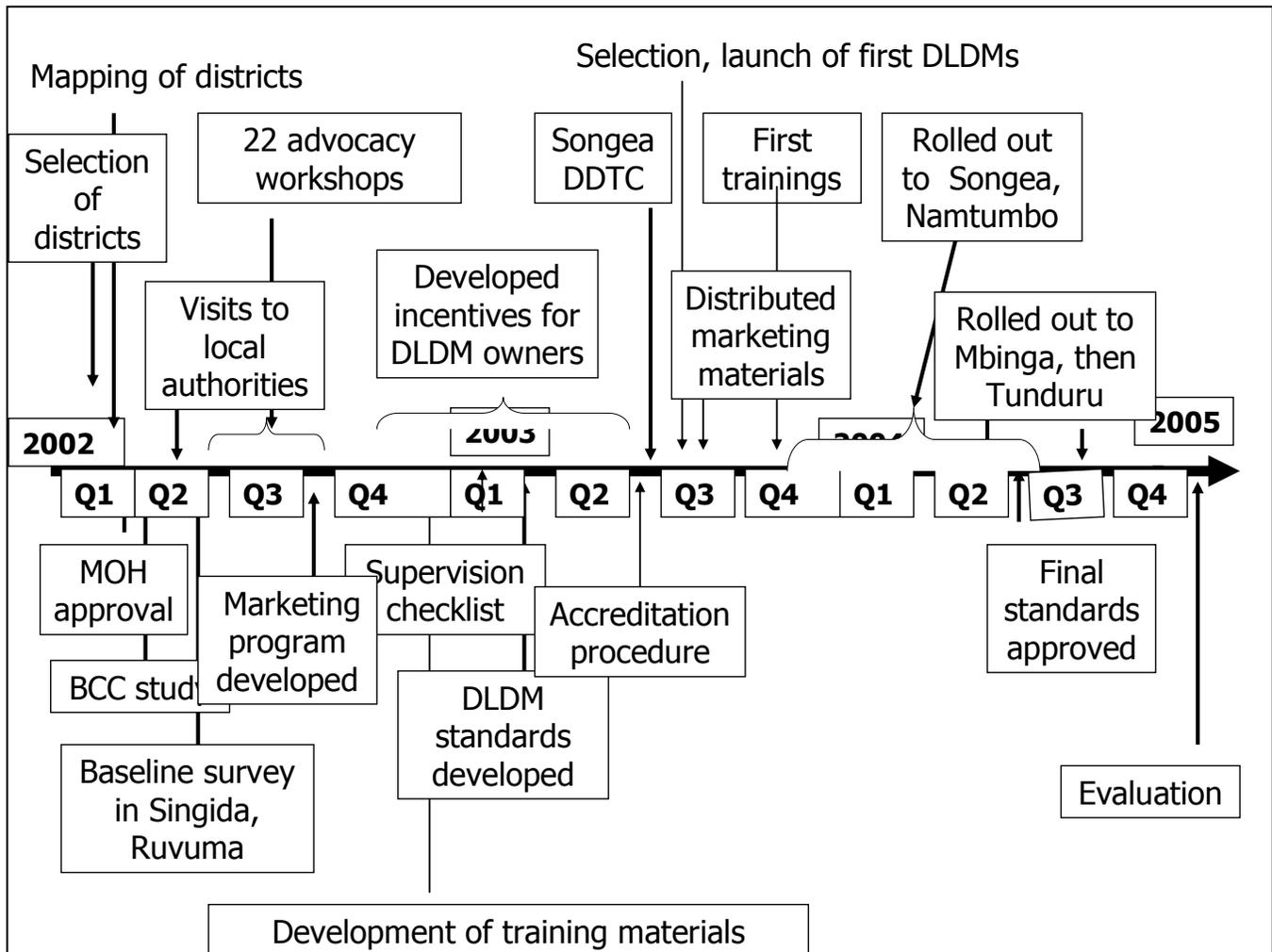


Figure 3. Timeline of major activities in creating ADDO program.

ACTIVITIES	TOOLS/ RESOURCES
Program Development	
Completed data collection and options analysis for the Tanzanian pharmaceutical sector for creation of an accreditation/regulation model for private sector drug sellers	<ul style="list-style-type: none"> • SEAM 2001 Assessment Data Collection Forms (zip file) • SEAM 2001 Assessment Interview Guides (zip file) Materials used to complete the pharmaceutical sector analysis. • Access to Essential Medicines, Tanzania, 2001 (2003). Final assessment report of the Tanzanian pharmaceutical sector and options analysis.
Reviewed drug shop work done elsewhere in Africa to glean lessons learned and inform the ADDO design process. This included work in Kenya, Uganda, and Nigeria, as well as hospital accreditation experience in South Africa and Zambia.	
Based on SEAM’s program design, discussed a new category of accredited private drug-dispensing outlets with the Tanzanian government, which gave approval for initiating the ADDO program.	Initial ADDO project description (2002) This later changed as the project evolved.
Agreed to a formal memorandum of understanding (MOU) between MOH and SEAM for all aspects of the country program	Memorandum of understanding (2002)
<p>Developed and used a formal method for selecting intervention and control districts for the ADDO program—</p> <ul style="list-style-type: none"> • Initially selected 10–12 potential districts • Gathered preliminary details on each district and region • Made preliminary visits to districts • Evaluated information and selected districts (Songea Urban and Rural, Namtumbo, and Mbinga) • MOH approved district selection 	<ul style="list-style-type: none"> • ADDO District Selection Criteria (2002) Description of the evaluation process used to choose the ADDO pilot district. • District Selection Comparison Tables (2002) Comparison of each district by selection criteria. • District Selection Evaluation Table (2002)[Excel] Ratings of each district based on selection criteria. • ADDO District—Short Listing Decisions (2002) Summary of final candidates for the ADDO pilot.

ACTIVITIES	TOOLS/ RESOURCES
<p>Developed ADDO selection criteria and application process for DLDBs to transform their shops into ADDOs, completed a survey of more than 50 DLDB in the first implementation district, and selected the first 23 shops eligible to join the ADDO program. ADDO accreditation is based upon meeting all ADDO regulations pertaining to premises and certification by the TFDA.</p>	<p>ADDO Selection Workshop Report (2003) A brief summary of a workshop with 50 DLDB owners to present the requirements for converting into ADDOs.</p>
<p>Met with Ministry of Health regional and local government officials regarding the initiation of the ADDO program in Ruvuma region.</p>	
<p>Held discussions with a number of wholesalers to explain the ADDO program and encourage them to provide a wholesaling service to the new ADDOs in Ruvuma Region. Three companies expressed a serious interest—two by opening outlets in or close to Songea, the regional capital.</p>	
<p>Traveled to Ruvuma to map locations of DLDBs in region and collect information.</p>	<ul style="list-style-type: none"> • Questionnaire/Mapping Tool for Local Officials (revised 2006) (English and Swahili) (Annex 1 of ADDO Implementation Manual) • Questionnaire/Mapping Tool for DLDB Owners (revised 2006) (English and Swahili) (Annex 2 of ADDO Implementation Manual) <p>These two forms and interview guides are used to collect information on existing DLDBs in preparation for introducing ADDOs.</p> <ul style="list-style-type: none"> • Ruvuma Mapping Report (2003) Summary of the original mapping exercise in Ruvuma districts comprising interviews with local officials.
<p>First set of DLDBs enter applications to become ADDOs; first shops selected for training and accreditation.</p>	<ul style="list-style-type: none"> • ADDO Implementation Manual (revised 2007) • TFDA standard criteria for ADDO premises (revised 2007) (Swahili) • ADDO establishment application permit (revised 2007) (Swahili)

ACTIVITIES	TOOLS/ RESOURCES
	<p>TFDA document that DLDB owners or new ADDO owners must fill out to apply for a permit to do business.</p> <ul style="list-style-type: none"> • Post application questionnaire for DLDB dispenser (English and Swahili) Questionnaire to confirm information that the DLDB owner gave in the ADDO application on the qualifications of dispensers.
<p>Officially implemented ADDO program in the Ruvuma region, with launches in Songea Urban, Songea Rural, Namtumbo, and Mbinga.</p>	<p>ADDO launch slideshow [link to SEAM website] http://www.msh.org/seam/country_programs/3.1.4b.htm</p>
<p>Development and Approval of ADDO Standards</p>	
<p>Researched the labor market in the region to set the education standard necessary for ADDO dispenser training. The most available level of worker was the Nurse Assistant, so in keeping in line with the reality of the local labor market, the standard for entry level personnel was Nurse Assistant.</p>	<p>Ruvuma Mapping Report (2003) Summary of the original mapping exercise in Ruvuma districts comprising interviews with local officials.</p>
<p>Drafted inspection protocols and procedures.</p>	<p>ADDO Implementation Manual (revised 2007) Annexes of the manual contain inspection procedures and forms in English and Swahili, including premises inspection standards , routine inspection checklist,</p>
<p>Held two-day retreat held in Dar es Salaam to discuss program design and draft standards—participating were district commissioners, TFDA officials, the regional medical officer, district medical officers, the regional pharmacist, and staff from SEAM. Draft standards circulated for comment to TFDA technical committees.</p>	
<p>Reviewed and revised draft standards; approved by TFDA technical committees. The TFDA approved standards for ADDO facilities, including inspection and sanctions, personnel requirements, training and continuing education, formulary development and use, drug quality, record keeping, code of business ethics, dispensing practice, reference materials, and wholesalers. TFDA approval was the final step before the standards were approved by the Ministry of Health and signed into law.</p>	

ACTIVITIES	TOOLS/ RESOURCES
<p>The TFDA had clauses placed in the Tanzania Food and Drug Bill, as it passed through Parliament, that empower the Tanzania Food and Drugs Authority to establish ADDOs and the regulations governing them. The Minister of Health approved and signed into law legally enforceable standards and a code of ethics. The ADDO standards and code of ethics were developed with the active involvement of all stakeholders, who were sought out and included through a comprehensive, wide-ranging consultative process. Altogether, nearly 400 people participated, including regional and district medical officers, members of parliament, councilors, and owners of DLDB.</p>	<ul style="list-style-type: none"> • Standards for Accredited Drug Dispensing Outlets and Code of Ethics, Tanzania Regulations (2003) A copy of the actual government regulation. • TFDA Standard for Establishment of ADDOs (2003) (Swahili) A brief list of requirements needed to become an ADDO.
Training, Supervision, and Continuing Education	
<p>Established and obtained TFDA approval for ADDO standards for training and continuing education (continuing education is an area that needs to be addressed in the program roll out).</p>	
<p>The Muhimbili School of Pharmacy, with guidance from the TFDA and SEAM, drafted an ADDO dispenser and shop owner curriculum, together with dispenser and owner training materials and a teacher facilitator manual. Personnel possessing the minimum requirement of nurse assistant or above are required to complete a four-week TFDA-approved training course. Trainee competency and training effectiveness are evaluated at the end of the course; those who pass are awarded a TFDA ADDO Dispensing Certificate. An ADDO dispensers' reference manual is distributed to students who complete training successfully.</p>	<ul style="list-style-type: none"> • ADDO Facilitation Training Guide (revised 2007) (English and Swahili) • ADDO Dispensers Training Manual (revised 2007) (English and Swahili)
<p>TFDA developed training program and curricula for ward inspectors and District Drug Training Committees</p>	<ul style="list-style-type: none"> • Training materials for inspectors (revised 2007) (Swahili) • Presentation slides for inspector training (revised 2007) (medicine control, ADDO establishment criteria, ADDO application procedures, ADDO operations procedures, ADDO inspection procedures) (Swahili)

ACTIVITIES	TOOLS/ RESOURCES
TFDA developed and implemented a certification process for dispensers and inspectors.	
Solicited local expertise to develop a three-day communications skills training module as part of the dispensers' course. The course was modified later in the program based on experience.	Communications Skills Training for ADDO Dispensers (2003) (now part of the revised dispenser training manual)
Developed useful job aids (in Kiswahili) to assist with dispenser supervision.	
MEDA conducted a training needs assessment, then developed and provided a three-day business skills training session for ADDO owners. Training covers basic bookkeeping and financial management, inventory control, record-keeping, and marketing. Attendance at the course is a requirement for all ADDO owners and is also necessary to access the microloans.	<ul style="list-style-type: none"> • MEDA Training Needs Assessment (2003) A report that details the types of business skills that ADDO owners need to learn as part of a training course. • Basic Business Management Course Manual (2004)
Developed supervision strategy, tools, and training; pharmacy professionals supportively supervised dispensers and owners in four districts	<ul style="list-style-type: none"> • ADDO Supervision Checklist (revised 2007) (Swahili)
Advocacy and Development of Ownership	
Summa Foundation assessed the financing and business skills training needs of drug shops that may participate in the ADDO program and identified potential partners in the microfinance and business training industries.	Summa Financing and Business Skills Assessment (2003)
Held three workshops to brief regional and district officials and promote advocacy for the program; held 20 workshops with stakeholders in Ruvuma region to develop advocacy and support for the ADDO concept and solicit views on what standards should be included in the ADDO program.	Sensitization seminar slides (revised 2007) (Swahili) <ul style="list-style-type: none"> • Overview of DLDB • Pharmacy Sector Survey • ADDO Pilot Project • ADDO Program System Framework • Standards and Code of Ethics for ADDO
Developed interest among DLDB owners in transforming their shops into ADDOs by engaging them in discussion and incorporating their concerns into the program. Addressed	

ACTIVITIES	TOOLS/ RESOURCES
their business requirements as part of the core of the program, including loans, regulation of prescription medicines, and taxes.	
Conducted a selection workshop where all interested shop owners were walked through the accreditation process and given assistance to complete the application forms.	
Conducted a study to examine the justification and feasibility of modifying taxes and licensing fees in order to encourage DLDB owners to convert their shops to ADDOs. Due to difficulties with tax authorities, the attempt to rationalize taxes was ultimately unsuccessful.	Tax and Fee Reduction Feasibility Study (2003)
Commissioned a study to evaluate whether a relationship between ADDOs and the National Health Insurance Fund and/or community health fund was feasible. Recommendations stemming from the study results were approved by the TFDA and regional and local governments; however, problems with creating a reimbursement mechanism prevented the collaboration from advancing. Held one-day workshop to discuss report.	ADDO and National Health Insurance Fund. Community Health Fund Linkage Report (2003) Analysis conducted by Muhimbili University College of Health Sciences.
Summa Foundation and SEAM approved a program to make small to medium-size loans available for ADDO owners, mainly for working capital; Summa provided the loan finance, which MEDA administered. SEAM paid the costs of MEDA administration for two years, then MEDA transferred the ADDO portfolio (36 of 41 loans) to the Tanzanian National Microfinance Bank.	ADDO Loan Fund and Monitoring Proposal (2003) MEDA prepared the proposal describing how they would administer and monitor the microfinance loans for ADDO owners.
The owners of each of the 23 shops made investments from their own resources (several hundred dollars) to upgrade premises to meet required ADDO standards. Not only were significant improvements made to a number of shops, many in poorly served parts of Songea town, but also the owners were imbued with a sense of pride and ownership.	
Assisted a group of more than 20 DLDB shop owners in establishing a shop-owners' association. Provided technical assistance and advice on the role of the group,	

ACTIVITIES	TOOLS/ RESOURCES
development of a constitution, and establishing the association as a legal entity. Ultimately, the association did not play a role in the ADDO program.	
Regulation and Monitoring	
Developed terms of reference and proposal for accreditation and licensing procedures. Approved by TFDA and Minister of Health.	
Established and communicated procedures for personnel, formulary, quality, record keeping, location, and buildings.	<ul style="list-style-type: none"> • Drug Register (Swahili) • Expired Drug Form ER • Patient Complaint/Adverse Drug Reaction Form ER
An important change in the regulations was giving ADDOs permission to sell some prescription drugs at TFDA’s discretion to make it easier to fill gaps in public sector availability. The expanded drug list for ADDOs includes some prescription and basic lifesaving drugs based on what is approved for primary health care facilities in the public sector.	See Box 5
Recognizing that the central authority does not have the resources to adequately police the thousands of drug shops in the country, the TFDA agreed to deputize local government officials at district and subdistrict levels to carry out carefully designed inspection activities (ward inspectors and district drug technical committees). This action indicates the TFDA’s willingness to adopt innovative measures to overcome constraints by using available resources.	
Developed and implemented local inspector training program in the Ruvuma region; local government inspectors take a short TFDA course covering the basic inspection responsibilities.	<ul style="list-style-type: none"> • Training materials for inspectors (revised 2007) (Swahili) • Presentation slides for inspector training (revised 2007) (medicine control, ADDO establishment criteria, ADDO application procedures, ADDO operations procedures, ADDO inspection procedures) (Swahili)

ACTIVITIES	TOOLS/ RESOURCES
<p>Arranged to have MEDA monitor, evaluate, and report on the business performance of the ADDOs in Mbinga as part of its contract with SEAM. MEDA collected baseline data in Mbinga in April 2004 and did a follow-up assessment in January 2005.</p>	<ul style="list-style-type: none"> • Mbinga ADDO Business Assessment Tool (2004) • Mbinga Baseline Assessment Report Summary (April 2004) • Mbinga Follow-Up Assessment Report (January 2005)
<p>Designed and conducted drug register analysis to monitor dispensing activities at ADDO shops, which included data from September 2003–June 2004. The assessment provided evidence of how the ADDO shops were doing in treating of illnesses of major public health concern.</p>	<p>ADDO Drug Registry Study (2005)</p>
<p>TFDA assessed the ADDO regulatory activities in Ruvuma.</p>	<p>ADDO Survey Report Songea (2005)</p>
ACTIVITIES	TOOLS/ RESOURCES
Marketing and Promotion	
<p>Conducted formative research for behavior change communication strategy development using focus group discussions—</p> <ul style="list-style-type: none"> • Defined audiences and desired behaviors • Prepared and tested materials for 28 focus group discussions with consumers, DLDB owners and dispensers, and community leaders • Conducted three focus group discussions in intervention districts • Conducted 15 in-depth interviews with key government informants • Analyzed and reported findings • Met to discuss findings 	<p>See Box 6 for a summary</p> <p>Behavior Change Communication Strategy for ADDOs (2003)</p>
<p>Contracted with a social marketing expert who provided technical leadership and developed a marketing plan including advising on selecting and advertising agency and a billboard company. The strategy was based on the results of the formative behavior change research.</p>	<p>ADDO Marketing Plan (2003)</p>

ACTIVITIES	TOOLS/ RESOURCES
Contracted with a professional advertising firm to develop logo and radio spots, help with name selection, and billboard creation, all centered on the theme of <i>Trust</i> .	<ul style="list-style-type: none"> • Lowes Scanad Contract with SEAM Program (2003) • Text for four radio spots (Swahili and English)
Conducted focus group discussions to evaluate the ADDO brand/logo and radio scripts, with subsequent TFDA approval of the brand name <i>Duka la Dawa Muhimu</i> (loosely translated as “Essential Drugs Store”), the logo, and radio scripts. Consumer opinion drove the final decision on the name and logo.	ADDO Focus Group Discussion Guides (2002) <ul style="list-style-type: none"> • Community Leaders • Owners • Consumers • Sellers
TFDA formally approved all ADDO marketing campaign material before implementation.	
ACTIVITIES	TOOLS/ RESOURCES
Evaluation	
Developed and documented ADDO program evaluation process and plan.	<ul style="list-style-type: none"> • SEAM Evaluation Process (2005) • SEAM Evaluation Plan (2005) Both documents cover the evaluation process and plans for all SEAM Program activities, not just ADDOs.
Developed and tested evaluation tools <ul style="list-style-type: none"> ○ Simulated client visit for childhood malaria ○ Background ○ Drug management ○ Training ○ Drug availability and price ○ Registration status of products sold <ul style="list-style-type: none"> • Quiz 	ADDO Data Collection Forms (revised 2004)
Conducted baseline and endline evaluation of DLDBs in the pilot (Ruvuma) and control (Singida) regions to measure aspects of drug availability, affordability, and pharmaceutical services <ul style="list-style-type: none"> • Baseline evaluation conducted in March 2003 	<ul style="list-style-type: none"> • Data QA and and Analysis Process (2005) Describes the data collection, analysis, and quality assurance process for the baseline and endline data, including problems encountered.

ACTIVITIES	TOOLS/ RESOURCES
<ul style="list-style-type: none"> • Endline evaluation conducted in November 2004 	<ul style="list-style-type: none"> • ADDO Evaluation Training Presentation (2004) PowerPoint presentation for data collectors' training. Evaluation results follow in this report.
<p>Completed participatory analysis and forward planning</p> <ul style="list-style-type: none"> • Local stakeholder workshops held in January and February 2005 to review evaluation findings, discuss implications, and prepare next steps. 	<ul style="list-style-type: none"> • Stakeholder Evaluation Interview Notes (2005) Summary of interviews with ADDO stakeholders regarding their perceptions of the ADDO program. • ADDO Project Evaluation Workshop Handout (2005) Draft evaluation results and workshop materials handed out to workshop participants in advance. • ADDO Project Evaluation Workshop Summary Notes (2005) A summary report of the workshop proceedings.

ADDO PROGRAM EVALUATION

Evaluation Methodology

Each analysis was conducted using data from a sample of facilities in intervention and control groups.

Intervention Group: The ADDO model was introduced in three districts that were identified as having met prerequisite criteria for readiness in the Ruvuma region (Songea Urban, Songea Rural and Namtumbo districts). At the start of the program, 127 DLDBs were operating in the Ruvuma region. As of August 2005, approximately 151 ADDOs had opened or converted from DLDBs to ADDOs. At the time of the endline survey, only 16 DLDBS in Ruvuma remained. Five of these were visited and data were gathered for the endline study. Because of the small sample size, the data from these five facilities are not included in the analysis presented in this report.

Control Group: Singida region DLDBs were selected as the control group. The population⁶ of Singida was 1,134,578 with 193 known DLDBs in 2003. At baseline, 76 DLDBs in Singida were visited and 70 visited in Ruvuma. At endline, the performance of a sample of 50 ADDOs in the Ruvuma region was compared with 60 DLDBs in comparable districts in Singida region. The comparison groups and sample sizes are summarized in Table 4 below.

Table 4. Comparison Groups and Sample Sizes

Regions	Baseline Districts	Baseline Sample	Endline Districts	Endline Sample
Ruvuma	Songea Urban	70 randomly selected DLDBs	Songea Urban	50 selected randomly out of 69 DLDBs
	Songea Rural* Mbinga		Songea Rural Namtumbo* Mbinga	
Singida	Iramba	76 randomly selected DLDBs	Iramba	60 randomly selected DLDBs
	Manyoni		Manyoni	
	Singida Rural		Singida Rural	
	Singida Urban		Singida Urban	

*Just prior to baseline surveys Songea Rural was divided to generate Namtumbo. For the purposes of the baseline survey, it was treated as one district. As project implementation and the endline evaluation proceeded, they were treated as two districts.

There were broad similarities between the two regions at the time of the assessments. Both have a mean household size of five and a predominantly rural population (85 percent Ruvuma and 90 percent Singida). Rural households have virtually no electrical supply (1 and 3 percent), predominantly use firewood for fuel (87 and 82 percent), and have poor access to protected water sources (53 percent and 61 percent). Twenty-seven percent and 28 percent of households are below the food poverty line and 41 and 55 percent are below the basic needs poverty line.

However, there were some differences as well: Ruvuma is a little better educated with 15 percent with no schooling at all (vs. 27 percent in Singida) and 84 percent adult literacy (vs. 71 percent

⁶ The demographic data comes from the MOH 1999 Health Statistics (Dar es Salaam, Tanzania MOH 2000)

in Singida). More households sell cash crops (56 percent vs. 6 percent) and the median household income is TSH 7,800 as opposed to TSH 4,258 in Singida.⁷

Sample Selection

At baseline, all 144 known DLDBs in Ruvuma were listed and mapped. This list was compiled by the local SEAM staff asking divisional secretaries and ward district and health officers to send in a list of current shops. This data was more up to date in Singida than Ruvuma. Eighty shops from each region were systematically and randomly selected from these lists.

At endline, a list of the 69 ADDOs in Ruvuma in operation from August 2003 to January 2004 was prepared and divided by district. A total of 50 shops were randomly selected. A similar process was followed in Singida to select 60 DLDBs from the 143 in operation.

Data Collection Process

Baseline

The ADDO evaluation process began with a baseline evaluation that covered a key set of indicators and gathered information used for project planning. SEAM Program staff developed the indicators and relevant survey instruments based on those used in the SEAM 2001 country-wide assessment. A local contractor was hired to manage the data collection process, and data collectors were trained March 5–7, 2003. Following training, data collectors were sent to the field to collect data in Ruvuma and Singida. The baseline evaluation included the following seven data collection instruments—

- Simulated client visit for childhood malaria
- Background
- Drug management
- Training
- Drug availability and price
- Registration status of products sold
- Quiz

Following data collection, the data collection firm performed data entry in Tanzania and SEAM staff analyzed the data. SEAM staff prepared a baseline summary report in June 2003.

Endline

To follow up on the baseline evaluation and to assess the impact of the ADDO intervention, an endline evaluation was planned in 2004. The endline evaluation incorporated many of the indicators collected in the baseline assessment. Some additional areas of study were assessed in the endline study (indicators and data collection tools are discussed in more detail below). Some of the survey tools applied at baseline were not applied at endline because they were intended to

⁷ National Bureau of Statistics Tanzania. 2002. *Household Budget Survey 200/01*. Dar es Salaam, Tanzania: National Bureau of Statistic Tanzania, pp. 78-79.

inform program design instead of the evaluation. The endline study included the following five areas of study—

- Stock availability and price
- Client exit interview (to assess satisfaction)
- Malaria simulated client
- Upper respiratory infection simulated client
- Product registration status survey

The endline data collection and analysis required a set of preparatory and participatory activities, which are summarized below—

- Reviewed documents and reports from the project
- Conducted site visits to ADDOs and *Duka la dawa baridi*
- Reviewed performance monitoring data studied by SEAM
- Conducted in-depth interviews of key actors in Ruvuma and Dar es Salaam
- Developed evaluation tools

Endline Data Collector Training

A local contractor, HealthScope, managed the data collection process. Data collector training and tool testing was held October 27–29, 2004 in Dar es Salaam in collaboration with the local data collection coordinators. The objectives of the training were to—

- Build capacity to collect data accurately
- Provide hands-on practice in filling out the forms
- Ensure consistency in data collection by giving everybody the same instructions and information
- Assign roles and responsibilities of each team member

Endline Data Collection

Data were collected from October 28 to November 19, 2004. This included two visits to each site. The first visit was intended to collect data on all forms and to conduct the malaria simulated client scenario. Two weeks later the shops were visited again to conduct the upper respiratory tract infection (URTI) simulated client scenario only, plus any outstanding client exit interviews. During field activities, regular scheduled calls were held with teams to review issues and provide updates.

Endline Data Entry

Databases and database instructions were prepared to facilitate data entry. Data were entered into prepared Access databases by HealthScope in November and December 2004. The databases and copies of the original data collection forms were provided to SEAM staff in December 2005. Baseline databases were also reviewed at that time by SEAM staff.

Endline Data Entry Quality Assurance

A quality assurance process was implemented to check the quality of data entry and to identify any missing or questionable data. All entries were checked against the original data collection

forms. All queries were sent to SEAM/Tanzania and HealthScope. In addition, the baseline databases were checked for any data quality questions, but the original baseline data collection forms were unavailable for double-checking of data entry.

Endline Data Analysis

SEAM staff analyzed data in December and January 2005 using Access and Excel database tools. In most cases, data were exported from Access into Excel, coded as appropriate, and pivot tables were run to calculate indicators. All baseline indicator data were reanalyzed at the time of the endline to ensure consistency of calculation. Tables and graphs were prepared and disseminated for review in Word format.

Evaluation Data Collection Tools

A number of data collection techniques were used to conduct the final assessment of the ADDO program. They are summarized below.

Survey Type	Baseline?	Endline?	Tool Description
<i>Simulated Client</i>			
Malaria Simulated Client	Yes	Yes	<p>Data collectors conducted the malaria simulation at the start of their first visit to the shop. In both scenarios, data collectors were instructed to conduct the scenario, purchase the recommended products (up to a predetermined price limit), and leave the premises before noting their observations on the forms.</p> <p>For malaria, the simulated client case was based on the National Guidelines for malaria diagnosis and treatment in Tanzanian 2000 for Level I health care delivery. The data collector plays the role of a parent/relative of a six-year-old child with classic symptoms of uncomplicated malaria. Specifically, a six-year-old girl who has had a fever on and off for a week. The ideal scenario would be for the shop keeper to ask the client questions about the symptoms and medication history. On the basis of this, the attendant may refer the parent to a health care professional or may recommend SP in doses appropriate for a six-year-old child. No antibiotics or injections of any kind are indicated.</p>
Upper Respiratory Tract Infection (URTI) Simulated Client	No	Yes	<p>To avoid conducting two scenarios on the same date, the second scenario for URTI was conducted a couple of weeks later during a second visit to each facility. At that time, only the URTI simulated client scenario was carried out, though in some cases additional client exit interviews were gathered if needed.</p> <p>Data collectors were instructed to conduct the scenario, purchase the recommended products (up to</p>

Survey Type	Baseline?	Endline?	Tool Description
			<p>a predetermined price limit), and leave the premises before noting their observations on the forms.</p> <p>For URTI, the simulated client plays the role of a parent of a child with symptoms of URTI. Specifically the child has had a cough and a runny nose for two days. She has not slept well throughout the night. The ideal scenario would be for the shop keeper to ask the client questions about the symptoms and medication history. On the basis of this, the attendant may refer the client to a health care professional or may recommend a medicine in doses appropriate for the age and symptoms of the child. No antibiotics or injections of any kind are indicated to be sold.</p> <p>While there was no baseline survey data, the original SEAM Tanzania country assessment included a URTI simulated client that visited 33 <i>duka la dawa baridi</i> around the country (not just in Ruvuma and Singida).</p>
<p>Inspection/Observation Drug Availability and Price Survey</p>	Yes	Yes	<p>A tracer list of 20 key drugs (Annex 2) was used to check the status of availability and price. The same tracer list was applied in the baseline and endline. Data collectors introduced themselves to shop attendants and asked permission to note the availability and price of all items on the tracer list.</p> <p>The tracer items were classified as Part I or Part II drugs. According to Tanzania Pharmacy Board regulation, Part II drugs are non-prescription drugs and may be sold without a prescription by DLDBs (Part II shops) or pharmacies (Part I shops). Part I drugs are prescription drugs and, at baseline, were only allowed to be dispensed against a prescription by Part I shops. The ADDO program included a revision to this regulation which allows ADDOs to sell certain Part I medicines. At the time of the endline survey, all of the Part I items on the tracer list were approved for sale in ADDOs but were not approved for sale by DLDBs.</p>
Registration Status Survey	Yes	Yes	<p>To determine registration status, data collectors were assigned a defined alphabet range of drug names (A to E, F to L, M to Q, or R to Z). The teams started at the assigned range then cycled through the alphabet at subsequent facilities. Data collectors asked the attendant to show them any 10 drugs stocked by the shop with names starting with those letters. Data collectors recorded the brand name and the manufacturer exactly as they appeared on the label for each of the 10 products. In some cases, 10 products in the alphabet range were not available.</p> <p>The information collected was compared to a list of</p>

Survey Type	Baseline?	Endline?	Tool Description
Interview/Survey Drug Management Interview form	Yes	No	<p>registered drugs provided by the Tanzania Pharmacy Board (PB) of the Tanzanian Food and Drug Administration (TFDA). Medicines were coded as registered, unregistered, and locally manufactured.</p> <p>The Drug Management Interview form was applied to gather information on shop characteristics, dispenser knowledge, and dispenser practices. The tool was used in the baseline survey to gather information to guide the ADDO intervention. It was not replicated in the endline evaluation.</p>
Training Interview	Yes	No	<p>The Training Form was applied at baseline to find out whether dispensers had participated in any basic training or any recent training in managing key conditions (malaria, sexually transmitted diseases, diarrhea, parasites, and others). This information was used to assess training needs and to inform the ADDO training program. This questionnaire was not replicated in the endline evaluation.</p>
Attendant Quiz	Yes	No	<p>The Attendant Quiz tool was used to assess the knowledge that the dispensers had for dealing with three key conditions (diarrhea, acute respiratory infection, and sexually transmitted diseases) and for detecting poor quality drugs. The questions were designed to find out whether the dispensers knew the correct questions to ask and the appropriate advice and treatment to provide. The results were used to assess knowledge and training needs for the ADDO intervention. The quiz was not replicated in the endline evaluation.</p>
Client Exit Interview Form	No	Yes	<p>The client exit interview form assesses the satisfaction and dissatisfaction of shop clients with products and services. It was conducted in the endline assessment only.</p> <p>For the purposes of the interview, “customer” or “client” refers to people leaving the shop after having entered to obtain products in the shop. Data collectors were instructed to introduce themselves, obtain consent for the interview, and to make an effort to be personable and develop a rapport with the client. Interviews were conducted as the client left the shop, not as they entered the shop.</p> <p>Data collectors performed up to five exit interviews of clients who were leaving each shop. The questionnaire included 21 qualitative and quantitative questions that ascertained perceptions of shop service and products.</p>

Outcome Measures: The table below describes the key outcome indicators that were applied to evaluate the results of the ADDO program. Each indicator is listed along with the source of the data, the comparison groups, and the number of facilities included in the comparison groups.

Service Characteristics and Access Dimensions	Key Indicators	Data Source (Instrument)	Baseline Comparison Design	Endline Comparison Design	Comments
Quality of services (Appropriateness of Recommendations)	% encounters in which appropriate first line antimalarial was sold treatment of malaria	Malaria Simulated Client Form (in English and Swahili)	<p>March 2003</p> <p>Intervention 69 DLDBs Ruvuma Region</p> <p>Control 77 DLDBs Singida Region</p>	<p>November 2004</p> <p>Intervention 50 ADDOs Ruvuma Region</p> <p>Control 61 DLDBs Singida Region</p>	<p>Supplementary indicators:</p> <ul style="list-style-type: none"> • % encounters in which appropriate first line antimalarial was dispensed consistently with STGs for treatment of malaria • % encounters in which any antimalarial was sold for treatment of malaria • % of encounters in which any antimalarial was sold or recommended for treatment of malaria • % encounters in which the attendant referred the client to a to a doctor or clinic
Quality of Services (Appropriateness of Recommendations)	% encounters in which an antibiotic was sold for treatment of Upper Respiratory Tract Infection (URTI)	URTI Simulated Client Form (in English and Swahili)	<p>February-May 2001</p> <p>SEAM Tanzania Country Assessment</p> <p>33 DLDBs in multiple regions</p>	<p>November 2004</p> <p>Intervention 49 ADDOs Ruvuma Region</p> <p>Control 59 DLDBs Singida Region</p>	<p>Supplementary indicators:</p> <ul style="list-style-type: none"> • % encounters where an antibiotic was sold or recommended for treatment of URTI • % encounters in which the attendant referred the client to a to a doctor or clinic

Service Characteristics and Access Dimensions	Key Indicators	Data Source (Instrument)	Baseline Comparison Design	Endline Comparison Design	Comments
Quality of Services (Dispensing Communications)	% encounters in which attendant provided instructions on how to take the medication	Malaria and URTI Simulated Client Forms	See above for Malaria and URTI scenarios	See above for Malaria and URTI scenarios	Supplementary indicators: <ul style="list-style-type: none"> • % encounters in which attendant gave information on possible problems with medications (danger signs) • % encounters in which attendant asked about the symptoms of the child and any medications the child may have taken
Quality of Products	% of items sampled that are registered with the TFDA or locally manufactured % of Drug Unapproved for the Tanzanian Market	Registration Status Form	March 2003 Intervention 70 DLDBs Ruvuma Region Control 76 DLDBs Singida Region	November 2004 Intervention 50 ADDOs Ruvuma Region Control 60 DLDBs Singida Region	Pre-post comparison of 10 drugs whose manufacture information was gathered
Affordability	Average % difference in median price to patients between ADDOs and DLDBs for a set of tracer items (Part I and Part II Medicines)	Price and Availability Form	March 2003 Intervention 70 DLDBs Ruvuma Region Control 76 DLDBs Singida Region	November 2004 Intervention 50 ADDOs Ruvuma Region Control 60 DLDBs Singida Region	Pre-post comparison of a set of 20 tracer items Sample sizes for each individual median drug price vary depending on how many shops had the item available on the date of the visit.
Availability	% of a set of tracer items in stock (Part I and Part II Medicines)	Price and Availability Form	March 2003 Intervention 70 DLDBs Ruvuma	November 2004 Intervention 50 ADDOs	Pre-post comparison of a set of 20 tracer items

Service Characteristics and Access Dimensions	Key Indicators	Data Source (Instrument)	Baseline Comparison Design	Endline Comparison Design	Comments
			Region Control 76 DLDBs Singida Region	Ruvuma Region Control 60 DLDBs Singida Region	
Acceptability/ Satisfaction	% of customers who express satisfaction with service	Client exit interview (English and Swahili)	No baseline conducted	November 2004 Intervention 50 ADDOs Ruvuma Region Control 60 DLDBs Singida Region	The 21-question survey tool assessed overall satisfaction as well as other perceptions of service and quality

Key Documents Referenced in the Evaluation

In addition to the formal baseline and endline evaluation studies, several additional evaluation activities provided key information for the program assessment.

- Mapping and inventory of DLDBs and ADDOs (prepared by SEAM)
- Study of a sample of ADDO drug dispensing registry data (conducted by SEAM)
- Study of business practices in Mbinga (conducted by MEDA). See **Evaluating Sustainability and Financing of the ADDO Program** below for summary.
- Behavior change communication study of use and expectations of DLDBs by shop owners, dispensers, community leaders and members (focus groups, in-depth interviews). See Box 6 for summary.

Evaluation Results

The results are reported in relation to the SEAM Program objectives of improving the quality of drugs, availability of drugs, quality of pharmaceutical services, and affordability of drugs in the Ruvuma region.

Did SEAM improve the quality of drugs that people in Ruvuma were buying?

The registration status of medicines was studied in both the baseline and the endline as an indicator of the quality of drugs being sold in stores. To determine registration status, data collectors recorded the brand name and the manufacturer exactly as they appeared on the label for 10 products at each facility. The information collected was compared to a list of registered drugs provided by the TFDA. Medicines were coded as registered, unregistered, and locally manufactured. Tanzanian regulators consider locally manufactured drugs to be the legal equivalent to registered drugs.

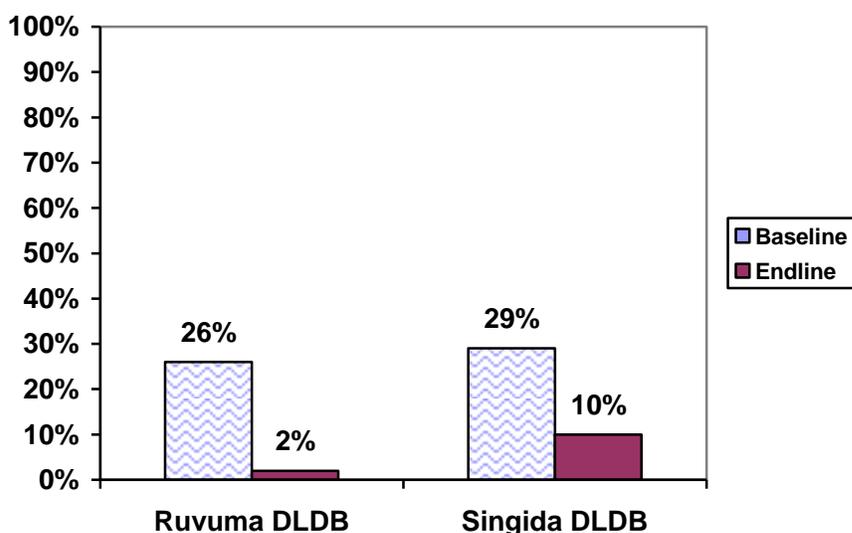


Figure 4. Percentage of unregistered drugs for sale in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOS and DLDBs).

Table 5. Percentage of Drugs Registered

	Baseline DLDBs		Endline	
	Ruvuma Baseline	Singida Baseline	Ruvuma ADDOs Endline	Singida Endline
Sample size	268	246	491	545
Registered	34%	27%	38%	36%
Not-registered	26%	29%	2%	10%
Locally manufactured	40%	43%	60%	54%

As seen in Table 5, at baseline, 26 percent of drugs found in Ruvuma DLDB were not registered; 29 percent of drugs in Singida DLDB were not registered. With the establishment of the ADDO program, the proportion of tracer list unregistered drugs in Ruvuma was reduced by a factor of 13, from 26 percent to 2 percent. In Singida, the proportion of unregistered drugs was also reduced, showing the effect of the broader work of the TFDA to improve registration, but the effect in Singida was not as great, with a reduction of unregistered drugs from 29 percent to 10 percent.

This improvement in the proportion of illegal products was likely due to several factors, including the much higher degree of oversight and transparency of the operation of the stores and a significant increase in local and TFDA inspections and confiscation of illegal products. In addition, with the formation of the ADDO shops, more rigorous TFDA inspections and enforcement efforts were established to target illegal wholesaler outlets in the region. These efforts improved the legitimate market as reflected in the increased numbers of locally manufactured products. Another important factor explaining this improvement is that the ADDO

program stimulated the local market sufficiently for a fully licensed wholesaler to open for the first time in Ruvuma Region.

As a result of this improvement, people in Ruvuma now have a 1 in 50 chance of buying an unapproved drug, compared to a 1 in 10 chance for the people of Singida.

In addition to the registration status analysis, the survey exit interview included a drug quality component. Data collectors asked clients leaving the facilities to rate the quality of the drugs they had purchased (Figure 5).

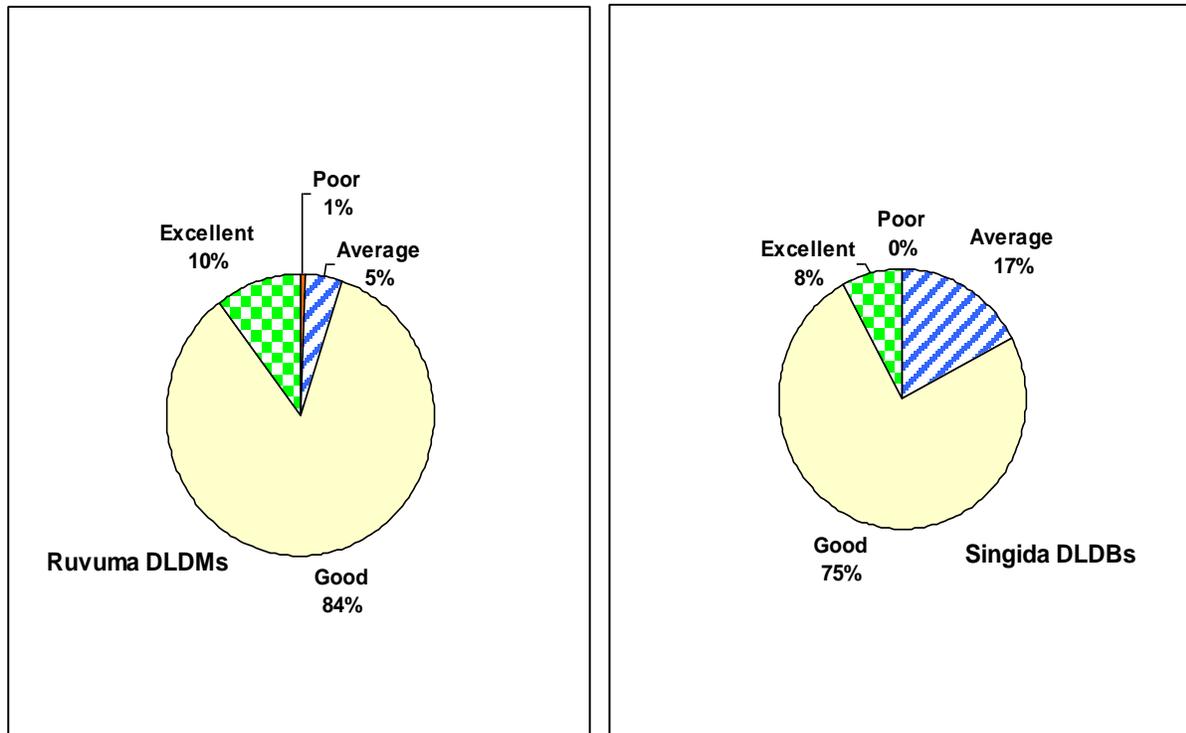


Figure 5. Comparison of respondent ratings of quality of drugs at ADDOs and DLDBs.

When respondents in the exit interview were asked to rate the quality of drugs at endline, a higher percentage of Ruvuma clients answered “Good” or “Excellent” (94 percent) compared with Singida (83 percent). This question was included in the exit interview in part because the baseline behavior change communications study⁸ had identified “expired” and “low quality” drugs as important consumer concerns.

⁸ Mary E. Taylor, Clement Kihinga, Romuald Mbwas, William Mfuko. 2003. Transforming *Maduka ya Daw* *Baridi* into Accredited Drug Dispensing Outlets Designing a Behavior Change Communications Strategy. Management Sciences for Health; Healthscope Ltd.

Did SEAM increase the availability of those products throughout the region?

Physical Availability

A tracer list of 20 key drugs (Annex 2) was used to check the status of availability and price at each facility. The tracer items were classified as Part I or Part II drugs. According to TFDA regulation, Part II drugs are nonprescription drugs and may be sold without a prescription by DLDBs (Part II shops) or pharmacies (Part I shops). Part I drugs are prescription drugs and, at baseline, were only allowed to be dispensed against a prescription by Part I shops. As part of the SEAM Program, a revision to this regulation specifically allows ADDOs to sell certain Part I medicines, such as antibiotics. At the time of the endline survey, all of the Part I items on the tracer list were approved for sale in ADDOs but were not approved for sale by DLDBs. Therefore, DLDBs in Singida should not be selling Part I drugs.

The availability of tracer list drugs has increased in both Ruvuma and Singida since the baseline survey was done. The increase in availability in Ruvuma was greater overall and was most marked for prescription drugs (Part I), which is due to the change in regulation. At endline, the average availability of prescription drugs in Ruvuma was nearly double the average availability in Singida (Figure 6).

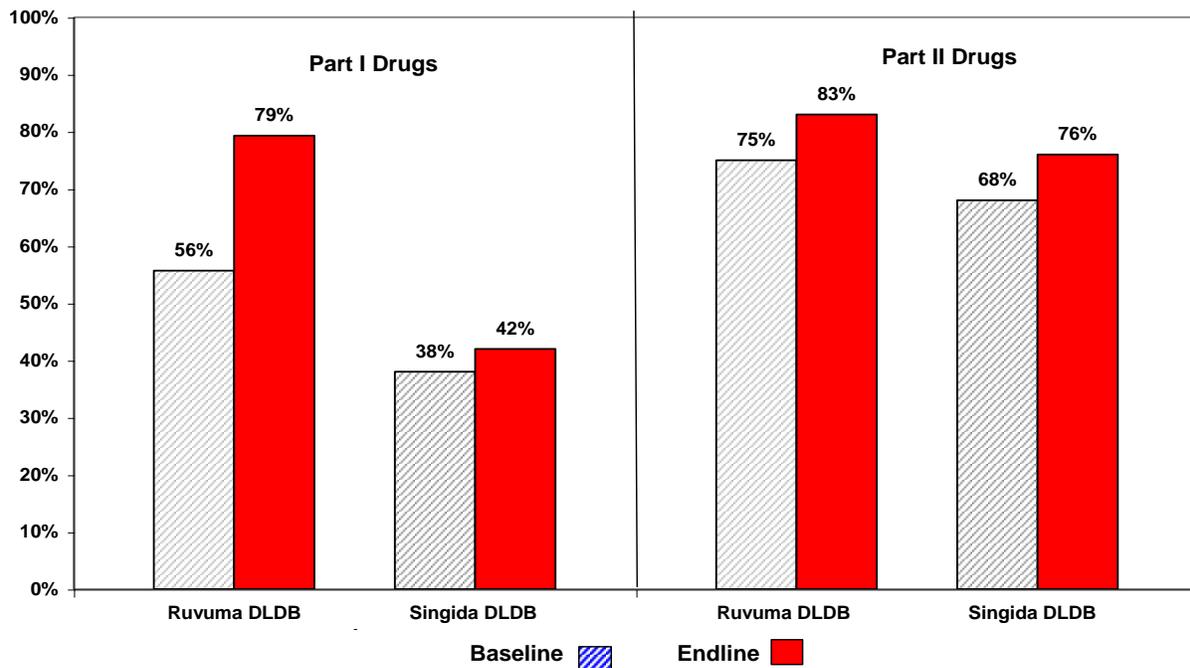


Figure 6. Average availability of Part I and Part II tracer drugs in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

In addition to increases in availability of Part I and Part II tracer drugs, average availability of all tracer items in Ruvuma was 80 percent at endline as compared with items in Singida (53 percent). Ruvuma started out with better availability than Singida (61 percent compared with 47 percent) but showed a much greater change overall. Availability increased among ADDOs by 19

percent, while among DLDBs in Singida availability increased by only 5 percent (Figure 7 and Table 6 below). Again, this can be attributed to the change in regulation that allows ADDOs to sell certain Part I drug items.

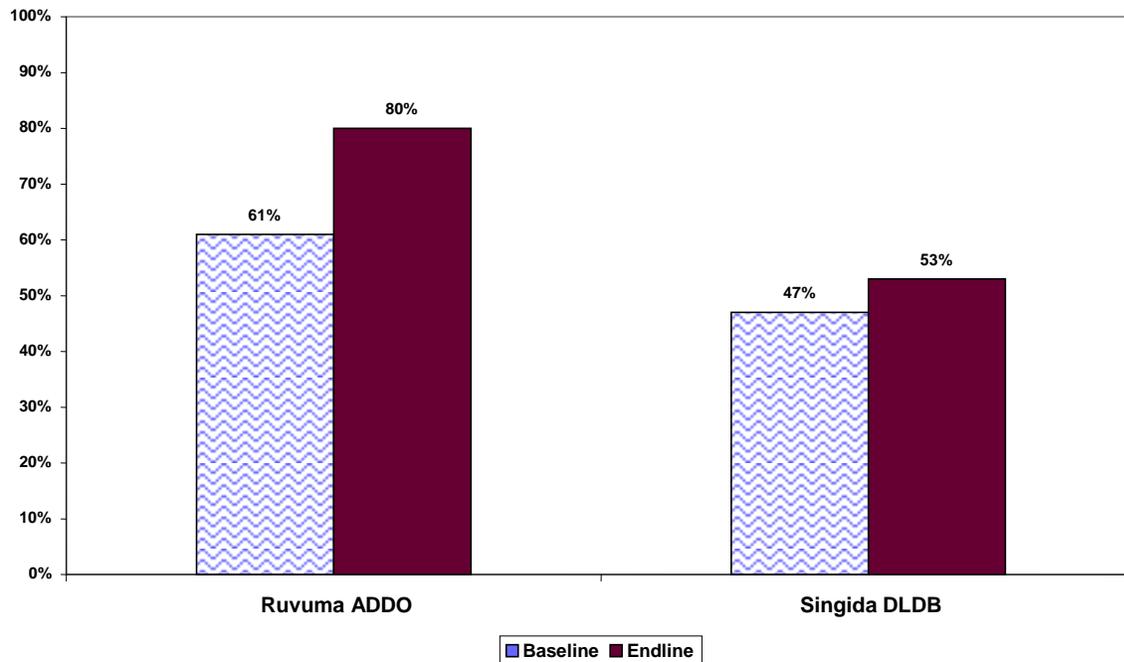


Figure 7. Comparison of average availability of all tracer drugs in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

Table 6. Average Percent Availability of Tracer Items

		Baseline		Endline		Calculations		
Drug Type		Ruvuma	Singida	ADDOs Ruvuma	Singida DLDBs	Improve- ment Ruvuma ADDOs	Improve- ment Singida	Difference of Differences ADDOs- Singida
Drug		70	76	50	60			
Part I	02. Amoxicillin	69%	33%	96%	38%	27%	5%	22%
	03. Benzyl penicillin powder inj	34%	17%	46%	12%	12%	-5%	17%
	04. Cotrimoxazole	86%	51%	96%	52%	10%	0%	10%
	05. Diclofenac	81%	67%	98%	81%	17%	14%	2%
	06. Doxycycline	34%	20%	68%	28%	34%	9%	25%
	07. Metronidazole	83%	66%	98%	61%	15%	-5%	20%
	08. Nystatin suspension	20%	7%	52%	20%	32%	14%	18%
	09. Praziquantel	24%	22%	42%	29%	18%	7%	11%
	10. Phenoxymethyl penicillin	76%	47%	92%	40%	16%	-7%	23%
	11. Procaine penicillin fortified	32%	22%	70%	16%	38%	-7%	45%
	12. Quinine	83%	42%	96%	50%	13%	8%	5%
	13. Erythromycin	40%	36%	72%	31%	32%	-5%	37%
16. Contraceptive pill	29%	37%	88%	56%	59%	19%	40%	
20. Indomethacin	89%	71%	96%	78%	7%	7%	1%	
Part I Total		56%	38%	79%	42%	24%	4%	20%
Part II	01. Amodiaquine	90%	84%	96%	88%	6%	4%	2%
	14. Sulfadoxine pyrimethamine	83%	80%	98%	78%	15%	-2%	17%
	15. Sulphametopyrazine pyrimeth	39%	32%	68%	69%	29%	37%	-8%
	17. Mebendazole	86%	80%	78%	72%	-8%	-9%	1%
	18. Salbutamol	54%	33%	58%	57%	4%	24%	-20%
19. Paracetamol	99%	99%	100%	93%	1%	-5%	7%	
Part II Total		75%	68%	83%	76%	8%	8%	0%
Overall Total		61%	47%	80%	53%	19%	5%	14%

Figure 8 shows the average availability of antimalarials (classified as Part II drugs) at baseline and endline for Ruvuma and Singida. In Ruvuma, the average availability for antimalarials increased from 74 to 90 percent. Singida also experienced an increase in the availability of antimalarials (60 to 71 percent). This improvement in the ADDOs is not a reflection of the regulation change, as antimalarials are allowed to be sold in both DLDBs and ADDOs.

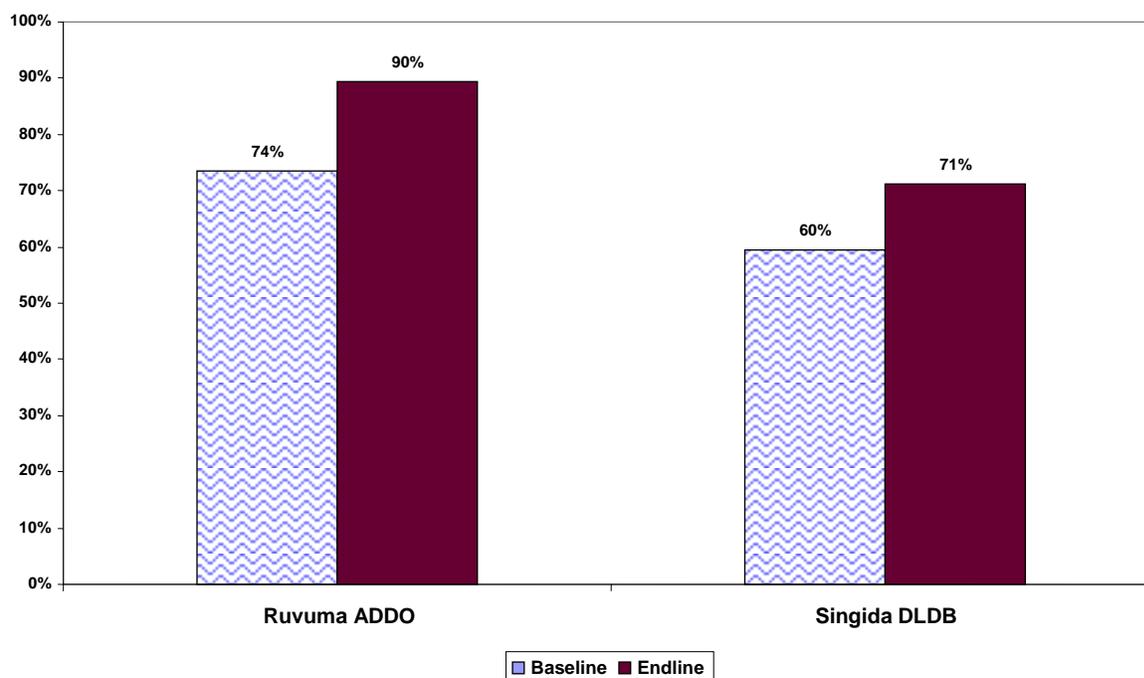


Figure 8. Average availability of antimalarials in Ruvuma and Singida at baseline (DLDB) and endline (ADDOS and DLDB).

Key reasons cited for improved availability in the February 2005 stakeholder meeting include—

- Authorizing ADDOs to carry some Part I tracer items (primarily some antimicrobials)
- Providing programmatic financial support
- Training for resource management from MEDA
- Establishing a reputable wholesaler in the Ruvuma region

Client Perceptions of Availability

In addition to assessing the physical availability of key medicines, the client exit interview data were analyzed to ascertain clients’ perceptions of availability. When asked why they visit the store, relatively few clients in Ruvuma ADDOs (N=11) or Singida DLDBs (N=6) listed drug availability as a main reason. However, when clients were asked at the end of the interview to suggest changes to the shops, 22 percent of ADDO clients did suggest “adding drugs.” In comparison, 70 percent of Singida DLDB clients mentioned adding drugs as a suggested improvement. This suggests that drug availability may be a more important issue for Singida clients than for ADDO clients, which is consistent with the above findings on physical availability.

Did SEAM improve the quality of dispensing services?

A simulated client, or “mystery shopper,” approach was applied to assess the quality of dispensing services in Ruvuma ADDOs and Singida DLDBs. This methodology has been widely

used to evaluate health and pharmaceutical services⁹. Two different scenarios were applied—one for symptoms of uncomplicated malaria and one for symptoms of URTI. Both scenarios were for a six-year-old child. Data were collected at baseline and endline for the malaria scenario. For the URTI, there was no baseline data. However the original SEAM Tanzania country assessment conducted in 2001 included a URTI simulated client scenario. That assessment includes data from multiple facilities, including 33 *duka la dawa baridi* around the country (not just in Ruvuma and Singida). This report references data from those 33 facilities.

In addition to the simulated client, interviews with clients exiting shops included questions about the quality of services and communication. Also, store registers (client logs) were analyzed for various rational use indicators. Data from simulated client scenarios, exit interviews, and store registers are reported below.

Use of Antibiotics

One of the most important indicators of rational drug use was the number of shopkeepers that did not provide an antibiotic for treating URTI, which is not the recommended treatment. Using simulated patients, endline data showed that fewer shopkeepers gave or recommended antibiotics for URTI in Ruvuma (14 percent) than did so during the SEAM baseline assessment in 2001 (39 percent countrywide) or in Singida (25 percent) during the endline evaluation (Figure 9).

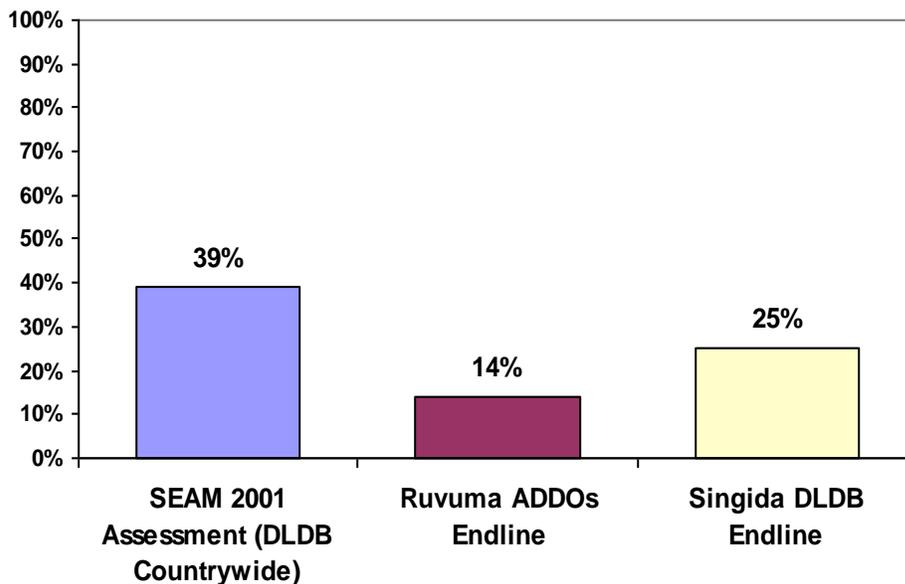


Figure 9. Percentage of simulated URTI clients dispensed or recommended antibiotics during 2001 countrywide DLDB assessment and at endline in Ruvuma (ADDOS) and Singida (DLDBs).

Similarly, among malaria simulated clients for whom no antibiotic was indicated, no antibiotics were dispensed at endline in ADDOs (0 percent), while five percent of DLDBs in Singida dispensed an antimalarial for treatment of malaria.

⁹ For example—Madden JM, Quick JD, Ross-Degnan D, Kafle KK. 1997. Undercover careseekers: simulated clients in the study of health provider behavior in developing countries. *Soc Sci Med* 45(10):1465-82.

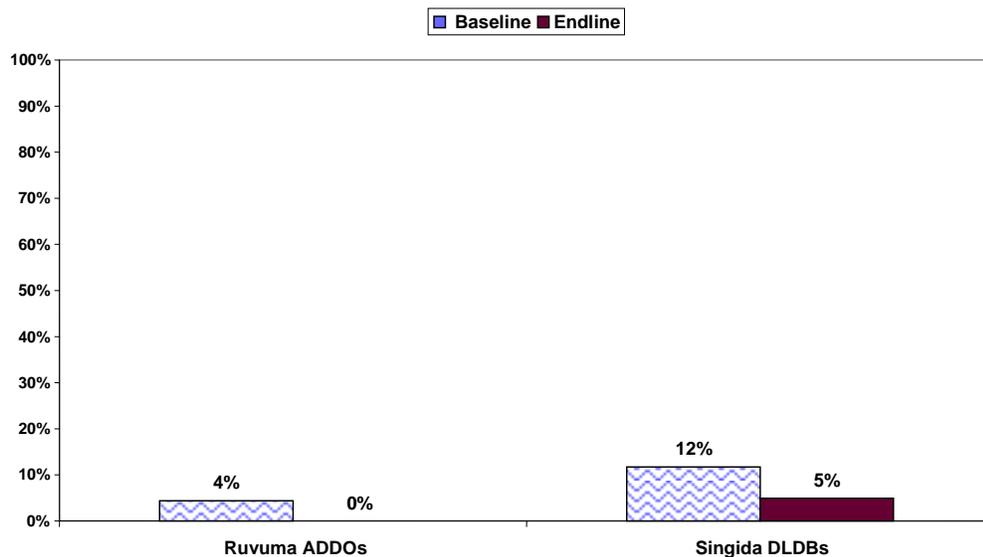


Figure 10. Percentage of malaria simulated clients in Ruvuma and Singida dispensed antibiotic at baseline (DLDBs) and endline (ADDOs and DLDBs).

This is a very important finding for ADDOs: They now have a legal right to sell selected antibiotics and are shown to be selling them more responsibly than during the 2001 assessment. This finding provides support to the argument that legalizing the selling of selected prescription drugs at the ADDO level does not necessarily lead to the overuse of antibiotics.

Number of Medicines Dispensed per Encounter

The number of drugs dispensed in an encounter is another key measure of rational drug use. The average number of drugs dispensed per malaria simulated client encounter dropped slightly from baseline to endline among Ruvuma ADDOs (1.6 to 1.4) and Singida DLDBs (1.9 to 1.8). Moreover, ADDOs dispensed fewer drugs per encounter at both baseline and endline than did the control group.

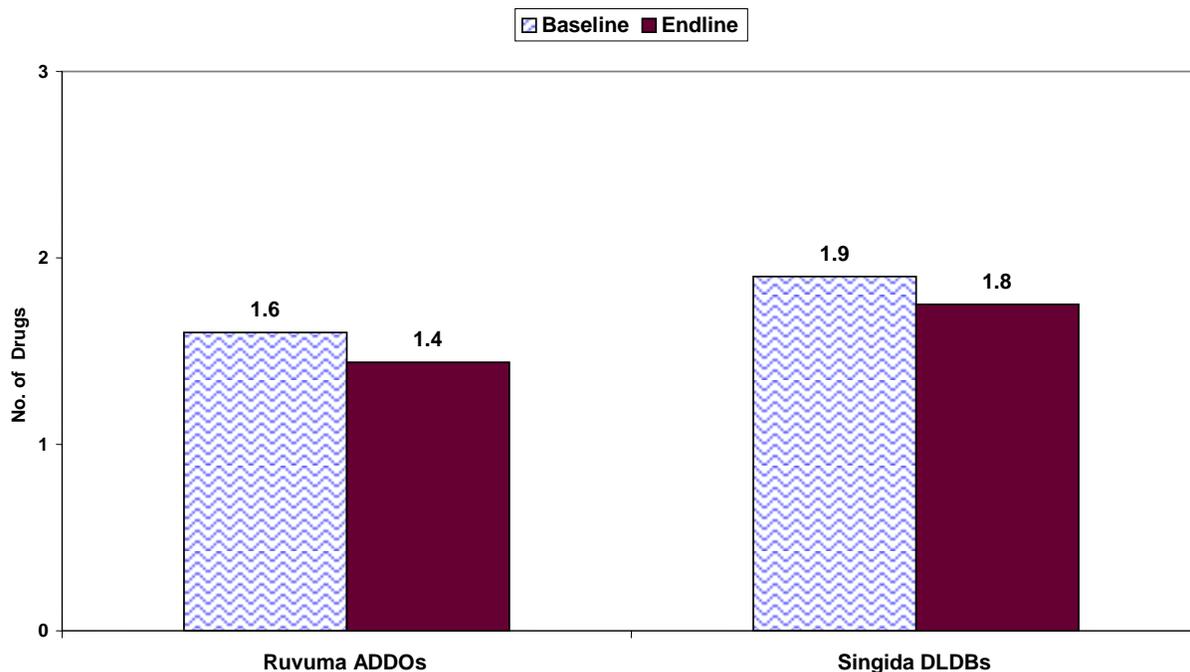


Figure 11. Average number of drugs dispensed for malaria treatment in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOS and DLDBs).

The average number of drugs dispensed in the URTI scenario suggests that ADDOs in Ruvuma dispensed fewer drugs per encounter (1.5) in the endline than were documented in DLDBs visited the 2001 SEAM assessment (2.3). At endline, the average number of drugs dispensed per encounter was the same among both Ruvuma ADDOs and Singida DLDBs (1.5).

It should be noted that the calculation of the average number of drugs dispensed in these encounters included any item that the dispenser recommended, including an analgesic or even a bed net. Therefore, though the Tanzanian standard treatment guidelines for malaria recommend one drug, sulfadoxine-pyrimethamine (SP) for first-line treatment, the ADDO dispenser may have also sold paracetamol, which would have been included in Figure 12.

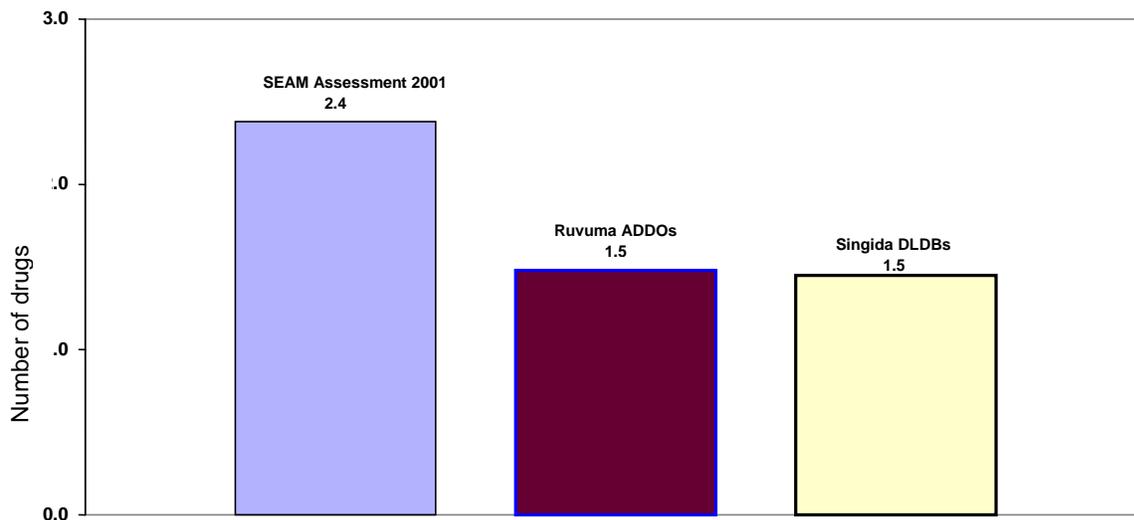


Figure 12. Average number of drugs dispensed per treatment of URTI in ADDOs and DLDBs (compared to 2001 SEAM Assessment DLDBs as baseline).

The survey findings are supported by evidence from the drug registers that ADDOs are required to maintain. Analysis of these registers showed that each patient patronizing an ADDO is receiving on average 1.3 drugs regardless of age, which is consistent over surveys and districts. Some 22 percent of patients receive antibiotics. In the 2001 SEAM assessment, patients received 1.7 drugs per visit on average overall (1.6 drugs at MOH establishments, 1.9 at private institutions, and 1.8 at NGOs). The ADDO number of 1.3 medicines per client compares favorably to these figures. The percentage of patients receiving antibiotics (22 percent) is also favorable compared with the percentage of patients receiving antibiotics at these other establishments (30 percent, 56 percent, and 17 percent, respectively) as identified in the SEAM 2001 assessment (Table 7).

Table 7. Dispensing Data per Facility Type

	ADDOs: Monitoring Data from Drug Registers	All SEAM Assessment Facilities*	MOH*	Private*	NGO*
No. of facilities	201	41	21	14	6
No. of patients	20,197	1473	755	502	216
No. of drugs per case	1.3	1.7	1.6	1.9	1.8
% all cases given antibiotics	22.4%	37%	30%	56%	17%

*Data from the 2001 SEAM assessment.

Appropriateness of Recommendations

To assess the malaria dispensing practices the evaluation team compared the various treatment recommendations of shop attendants to the Tanzanian national guidelines for malaria treatment.

The national guidelines specify 1.5 tablets of SP as the first-line treatment (Table 8), though any encounters in which amodiaquine or quinine were dispensed were also evaluated against the guidelines.

Table 8. Malaria National Treatment Guidelines

Treatment		Correct Dose
SP (1st Line)	Tablet	1.5 tablets once (1.5 tabs total)
Amodiaquine (2nd Line)	Tablet	1.25 tabs for day one and two, and 0.5 tabs for day three (3 tabs total).
	Syrup	25 ml for day one and two, 10 ml for day three (60 ml total)
Quinine (3rd Line)	Syrup	11.25 ml three times a day for 7 days (236.25 ml total)
	Tablet	0.75 tablets three times a day for 7 days (15.75 tabs)

Overall, the dispensing of any antimalarial fell slightly in Ruvuma (from 54 percent to 46 percent) (Figure 13). In Singida, more shopkeepers dispensed antimalarials (74 percent at baseline and 77 percent at endline). However, for all antimalarials, the percentage dispensed according to guidelines increased in ADDOs from 6 percent to 32 percent; this percentage did not change much in Singida (22 percent and 25 percent).

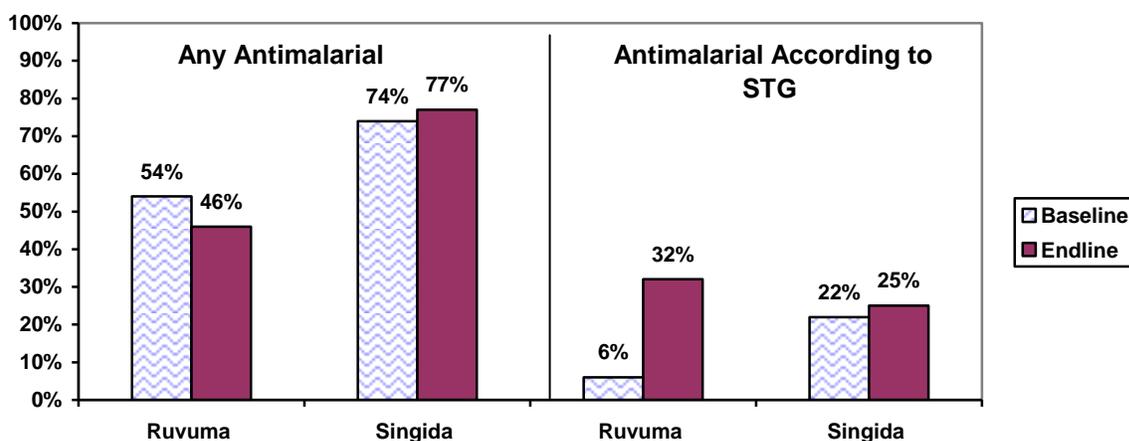


Figure 13. Percentage dispensing any antimalarial or treatment according to STGs to simulated clients at Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

The figure below compares the type of antimalarial sold at both baseline and endline. Attendants dispensed the first-line medication, SP, more frequently at endline in both Ruvuma (from 16 percent to 32 percent) and Singida (29 percent to 48 percent), though overall, Singida DLDBs were more likely to dispense SP at baseline and endline. Ruvuma ADDOs also had a greater improvement in dispensing SP exactly according to STGs (+18 percent) compared with Singida DLDBs (+12 percent).

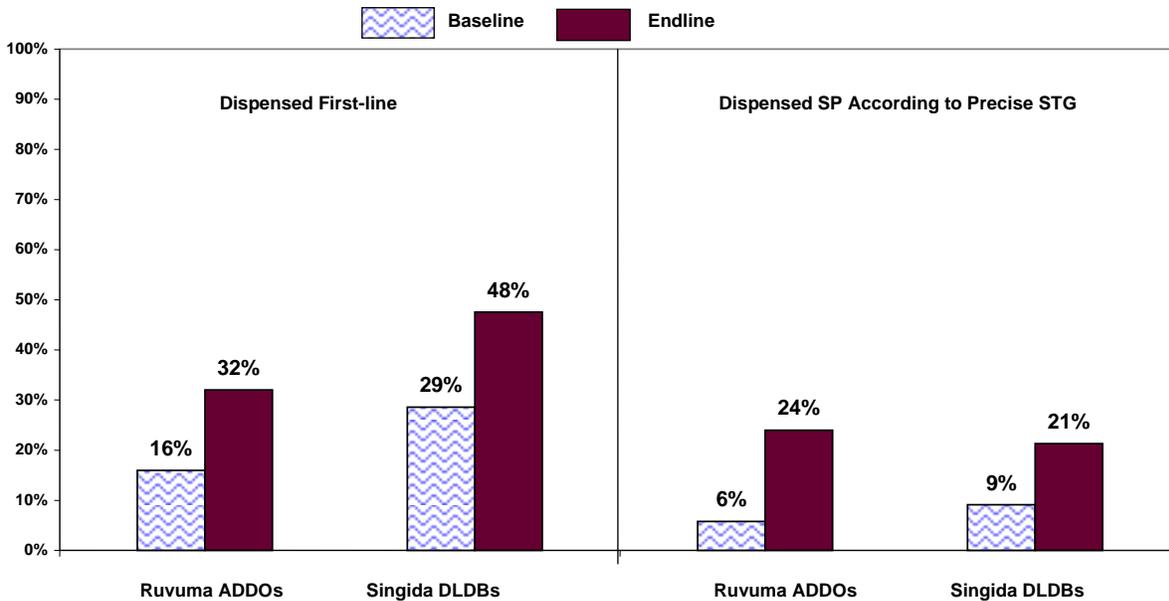


Figure 14. Percentage of malaria simulated clients dispensed first-line drug (SP) or SP according to precise STG in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOS and DLDBs).

It is noteworthy that there was a significant increase in the percentage of referrals without antimalarials in Ruvuma, from 32 percent to 52 percent (Figure 12). Medical personnel attending the February 2005 stakeholders meeting to discuss evaluation findings (a full list of attendees can be found in Annex 3), who included the Regional Medical Officer of Ruvuma and District Medical Officers of Songea Urban/Rural, Mbinga, and Singida, interpreted this finding positively, as evidence of the efforts of ADDO dispensers to conduct business in an ethical and professional manner. While it was felt that it would have been better to treat with an appropriate first-line antimalarial, the evidence that dispensers did not put making a sale above their duty to the patient was seen as providing a solid basis for continuing education to sharpen the skills of the dispensers in recognizing and appropriately managing cases of uncomplicated childhood malaria.

Participants at the February 2005 workshop emphasized that ADDO training emphasized malaria treatment, but also encouraged attendants to refer clients to the next level of care in cases where they did not feel they could treat the patient. However, the objective of the training was to provide ADDO dispensers with enough information and confidence to adequately recognize and treat uncomplicated malarial without referral. The stakeholders therefore emphasized the need to focus on the malaria component of ADDO training in future rollouts and for continuing education activities.

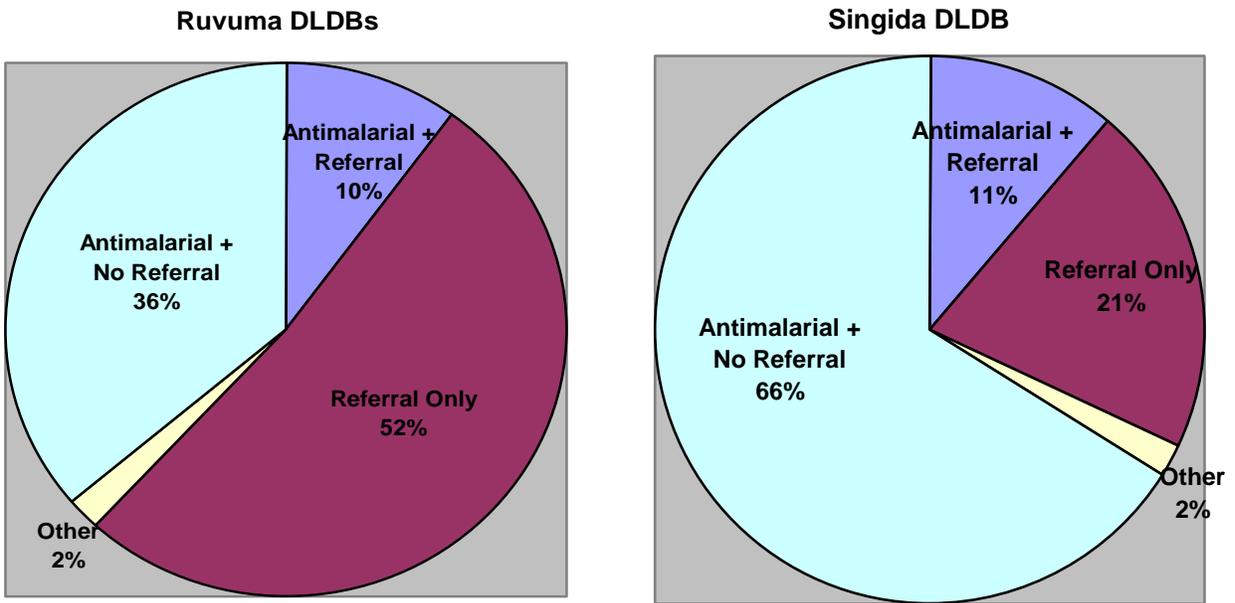


Figure 15. Treatment and referral of simulated cases of malaria in Ruvuma ADDOs and Singida DLDB at endline.

In addition, the workshop participants thought that a recent WHO campaign in Tanzania had advocated a malaria regimen that differed from the Tanzanian STGs, recommending three days of quinine plus one day of SP, which may have caused confusion.

Similarly, ADDOs were 21 percent more likely than DLDBs in Singida to refer for the URTI simulated client scenario (Figure 16).

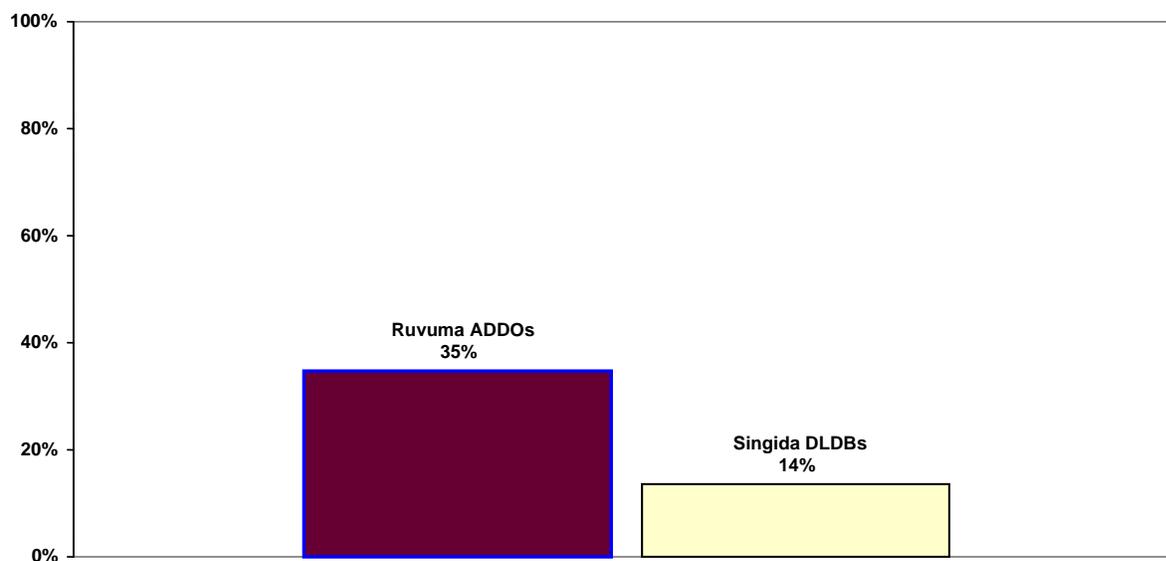


Figure 16. Percentage of facilities where attendant referred patient to a doctor or clinic for URTI at endline.

Dispensing Communication and Instructions

In addition to rational use and quality of services, the endline survey assessed the quality of dispensing communication and any instructions given by the attendant. At the end of the scenarios, data collectors noted key elements of the encounter, specifically—

- Did the dispenser ask about symptoms?
- Did the dispenser ask about medication history?
- Did the dispenser provide instructions on how to take the medications or mention any possible problems?

Questions about symptoms and medication history aim to demonstrate the attendant’s ability to assess the child’s condition. In the malaria simulated client, there was a slight five percent increase in the number of attendants of ADDOs who asked about both symptoms and medications, while there was a 10 percent decrease among DLDB attendants (Figure 17 below). However, DLDBs in Singida were more likely to ask the questions at both baseline and endline (Table 9).

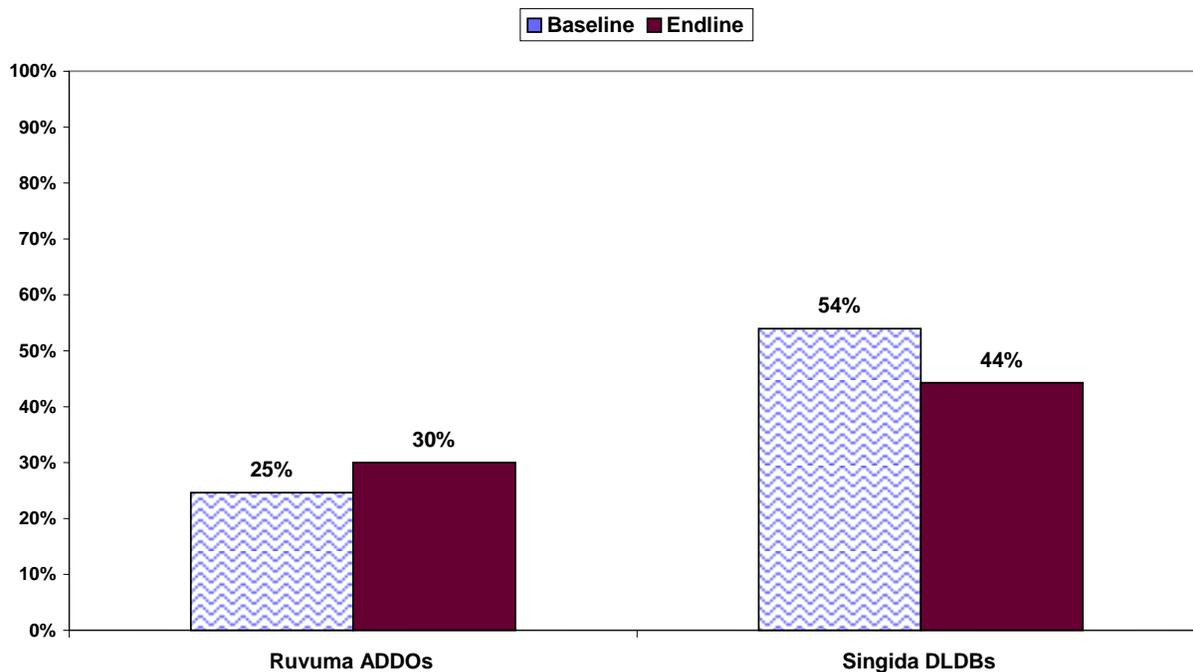


Figure 17. Percentage of malaria simulated clients asked about symptoms and other medications at Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

Table 9. Advice and Instructions Provided to Malaria Simulated Clients at Baseline and Endline

	Baseline		Endline	
	Ruvuma	Singida	Ruvuma ADDOs	Singida DLDBs
Did the drug seller ask about the symptoms of the child?	60%	66%	48%	61%
Did the drug seller ask about any other medications the child may have taken?	37%	63%	54%	61%
<i>Did the drug seller ask both of the above questions?</i>	25%	54%	30%	44%
Did the drug seller give instructions on how to take the medications?	81%	77%	60%	77%
Did the drug seller give information on possible problems with the medications?	3%	7%	4%	2%

In the URTI scenario, ADDOs asked about symptoms and medications more frequently (37 percent) than did DLDBs (20 percent).

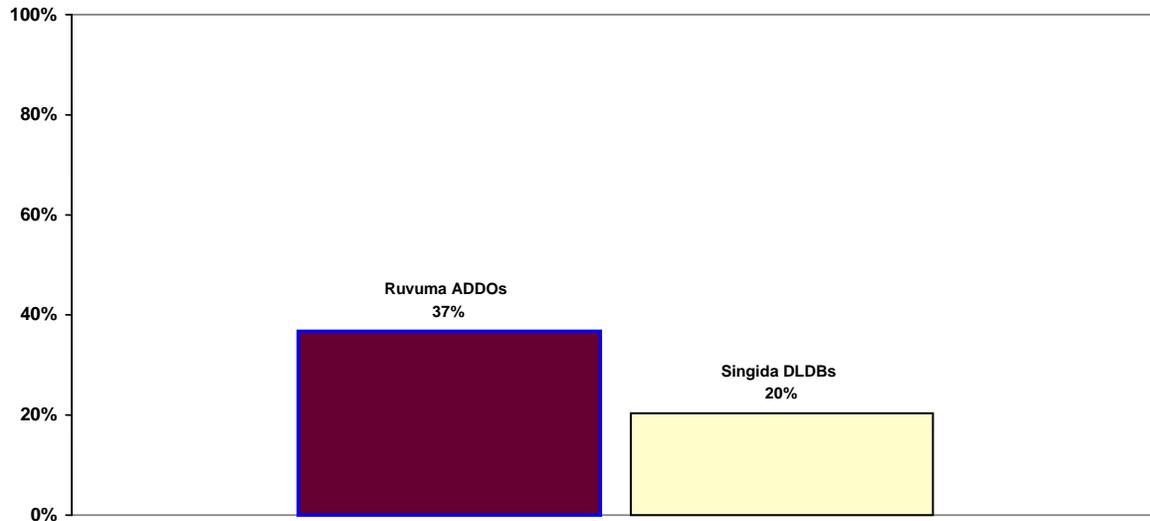


Figure 18. Comparison of percent of facilities where attendant asked questions about symptoms and previous medications when providing recommendations for URTI at endline.

The percentage of encounters in which attendants provided instructions on how to take the medications measures whether attendants communicate key information about medication administration. In the malaria simulated client exercise, there was no change among Singida DLDBs, while ADDOs provided instruction in 21 percent fewer encounters than at baseline (Figure 19 below).

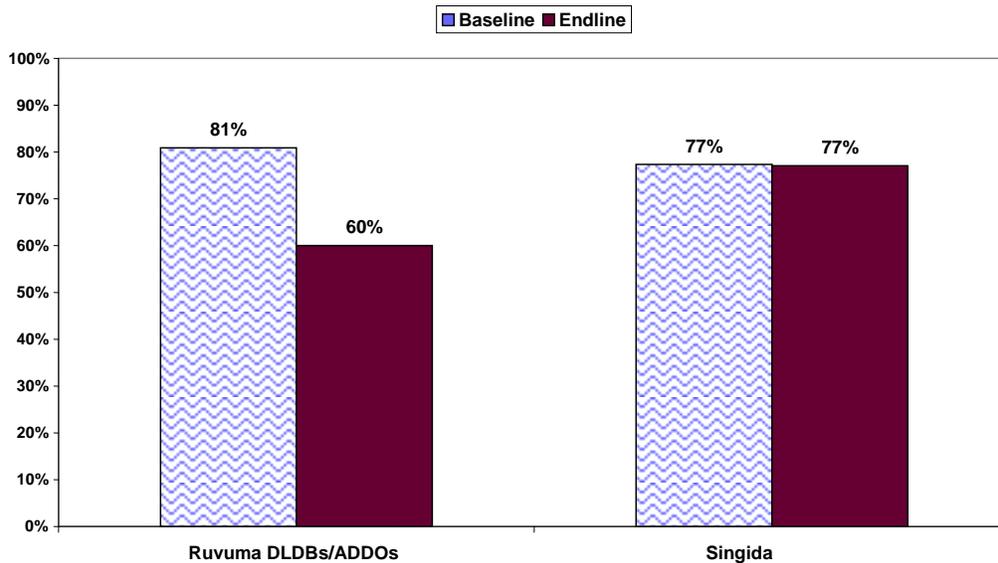


Figure 19. Percentage of malaria simulated clients advised how to take medications at Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

Similarly, in the URTI scenario, 88 percent of facility attendants provided instructions in the 2001 SEAM assessment, while at endline there was a slight drop to 78 percent at both Ruvuma ADDOs and Singida DLDBs.

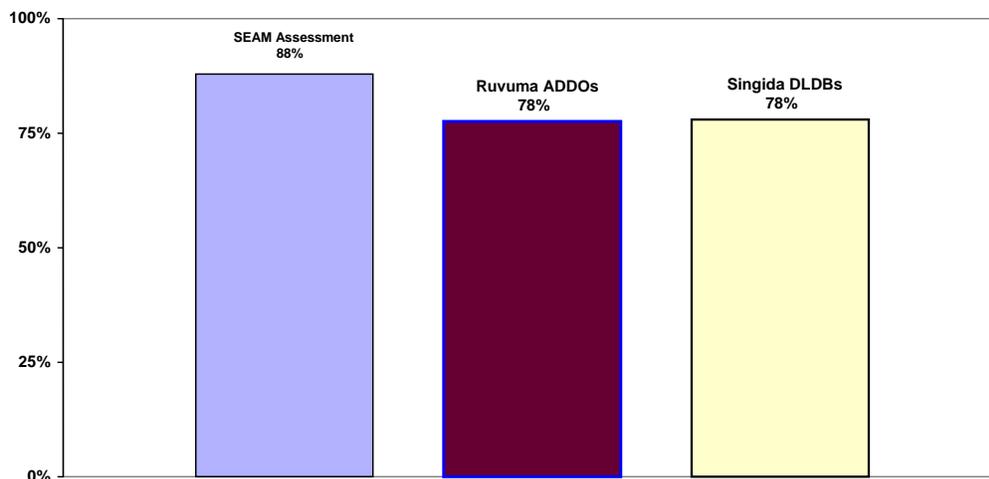


Figure 20. Percentage facilities in Ruvuma (ADDOs) and Singida (DLDBs) where attendant gave instructions on how to take medications for URTI (compared to 2001 SEAM Assessment DLDBs as baseline).

The survey findings are supplemented by the client exit interview, which included several questions relating to the client's perception of communication and instructions during their visit

to the shops. When asked to rate the information they were given about their medications, 28 percent of ADDO clients rated the information as “excellent,” while only 15 percent of DLDB clients responded “excellent” (Figure 21 below). Overall, 95 percent of ADDO clients rated the information as “good” or “excellent,” compared with 92 percent of DLDB clients.

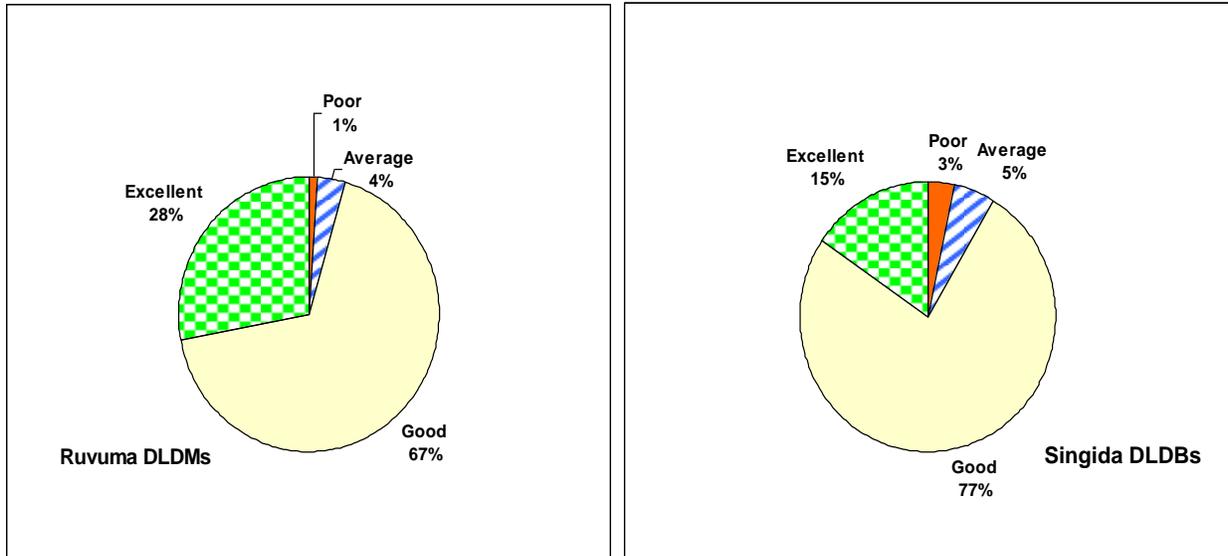


Figure 21. Respondent ratings for information received about taking drugs in Ruvuma ADDOs and Singida DLDBs.

Clients rated the knowledge and expertise of the dispenser along similar lines. Twenty-six percent of ADDO clients rated the dispenser’s knowledge as “excellent,” while only 16 percent of DLDB clients responded “excellent” (Figure 22 below). Overall, 95 percent of ADDO clients rated the dispenser’s expertise as “good” or “excellent,” compared with 83 percent of DLDB clients. DLDB clients were more likely to respond “average” (16 percent versus 5 percent), possibly indicating a stronger level of confidence in the knowledge of ADDO dispensers.

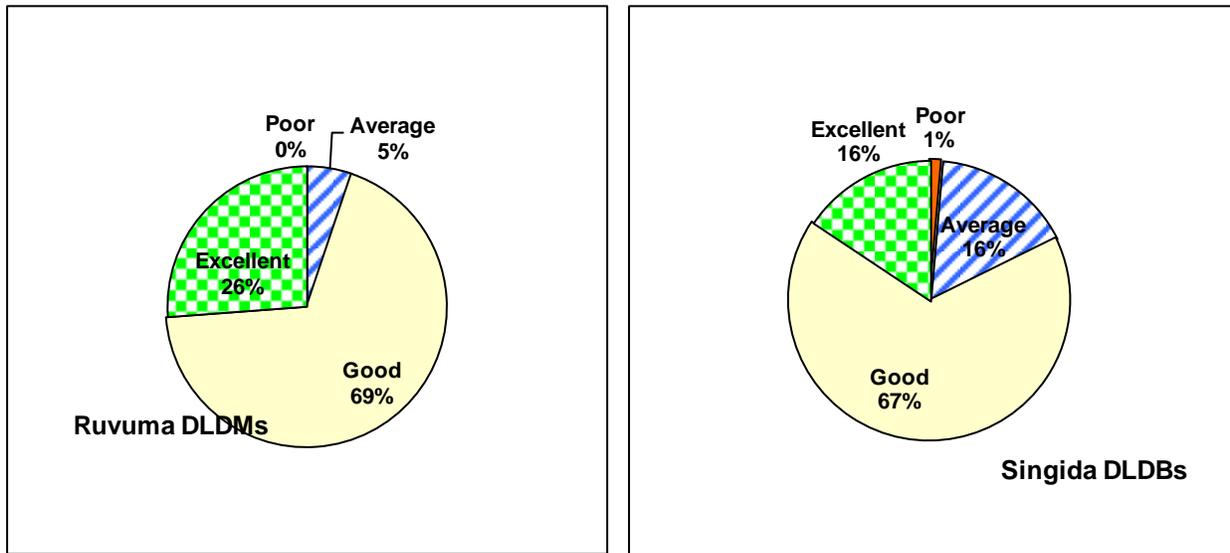


Figure 22. Respondent ratings for knowledge and expertise of dispensers in Ruvuma ADDOs and Singida DLDBs.

Did SEAM improve the quality of dispensing practices so that drugs and pharmaceutical services are affordable to people in the region?

Median Prices

The same tracer list of 20 key drugs (Annex 2) used to check availability at each facility was also used to check prices. The tracer items were classified as Part I or Part II drugs. Average median prices for Part I and Part II drugs increased from baseline to endline in both regions, with the increase more marked in Ruvuma (11 percent) than in Singida (< 1 percent), and with differences in the median prices of Part I drugs accounting for most of this variance. Average median prices for Part I tracer drugs increased in Ruvuma by 8.9 percent, but they decreased in Singida by 2.6 percent (Figure 23). However, it is important to note that at baseline the median prices of Part I tracer drugs were 10.8 percent lower in Ruvuma than in Singida. Average median prices for Part II tracer drugs rose in price 27 percent in Ruvuma, and 20 percent in Singida.

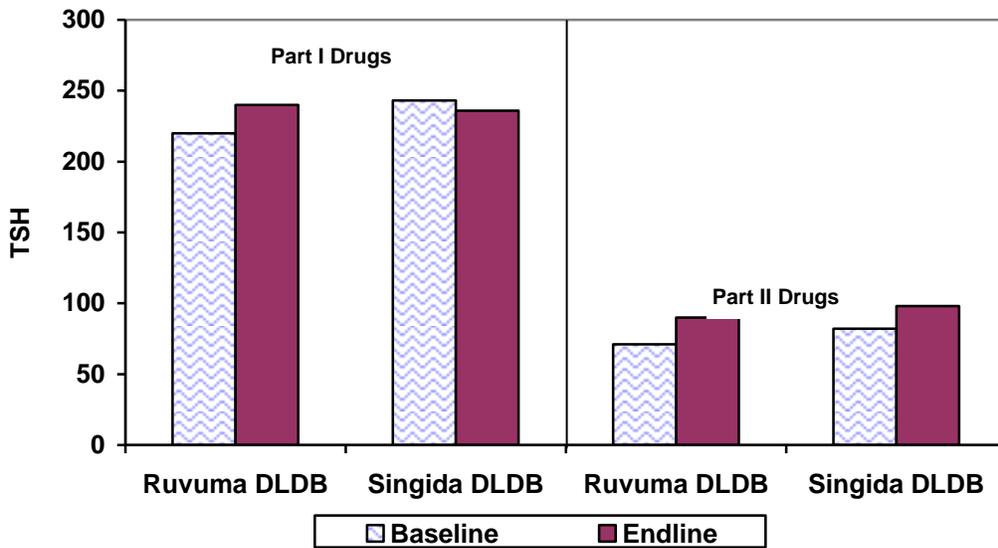


Figure 23. Change in median prices for Part I and Part II tracer drugs in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOS and DLDBs).

Although average median prices for all tracer drugs increased by 11 percent in Ruvuma and only < 1 percent in Singida, overall average median prices of tracer drugs were identical (TSH 195) at the time of the endline survey. Therefore, prices in both regions at endline were the same (see Figure 24).

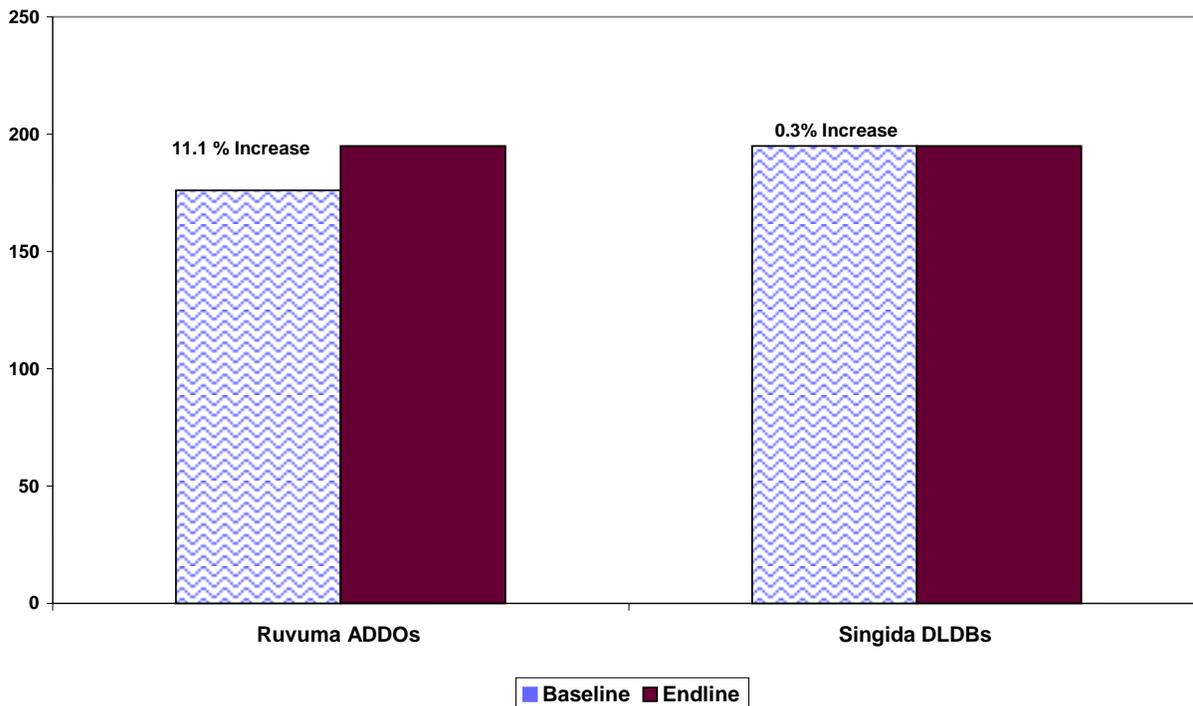


Figure 24. Increases in median prices for all tracer drugs in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOs and DLDBs).

At the February 2005 stakeholders workshop (which included the Chief Medical Officer, Regional Medical Officer of Ruvuma, Regional Pharmacists from Ruvuma and Singida, District Medical Officers from Songea Urban/Rural, Mbinga, and Singida, as well as the Regional Commissioner and all District Commissioners from Ruvuma), they noted that some of the costs incurred in the transition from DLDB to ADDO may have been incorporated into the ADDO prices, but their consensus was that the increase in prices had not affected access in Ruvuma.

Drug register data indicated that the customer base has remained stable, so it would appear that prices had not eroded the customer base over the nine-month period from March to November 2004. See Table 10.

Table 10. Number of Customers Recorded in Drug Register in the First Two Groups of ADDOs (69 shops in Songea Urban/Rural and Namtumbo)

Mar-04	Apr-04	May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04
1,065	938	1,103	1,101	1,032	987	980	1,016	976

Overall, the stakeholders felt that prices in Ruvuma were now more in line with national market prices than they had been previously. Reasons for this included the improved regulation of the illicit market in Ruvuma following the TFDA’s seizure of a large stock of illegal and stolen drugs in August 2003.

Treatment Prices

To assess affordability in terms of local incomes, the average cost of a treatment for a normal course of therapy was calculated using the median prices charged per drug product. Average salary statistics were applied to these figures to calculate the average number of hours a worker would need to work to pay for the course of treatment. Two salary estimates were applied—that of the lowest government salary and the monthly per capita income in Ruvuma and Singida. Because the median prices at endline were identical in Ruvuma and Singida for the drugs selected for study, there is no difference in the price of treatment. However, because the monthly per capita household income in Singida is lower than that of Ruvuma, clients in Singida would have to work more hours to pay for each of the four courses of treatment than would those living in Ruvuma (Table 11 and figures below).

Table 11. Differences in Median Cheapest Price Per Course of Therapy in Ruvuma and Singida at Baseline (DLDBs) and Endline (ADDOS and DLDBs)

Price	Courses of Therapy	Baseline			Endline	
		Ruvuma DLDBs	Singida DLDBs	% Difference	Ruvuma ADDOs	Singida DLDBs
Median Price						
	Amoxicillin (250 mg, 30 tablets)	840	1200	-43%	900	900
	Co-trimoxazole (480 mg, 20 tablets)	400	400	0%	400	400
	SP (525 mg, 3 tablets)	150	300	-100%	300	300
	Mebendazole (100 mg, 6 tablets)	120	120	0%	120	120
Hours government worker needs to work to purchase treatment*						
	Amoxicillin (250 mg, 30 tablets)	3.4	4.8	-43%	3.6	3.6
	Co-trimoxazole (480 mg, 20 tablets)	1.6	1.6	0%	1.6	1.6
	SP (525 mg, 3 tablets)	0.6	1.2	-100%	1.2	1.2
	Mebendazole (100 mg, 6 tablets)	0.48	0.48	0%	0.48	0.48
Hours resident needs to work**						
	Amoxicillin (250 mg, 30 tablets)	17.2	45.1	-162%	18.5	33.8
	Co-trimoxazole (480 mg, 20 tablets)	8.2	15.0	-83%	8.2	15.0
	SP (525 mg, 3 tablets)	3.1	11.3	-266%	6.2	11.3
	Mebendazole (100 mg, 6 tablets)	2.5	4.5	-83%	2.5	4.5

*Lowest government monthly salary in 2000 = TSH 40,000

**Monthly household per capita income in 2000: Ruvuma = TSH 7,800; Singida = TSH 4,258

The simulated client scenarios also gathered information on treatment cost. Data collectors were asked to note the prices they were charged for the course of treatment recommended. The simulated client scenarios also gathered information on treatment cost. Data collectors were asked to note the prices they were charged for the course of treatment recommended. Findings indicate that while the median cost of treatment decreased for both DLDBs and ADDOs, malaria treatment prices dropped by 44 percent among ADDO facilities, while the price decrease in

Singida DLDBs was only 9 percent. Overall, DLDBs in Singida charged 250 percent more for a median course of malaria treatment than did ADDOs. (Figure 25 below).

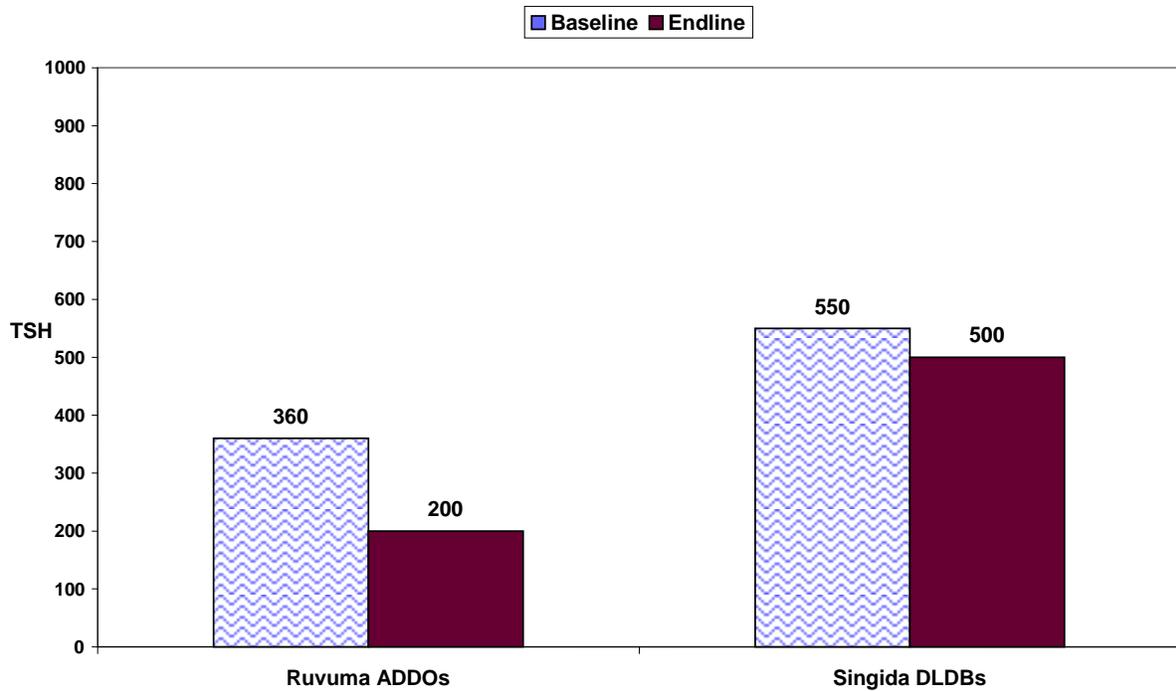


Figure 25. Comparison of median prices of malaria treatment Ruvuma ADDOs and Singida DLDBs at baseline and endline.

Endline URTI median treatment prices were compared with the median price charged at DLDBs in the 2001 SEAM assessment. While treatment prices increased for both study groups, they increased more among Singida DLDBs (43 percent) than ADDOs (29 percent) (Figure 26).

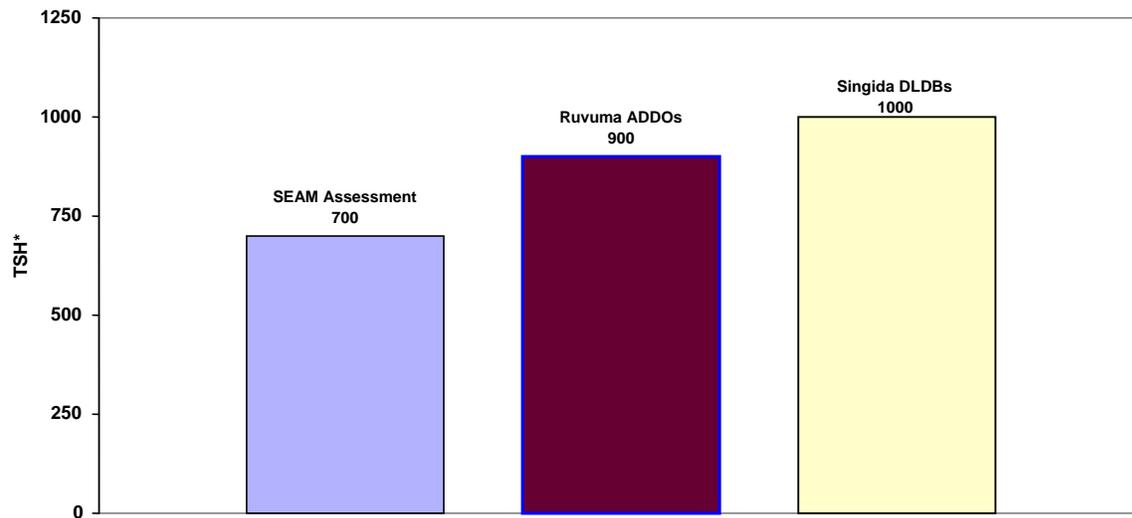


Figure 26. Median price per treatment of URTI in Ruvuma ADDOs and Singida DLDBs (Compared to 2001 SEAM assessment DLDBs as baseline).

Client Perceptions of Prices

A key question in the exit interview asked clients to rate the prices of the drugs they purchased that day. The responses show that 63 percent of ADDO clients rated prices as “good” or “excellent” compared to 56 percent of DLDB clients (Figure 27). In addition, few clients listed prices as a reason they visited either ADDOs or DLDBs. When asked to provide suggested improvements to the shops, only four percent of clients at each shop recommended lowering prices. Overall responses on prices are very similar for the ADDO clients and DLDB clients.

This supports the finding among participants of the February stakeholder workshop that prices were not a major concern among clients, prices are in line with national prices, and price increases have not hindered access. What the survey did not ascertain is if some individuals may not be coming at all to the ADDOs for pharmaceutical services because they cannot afford to pay.

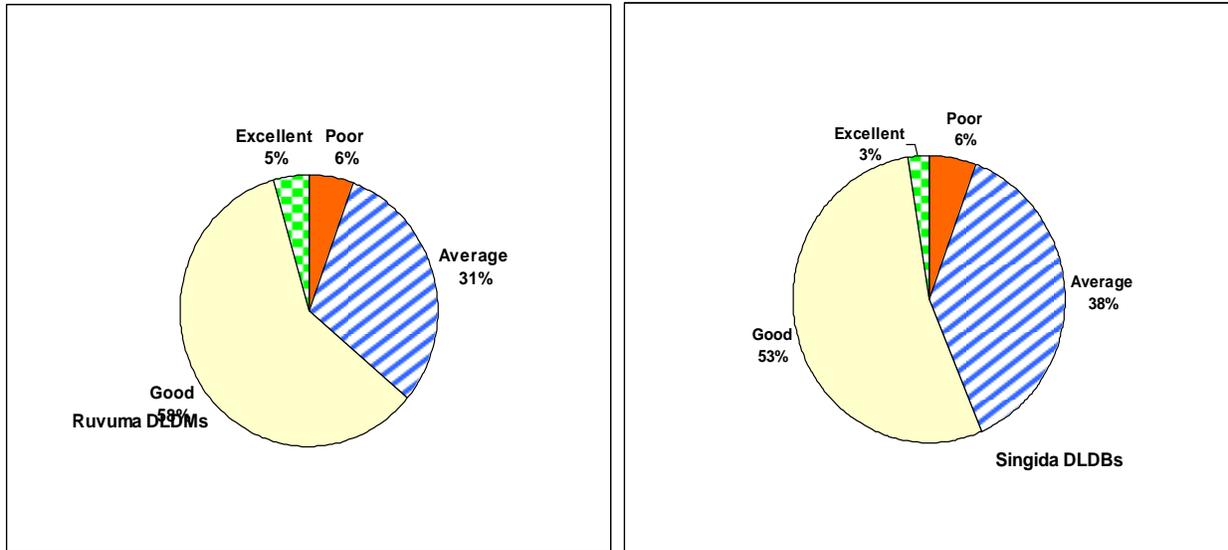


Figure 27. Respondent ratings of price of drugs in Ruvuma ADDOs and Singida DLDBs.

Did SEAM provide satisfactory and acceptable services to clients?

Overall Experience

The evaluation defined acceptability, a key component of the access framework, in terms of client’s satisfaction with services. As such, the client exit interview tool asked clients to rate certain aspects of their experience as they left the shop.

Five clients were interviewed at each shop as they left and were asked a series of 21 questions. Pilot testing of the exit survey tool identified reluctance among clients to rate shops negatively. For this reason, the rating scale was adjusted to provide one negative response and three levels of positive response—*poor*, *average*, *good*, and *excellent*. As previous discussion of the exit interview results show, a very small proportion of respondents replied “poor” to any of the questions. Therefore, much of the analysis centers on differences among responses of “average,” “good,” and “excellent.”

To ascertain overall satisfaction, the final questions in the survey asked clients to rate their whole experience at the shop that day. No clients felt the experience had been “poor,” while more DLDB clients rated the experience as “average” (12 percent) than did ADDO clients (4 percent). Approximately the same number of clients rated the experience as good at both ADDOs (83 percent) and DLDBs (84 percent). In turn, 13 percent of ADDO clients found the experience to be “excellent” while only 4 percent of DLDBs accorded shops an “excellent” rating.

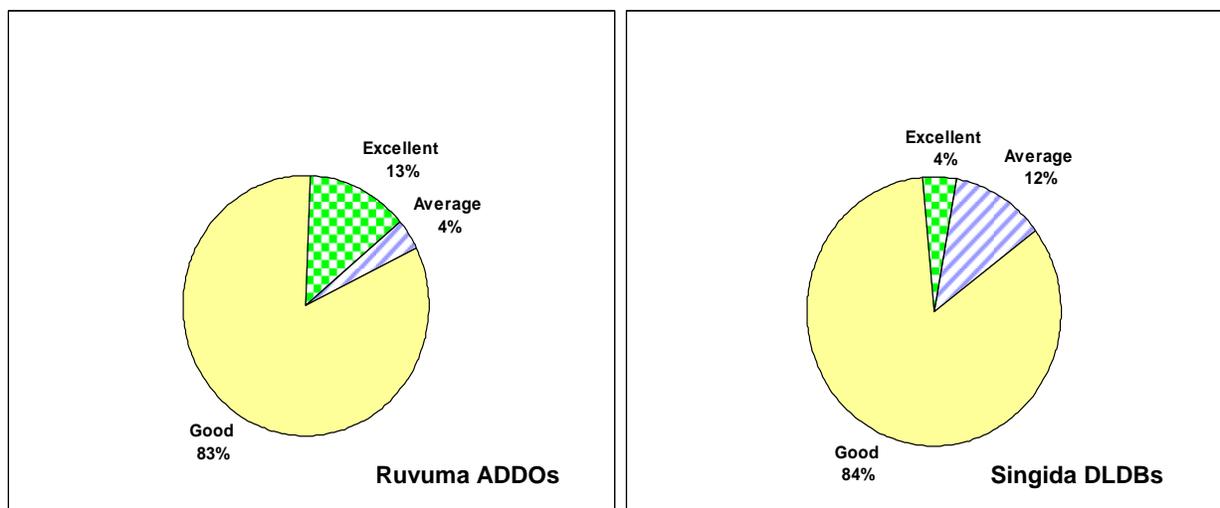


Figure 28. Respondent ratings of overall quality of experience in Ruvuma ADDOs and Singida DLDBS.

Shop Preferences

At the start of the interview, clients were asked, “Why did you come to this store instead of going to others?” Among ADDO clients, 38 percent cited proximity, 28 percent cited service quality, and 15 percent mentioned convenience. Other responses included loyalty and referral (13 percent), availability of medicines (7 percent), and prices (4 percent).

Among DLDB clients, 41 percent cited nearness, 23 percent cited service quality, and 17 percent mentioned convenience. Other responses included loyalty and referral (16 percent), availability of medicines (10 percent), and prices (4 percent).

Clients were also asked, “Do you prefer this store for purchasing drugs or supplies?” Eighty percent or more of clients at both types of shops reported that they preferred the shops they had just exited. When asked why they preferred the shop, the quality of services was listed as a key reason for 66 percent of ADDO clients and 47 percent of DLDB clients. Location was the second most important reason for preferring the shop and was mentioned by 31 percent of DLDB clients and 27 percent of ADDO clients. Other reasons listed were availability (12 percent for ADDOs and 16 percent for DLDBs) and price (6 percent for both ADDOs and DLDBs)

Over 80 percent of clients reported that they were able to purchase what they had come to the shop to buy. Few (5 percent) reported having had a problem with the shop at any time (Figure 29).

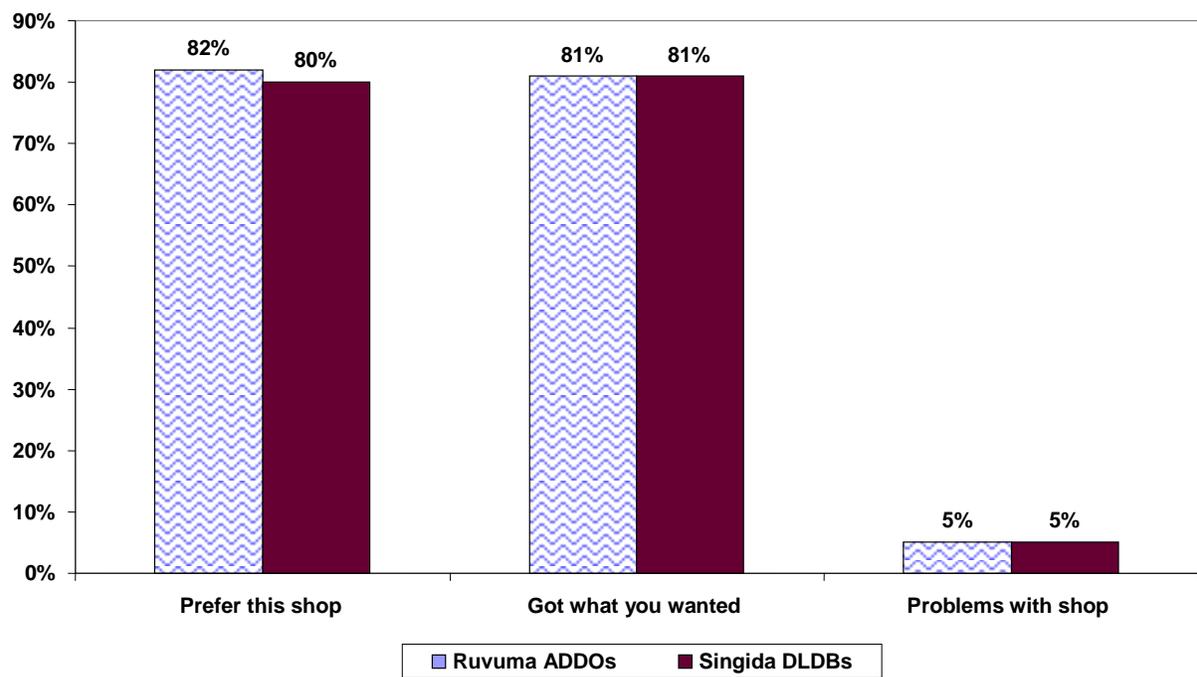


Figure 29. Percentage of “yes” responses to preferences and problems with Ruvuma ADDOs and Singida DLDBs.

Summary of Key Evaluation Findings

Accredited Dispensing Drug Outlet (ADDO) Network			Study Design and Key Metrics		
Program Target: 80 ADDOs accredited and operating in Ruvuma by mid-2005			Program Actual: 151 ADDOs accredited and operating by August 2005		
Design for Performance and Impact Evaluation			Pre-post comparison of intervention group with DLDBs in control districts in Singida		
Demonstration/Pilot Regions Evaluated			Ruvuma <ul style="list-style-type: none"> • 70 baseline DLDB facilities visited • 50 endline ADDO facilities visited 		
Comparison/Control Regions Evaluated			Singida <ul style="list-style-type: none"> • 76 baseline DLDB facilities visited • 60 endline DLDB facilities visited 		
Service Characteristic and Access Dimension: Availability					
Outcome Indicator: % of a set of tracer items in stock (Part I and Part II Medicines)					
Intervention Ruvuma	61%	80%	+31%	<p>According to Tanzania regulation, Part II drugs are non-prescription drugs and may be sold without a prescription by DLDB (Part II shops) or pharmacies (Part I shops). Part I drugs are prescription drugs and, at baseline, were only allowed to be dispensed against a prescription by Part I shops. At the time of the ADDO program there was a revision to this regulation that specifically allows ADDOs to sell certain Part I medicines. At the time of the endline survey, all of the Part I items on the tracer list were approved for sale in ADDOs but were not approved for sale by DLDB.</p> <p>Key reasons cited for improved availability in the February 2005 stakeholder meeting include:</p> <ul style="list-style-type: none"> • Authorizing ADDOs to carry some Part I tracer items • Programmatic financial support • Training for resource management 	<p>Pre-post comparison of a set of 20 tracer items</p> <p>Baseline March 2003</p> <p>Intervention 70 DLDB Ruvuma Region</p> <p>Control 76 DLDB Singida Region</p> <hr/> <p>Endline November 2004</p> <p>Intervention 50 ADDOs Ruvuma Region</p> <p>Control 60 DLDB Singida Region</p>
Control Singida	47%	53%	+13%		

				from MEDA	
				<ul style="list-style-type: none"> Establishment of a reputable wholesaler in the Ruvuma region 	
Service Characteristic and Access Dimension: Quality of Products					
Outcome Indicator: % of items sampled that were registered with the TFDA or locally manufactured					
Intervention Ruvuma	74%	98%	+32%	Improvements in both regions due to increased TFDA capacity to register drugs and inspect facilities for illegal products. Also, a strengthened legitimate market encouraged more locally produced goods, which the TFDA considers equivalent to registration.	Pre-post comparison of 10 drugs whose manufacture information was gathered Baseline March 2003 Intervention 70 DLDB Ruvuma Region Control 76 DLDB Singida Region <hr/> Endline November 2004 Intervention 50 ADDOs Ruvuma Region Control 60 DLDB Singida Region
Control Singida	70%	90%	+29%		
Control Singida	71%	90%	+27%		
Service Characteristic and Access Dimension: Quality of Services (Appropriateness of Recommendations) (malaria)					
Outcome Indicator: % encounters in which appropriate first-line antimalarial was sold for treatment of malaria					
Intervention Ruvuma	16%	32%	+100%	ADDOs and controls both experienced an increase in dispensing of appropriate antimalarial treatment, although results still need improvement. Participants of the February 2005 stakeholder workshop identified a need to emphasize the malaria component of ADDO training in future rollouts and for	Baseline March 2003 Intervention 69 DLDB Ruvuma Region Control 77 DLDB Singida Region
Control Singida	29%	48%	+66%		

				continuing education activities.	Endline November 2004 Intervention 50 ADDOs Ruvuma Region Control 61 DLDB Singida Region
Outcome Indicator: % encounters in which appropriate first-line antimalarial was dispensed exactly according to STGs for treatment of malaria					
Intervention Ruvuma	6%	24%	+300%		
Control Singida	9%	21%	+133%		
Outcome Indicator: % encounters in which any antimalarial was sold for treatment of malaria					
Intervention Ruvuma	54%	46%	-15%	The decrease in any antimalarial sold in Ruvuma was due to a 93% decrease in dispensing of the third-line treatment, quinine (30% vs. 2%).	
Control Singida	74%	77%	+4%		
Outcome Indicator: % encounters in which any antimalarial was sold or recommended for treatment of malaria					
No antimalarials were recommended, but not sold.					
Outcome Indicator: % encounters in which the attendant did NOT refer the client to a doctor or clinic					
Intervention Ruvuma	58%	38%	-34%	Medical personnel interpreted the increased rate of referrals as evidence of the efforts of ADDO dispensers to conduct business ethically and professionally; however, the goal is for dispensers to recognize and treat uncomplicated childhood malaria. Future training should focus on building these skills.	
Control Singida	70%	68%	-3%		
Service Characteristic and Access Dimension: Quality of Services (Appropriateness of Recommendations) (URTI)					
Outcome Indicator: % encounters in which an antibiotic was NOT sold or recommended for treatment of URTI					
Intervention	2001	86%	+41%	Antibiotics are not the recommended	Baseline

Ruvuma	DLDB: 61%			treatment for URTI. ADDOs in Ruvuma now have a legal right to sell selected antibiotics and are selling them more responsibly than in 2001, while DLDB, including those in Singida, the control region, are still legally restricted from selling prescription drugs. However, without baseline data it is difficult to associate the endline results with the intervention.	February–May 2001 SEAM Tanzania Country Assessment 33 DLDB in multiple regions Endline November 2004 Intervention 49 ADDOs Ruvuma Region Control 59 DLDB Singida Region
Control Singida	—	75%	-13% (compared with ADDOs)		
Outcome Indicator: % encounters in which the attendant did NOT refer the client to a doctor or clinic (URTI)					
Intervention Ruvuma	—	65%			
Control Singida	—	86%	+32% (compared to ADDOs)		
Service Characteristic and Access Dimension: Quality of Services (Dispensing Communications)					
Outcome Indicator: % encounters in which attendant provided instructions on how to take the medication (malaria)					
Intervention Ruvuma	81%	60%	-26%	Although the ADDO attendants had some improvement in assessing a child's malaria, dispensing communication needs additional focus in training.	See above for Malaria and URTI scenarios
Control Singida	77%	77%	0%		
Outcome Indicator: % encounters in which attendant provided instructions on how to take the medication (URTI)					
Intervention Ruvuma	2001 assessment 88%	78%	-11%		
Control Singida	—	78%	0% (compared to ADDOs)		

Outcome Indicator: % encounters in which attendant gave information on possible problems with malaria medications (danger signs)					
Intervention Ruvuma	3%	4%	+33%	Very few ADDO or DLDB attendants gave the client information on danger signs related to the medication.	
Control Singida	7%	2%	-71%		
Outcome Indicator: % encounters in which attendant gave information on possible problems with URTI medications (danger signs)					
Intervention Ruvuma	—	20%	+185% (compared to controls)		
Control Singida	—	7%			
Outcome Indicator: % encounters in which attendant asked about the symptoms of the child <u>and</u> any medications the child may have taken (malaria)					
Intervention Ruvuma	25%	30%	+20%	The ideal scenario would be for the shop keeper to ask the client questions about the symptoms and medication history. In the malaria simulated client, there was a 20% increase in the number of attendants of ADDOs who asked about both symptoms and medications, while there was a 19% decrease among DLDB attendants.	
Control Singida	54%	44%	-19%		
Outcome Indicator: % encounters in which attendant asked about the symptoms of the child <u>and</u> any medications the child may have taken (URTI)					
Intervention Ruvuma	—	37%	+85% (compared to controls)		
Control Singida	—	20%			
Service Characteristic and Access Dimension: Affordability					
Outcome Indicator: Average % difference in median price to patients between ADDOs and DLDB for a set of tracer items (Part I and Part II Medicines)					

Intervention Ruvuma	—	TSH 195	0% difference	<p>Though average median prices increased slightly from baseline to endline in both regions, prices in Ruvuma are more in line with national market prices than they had been. The average median price for a set of tracer items was the same at both Ruvuma ADDOs and Singida DLDB at endline.</p> <p>Endline patient register data show that the customer base has remained stable, suggesting that prices have not affected sales. The consensus of regional stakeholders is that the increase in prices has not impacted access in Ruvuma.</p>	<p>Pre-post comparison of a set of 20 tracer items Sample sizes for each individual median drug price vary depending on how many shops had the item available on the date of the visit.</p> <p>Baseline March 2003</p> <p>Intervention 70 DLDB Ruvuma Region</p> <p>Control 76 DLDB Singida Region</p> <hr/> <p>Endline November 2004</p> <p>Intervention 50 ADDOs Ruvuma Region</p> <p>Control 60 DLDB Singida Region</p>
Control Singida	—	TSH 195			
Outcome Indicator: Median cost for malaria treatment					
Intervention Ruvuma	—	TSH 200	-60% compared to controls		
Control Singida	—	TSH 500			
Outcome Indicator: Median cost for URTI treatment					
Intervention Ruvuma	—	TSH 900	-10% compared to controls		
Control	—	TSH 1000			

Singida					
Service Characteristic and Access Dimension: Acceptability/Satisfaction					
Outcome Indicator: % of customers who expressed satisfaction with service (Customer rating of overall quality of experience)					
Intervention Ruvuma	—	Average: 4% Good: 83% Excellent: 13%	9% more clients rated ADDOs as <i>excellent</i> regarding overall quality of experience	Though client perceptions of ADDOs were generally better, other dispensing communication indicators show that ADDO attendants need additional training and monitoring in this area.	The 21-question survey tool assessed overall satisfaction as well as other perceptions of service and quality Baseline None <hr/> Endline November 2004 Intervention 50 ADDOs Ruvuma Region Control 60 DLDB Singida Region
Control Singida	—	Average: 12% Good: 84% Excellent: 4%			
Outcome Indicator: % of customers who expressed satisfaction with information received					
Intervention Ruvuma	—	Poor: 1% Average: 4% Good: 67% Excellent: 28%	13% more clients rated ADDOs as <i>excellent</i> regarding quality of drug information		
Control Singida	—	Poor: 3% Average: 5% Good: 77% Excellent: 15%			
Outcome Indicator: % of customers who expressed satisfaction with knowledge of dispensers					
Intervention Ruvuma	—	Average: 5% Good: 69% Excellent: 26%	10% more clients rated ADDOs as <i>excellent</i> regarding attendant knowledge/expertise		
Control Singida	—	Poor: 1% Average:			

		16% Good: 67% Excellent: 16%			
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Evaluating Sustainability and Financing of the ADDO Program

In addition to SEAM’s formal evaluation of the affect of the ADDO program on accessibility to essential medicines, studies were conducted to measure parameters related to the sustainability of current successes in the ADDO program—especially affecting the program’s expansion and rollout to other regions. These parameters included the strength of the business model and the effectiveness of the regulatory framework that supports the ADDO program.

Assessment of the ADDO Business Plan

In an effort to gauge the impact of its support to ADDO businesses, MEDA proposed a simple business assessment to compare the performance of ADDOs before and after being accredited. This survey was not part of the original project design, but was proposed as a way to test whether this business-support component of the program should be included in any rollout of the pilot. The relatively small sample was not ideal (23 businesses, or 17 percent of the total number of ADDOs, participated), but it included old and new businesses in both urban and rural areas of the Mbinga district.

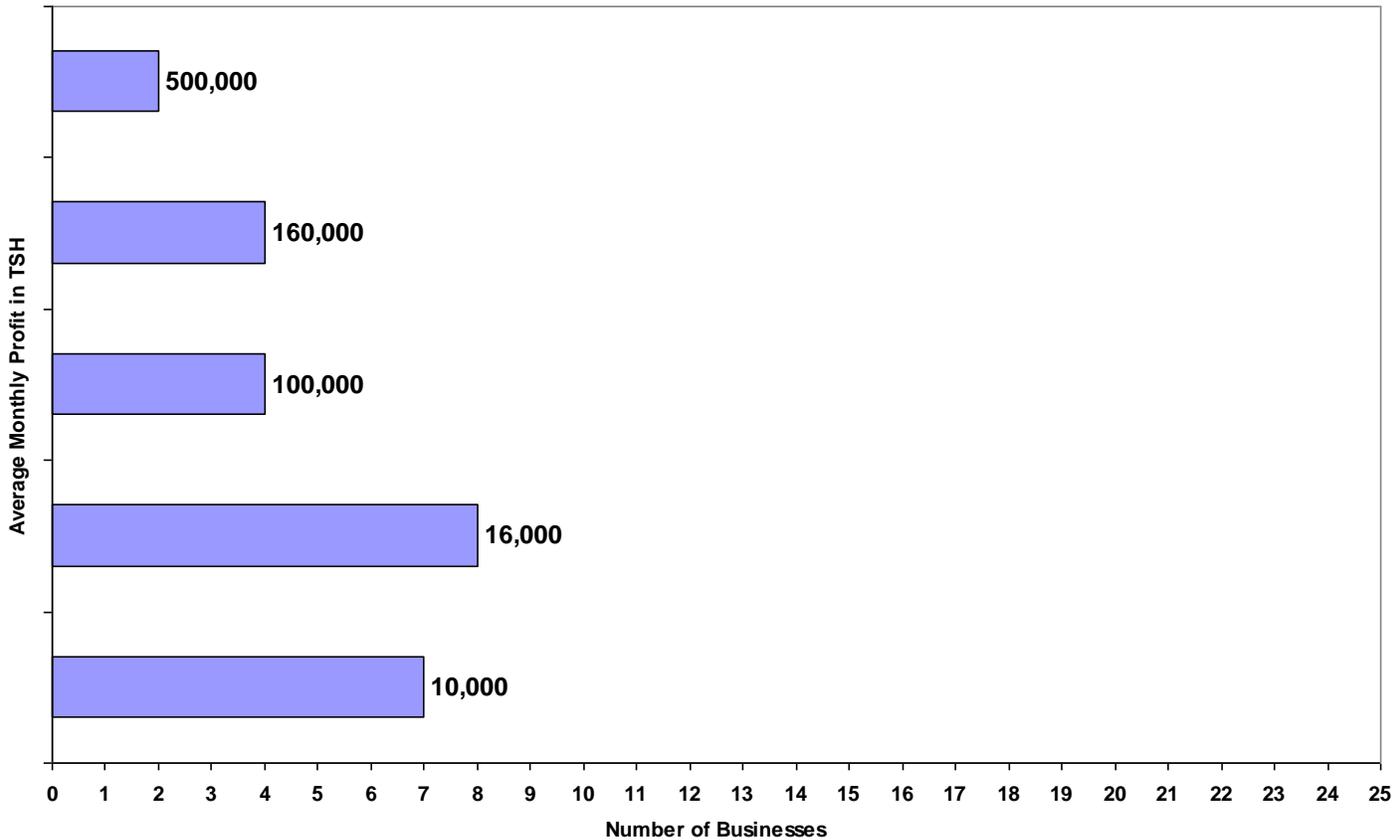
The study objectives were to gauge the impact of business support provided to small private drug shops through the ADDO program and to assess whether these private drug shops, with appropriate support, could afford and sustainably implement the investments necessary to increase the quality of their pharmaceutical services.

The study methodology is summarized as follows—

- A team of three MEDA staff with experience in monitoring and evaluation of urban and rural businesses visited 33 of the 36 private drug shops that had applied for accreditation in the Mbinga area.
- Data on business status and practices was gathered through interviews, on-site observation, and a questionnaire.
- A similar MEDA team returned to the Mbinga district eight months later, gathering information using the same tools applied during the initial assessment.
- Only 23 of the 33 shops that participated in the baseline survey could be reached for follow-up. Of the 10 shops that could not be visited—
 - One had been shut down by the authorities.
 - Two were temporarily closed.
 - Four shop owners had traveled outside of Mbinga.
 - Three could not be reached due to rain and transport difficulties.
- Therefore, only results from the 23 shops that were visited in both the baseline and follow-up surveys are available. These 23 shops represent about 17 percent of the total number of ADDOs participating in the program.
- About one-third of the businesses participating in the survey were start-up businesses.
- All research was conducted in Swahili.

Study results are split into six different categories—

Figure 30. Average Monthly Profits of DLDM Businesses in Mbinga



Financial Record Keeping

- The percentage of businesses that keep financial books increased from 48 to 96 percent.
- Business owners cited the following reasons for wanting to keep financial records—
 - To determine if the business is operating at a profit or a loss
 - To examine business progress
 - To track whether income is increasing or decreasing
 - To determine how much stock is purchased and sold (stock management)
 - To establish operating costs
 - To help in negotiating taxes with the Tanzania Revenue Authority

Profitability

- All businesses were able to gauge profitability, and the majority was earning a profit every month. (Figure 30).
- Forty-three percent of respondents reported an increase in profits; 17 percent reported a decrease in profits; 39 percent reported no change.

Access to Financial Services

- ADDO owners' access to financial services has increased since the baseline survey.
- ADDO owners have been able to reduce their reliance on friends, family, and savings to finance their businesses.

Purchasing Decisions

- ADDOs are purchasing from a wider range of suppliers, most of whom are local.

- Local access makes the supply of drugs cheaper in absolute terms and in terms of opportunity cost (e.g., purchasing supplies in the capital city can involve a 12-hour bus ride each way).
- The diversification of suppliers lowers the shops' exposure to risk (e.g., fluctuations in price and stock availability from a single supplier).

Improved Service to Customers

- Higher-quality services are being provided by professional dispensers.
- A wider range of approved drugs and a larger number of recognizable brands are available.
- The shops have a more reliable, constant supply of drugs and non-drug items.
- Signage is much more common and more attractive.
- Shops are cleaner and have better ventilation and/or better climate control.
- Operating hours have been extended to be more convenient for customers.
- Licenses and certificates are clearly displayed.
- Several businesses have created a place for customers to sit while waiting for service.
- Some customers are allowed to buy on credit.
- Two owners have initiated post-sales follow-up, which has helped to build long-term relationships with customers.
- One owner visits sick patients door-to-door for home treatment.

Benefits of Becoming an ADDO

- Ninety-six percent of shop owners mentioned access to business training as one of the benefits of being an ADDO.
- Owners ranked the most important benefits of participation in the ADDO Program as follows—
 - Increase in customers
 - Ability to provide better advice and guidance to customers
 - Free advertising obtained as part of the Duka la Dawa Muhimu marketing campaign
 - Ability to sell a wider range of drugs
 - Increase in profits
 - Access to business training
 - Access to dispenser training
 - Lower taxes
 - Access to credit

In conclusion, all but one business owner believed that it was worth the investment to become an ADDO, and this was despite the fact that 78 percent of all ADDO owners went into debt to finance their accreditation investments. This observation is particularly important given the initial concerns that the investment required by ADDOs to deliver higher-quality pharmaceutical services might be too great for the businesses to support. Therefore, the research suggests that, with appropriate support to business owners—including training, ongoing monitoring, and links to financial service providers—small drug shops can improve the quality of their products and services and do so in a profitable, and therefore sustainable, manner.

Assessment of ADDO Regulatory System

The sustainability of the ADDO program requires close regulation of both ADDOs and DLDBs to ensure adherence to established standards. However, because it does not have the resources to adequately inspect and report on all drug shops, the TFDA developed and implemented a decentralized system of regulation where local government, acting on behalf of the TFDA, is responsible for local regulation, including licensing and inspection.

A study carried out by TFDA¹⁰ found that administrative structures, reporting systems, roles and responsibilities, and financial mechanisms for supporting local government regulation were still in process of being finalized, and that not all systems were fully effective. However, regional and district drug technical committees had been formed in all Ruvuma districts and basic regulatory functions were being carried out. These include licensing, inspecting shops, documenting problems, and taking remedial actions where necessary.

The study also concluded that regulations governing ADDOs were widely accepted and broadly in line with requirements. Some revisions to the list of authorized prescription drugs were recommended, however, as well as changes in the structure of the district and regional committees in order to enhance their efficiency and effectiveness.

As part of its plans to strengthen and sustain regulation, TFDA plans to establish an ADDO unit within the TFDA. As the ADDO program is rolled out into new regions and districts, this unit will be responsible for overseeing, coordinating, and supporting all regulatory activities. Rolling out this program to all regions in Tanzania would be a massive undertaking, requiring this special ADDO unit to—

- Coordinate all program activities and resources directed to the implementation of the program
- Coordinate activities of all district drug technical committees
- Coordinate inspections, supervisions, training, and continuing education
- Carry out review or coordinate reviews of various program materials such as regulations and standards and training materials
- Serve as a central unit for reference and contacts

Evaluation Workshop

A stakeholder workshop was held in January 2005 in Bagamoyo, Tanzania, to review the preliminary findings. Participants requested additional analyses that were prepared in January and February in preparation for a second stakeholder workshop.

¹⁰ TFDA. 2005. Report of the assessment of the effectiveness of the duka la dawa muhimu (DLDM) regulatory system and acceptability of the programme in Ruvuma Region.

TFDA and SEAM organized a broader stakeholder workshop to review the program evaluation results. Held in February 2005, the workshop included local and national stakeholders as well as SEAM Program staff. The objectives of the workshop were to—

- Develop common understanding of the findings from the ADDO Program evaluation process
- Agree on explanations for what contributed to differences, changes, and achievements
- Discuss implications and develop ideas and options to take forward what had been learned

After discussions of the evaluation findings, the end of the workshop focused on specifically what it would take to roll the ADDO program out to the rest of the country. The participants broke into working groups to consider the following issues—

- Regulation
- Training and continuing education
- Supervision, monitoring, and improvement
- Supply, market, and business support
- Promotion, sensitization, and political support
- Coverage and roll out choices
- Resource mobilization

The workshop was an important way to share and discuss the initiation and development of ADDO program with key stakeholders and to focus on the issues inherent in rolling out the program to the rest of Tanzania. The workshop was the culmination of the program's efforts to maximize stakeholder participation. A summary of stakeholders' listing of ADDO program strengths is in Box 8.

Box 8. Program Strengths as Reported by Regional and District Stakeholders

- Participatory approach (involved political leaders too)
- Professionals doing supportive supervision
- Leadership teamwork
- District Councils do practical/applied work also (inspectors)
- Very fair District Drug Technical Committees and decision making
- Involved all stakeholders from the beginning (owners, leaders, dispensers, consumers)
- ADDO regulations—decentralized inspection, licensing—are clear
- Dispenser training
- Ability to “transcend” bureaucratic systems
- Sensitized everyone
- Respected what came from the local level (e.g., *Duka la Dawa Muhimu* name)
- Worked to be accepted by all levels

SUMMARY AND LESSONS LEARNED

Program Development

- Much research shows that the private retail sector is an important source of access to pharmaceuticals in developing countries, including Tanzania. What had not been established before the SEAM Program in Tanzania was the possibility of raising a broad range of product quality and service standards simultaneously within the private drug sector. Previous interventions in retail drug outlets tended to focus on single diseases or were otherwise limited in ambition due to a lack of time and resources. **Perhaps for the first time, SEAM worked with the shops in a holistic fashion, as an integral part of the national and local healthcare and economic sectors, and addressed the interests of a wide range of individual and group stakeholders to comprehensively raise standards in the retail drug sector.** The approach has established that pharmaceutical services in developing countries can be improved substantially through training, accreditation, and regulation of private-sector drug sellers, and to the surprise of many, drugs that were normally prescription-only can be managed responsibly by dispensers with a minimum level of training.
- At the beginning of the program, the complexities were not well understood; however, detailed planning and consultations made it clear that the program was far more comprehensive than traditional interventions, such as dispenser training in a small group of drug shops. Instead, it was a dynamic system that cut across public and private sectors comprised of institutions and stakeholders with interests that were not always well understood or mutually consistent; the stakeholders represented a cross-section of society and government, especially at local level. It became quickly apparent that significant time and resources would have to be invested in (1) undertaking formative research on stakeholder attitudes and interests, and (2) drawing all major stakeholders into the design, planning, and management of the program. This research/participatory approach became a central feature of the ADDO program that gave stakeholders a sense of ownership and gave SEAM a solid understanding of the complexities of the drug shop world (e.g., role in public health, place in local society and economy, supply systems, business financing and operations, public and other stakeholder expectations, regulatory strengths and weaknesses). **The key to the ADDO program achievements has been the broad-based support from all stakeholders from the public and private sectors built through a participatory approach to the project's design and implementation.**
- Equally important were key government stakeholders' flexibility and willingness to take risks on the program, most notably the TFDA and Chief Medical Officer, who often spoke for the Ministry of Health. Without their willingness to broaden the range of medicines that could be legally sold through ADDOs, for example, the program would have folded. It was fortuitous that new food and drug legislation was passing through parliament at the beginning of the SEAM Program and that the TFDA was willing and able to amend the bill to authorize the establishment of ADDOs.
- Without the willing involvement of the shop owners, the program could not have advanced. Therefore, **SEAM made a great deal of effort to understand the motivations and**

problems of the shop owners and, to the extent possible, incorporate their requirements into the basic program design. A crucial factor to gaining shop owner acceptance was broadening the range of drugs legally approved for sale in the ADDOs to include certain prescription medications. The SEAM Program also addressed owners' concerns about licensing procedures and taxes. While gaining concessions in what ADDOs could legally sell was undoubtedly vital to their owners' involvement, it was not always necessary to address every owner's demand successfully as long as they saw serious efforts made to accommodate them. For example, the program made little progress in the area of taxation, but a core group of shop owners was still willing to take an initial risk.

- Although regulatory and economic incentives were important for securing the participation of shop owners, political buy-in from local and national leaders was equally important. Some local leaders had a genuine interest in and commitment to the program; however, most saw it as an opportunity to enhance their reputations and political careers, while others went along because it quickly developed beyond the point where they could neither oppose nor ignore it. This momentum also drew previously reluctant or skeptical shop owners into the program. During the initial assessment phase, two or three key officials developed a wholehearted interest, while the Minister of Health's later enthusiastic involvement sealed the commitment of the MOH and TFDA and Ruvuma officials. Although widespread commitment appeared strong without the Minister's involvement, it did prevent other government stakeholders from opting out of the program. **Program support, therefore, developed across the full spectrum of the political and administrative sectors of government, from national to regional to district to ward.** Equally important, owners were attracted by the visibility of the political and administrative involvement, as well as by the prospect of legitimizing the previously illicit aspects of their business; they anticipated that both would increase their shops' profitability.
- Though the SEAM Program's strong relationships with the government was an essential aspect to the program's success, relations between SEAM and the TFDA and MOH were not always smooth. Tanzania was selected as a SEAM target country in part because the TFDA, as represented by its Director General, was an ambitious, forward-looking institution with visionary leadership that was willing to try something innovative, like the ADDO program. Initially, the TFDA Director General's personal involvement and her leadership role greatly facilitated interactions and general progress. As the program matured, it benefited from the continued involvement of the Director General; her flexibility and willingness to actively find solutions to problems and ensure the program continued to move forward were essential ingredients in the day-to-day management of the ADDO program. When the Director General of the TFDA was not personally involved, however, timely progress became more difficult to achieve. **Any complex intervention such as the ADDO program requires managers who not only have the necessary professional respect and technical experience, but who are willing and able to actively lead and manage the program through difficult situations, such as were sometimes encountered in Tanzania.**
- The flexibility and understanding of the Bill & Melinda Gates Foundation and senior SEAM management were crucial factors in the success of an innovative and complex program like the ADDO program, which had no blueprint to follow. **As funding agents, the light touch**

and flexibility of the Bill & Melinda Gates Foundation allowed SEAM to adjust the program’s design, work plans, and budgets swiftly in response to new understanding, insights, and problems as they arose. Plans and changes to those plans were made responsibly after consultation with the home office and Tanzanian partners, but the process was generally efficient and flexible.

- An initial assessment suggested that the existence of DLDBs together with the available local government and regulatory structure would provide the basis on which to launch the ADDO program. Though these existing structures were indispensable, by themselves they would have been inadequate to establish ADDOs. **The innovative and experimental nature of the ADDO program did not only mean that new structures and systems had to be developed (such as accreditation, supervision, strengthened links between local and central authorities, and microlending outside of traditional finance institutions), but also that existing structures had to be used in new ways (such as TFDA delegating shop inspections to ward level).** The open-minded and intrinsically experimental nature of the ADDO approach needs to be understood by anyone seeking to replicate the approach elsewhere. A willingness to take risks, make mistakes, learn from them, and revise plans on the basis of the lessons learned needs to be imbued into the philosophy and working practices of all partners involved.
- Because of the complex nature of the ADDO program, full implementation cannot fit into the typical development program time frame of three to five years. **Carrying out the work on a national scale requires a long-term vision, together with the resources over that time frame.** The problem is that long time frames do not fit easily with the expectations and operations of donors, governments, or technical agents like MSH. Nevertheless, expecting quick results undermines the work, and if the time and resource requirement is not feasible, then the question should be whether to attempt an ADDO-type project.

Development and Approval of ADDO Standards

- The ADDO standards emerged from a prolonged process of balancing competing interests through formal and informal consultation with all stakeholders. A team drawn from TFDA, MOH, local government officials, and MSH wrote the final draft, which was the culmination of the consultation process. **The wide acceptance of the final approved standards is a testament to the participatory process—all groups’ needs were taken seriously, and all groups were prepared to compromise in order to accommodate others’ interests.**
- Drug quality improved through the ADDO program. While new standards that improved shop conditions probably contributed, SEAM used product registration, rather than the intrinsic condition of the tablet, as a measure of quality. However, legalizing the sale of prescription drugs did enable legitimate, licensed wholesalers to sell such products to these shops legally for the first time. No longer needing to buy from questionable sources, the shops were able to buy drugs openly and, because of successful TFDA efforts over the previous years to strengthen the registration system, they generally bought drugs that were approved for sale by the TFDA. Improvements were also recorded in the control region, Singida, which probably reflects the broader improvements achieved by the TFDA, but since Singida shops were still

not allowed to sell prescription drugs, they continued to have some problems that had been largely eliminated in Ruvuma. **Therefore, a well-functioning registration system combined with the legalization of commercial activities that promote public health (e.g., selling common prescription drugs that are unavailable in public facilities) are vital underpinnings of efforts to improve product quality at the retail outlet level, such as ADDOs.** Compared to this, shop conditions are less important.

- **Standards should not be overly prescriptive and should allow flexibility; some standards should be guidelines that can be adopted and adapted to suit specific local conditions.** For example, the ADDO standards stipulate that each shop must employ two dispensers with a contract of employment with the owner. In practice, many owners balked at this provision, especially in poorer areas where sales were small, and attracting and keeping certified dispensers was difficult. In those areas where shops had only one dispenser, authorities understood the financial and practical difficulty of employing a second dispenser and simply ignored the infraction. Similar points can be made in relation to building standards that dictated the number and dimension of rooms, for example.

Training and Continuing Education

- Ideally, ADDO dispensers would have had a health or pharmacy background at the level of nurse or midwife or pharmacy assistant. The reality of the labor market, however, was that the pool of available labor largely comprised nurse assistants with one year of training. This created difficult questions including whether the health authorities would accept workers at the level of nurse assistant dispensing prescription drugs and if nurse assistants could acquire the basic knowledge and dispensing competence necessary for the ADDO program. The first issue was overcome because the reality of Tanzania is such that there was no alternative if sufficient dispensers were to be found for ADDOs; **a key lesson for other countries is to understand labor market realities and build human resource plans on that reality.** The second issue is more complex. SEAM showed that it is possible to train nurse assistants to a basic level of competence through traditional training methods, which has been critical to the success of the ADDOs. However, there are a number of training problems that the SEAM Program was not able to overcome with the time and resources available, especially when considering possible scale up. These include—
 - The length and cost of a training course. Because the dispensers started with so little training, the course was long and therefore expensive. The trainees' natural thirst for knowledge added pressure to this situation. The problem is how to shorten the course, which is vital for ongoing sustainability, without jeopardizing the quality of the training.
 - The ability to maintain skills following the training. Supervision and continuing education will be indispensable part of the sustainability of the ADDO program, but the challenge is how to do it on a mass scale.

Both of these raise a central question about how to approach the rollout of a complex and costly program in a resource- and leadership-poor setting.

- Initially the dispenser training program was largely pharmacy-based. Eventually, the program allocated a couple of days to communication skills. It became clear, especially during supervision, however, that not only was this a part of the course that the students enjoyed, but that it was essential in providing the skills that they needed in their daily interaction with customers. Often, dispensers would have the technical knowledge needed to assess a patient and recommend a medicine, but lacked the communication skills to explain it to the patient. **Over time, the importance of training time committed to communication skills and to supervision increased.** This shift improved both formal and on-the-job training, but at the price of lengthening the already long course and adding to the supervisory burden.
- **MEDA’s Basic Foundation Course in Business Management for ADDO owners was another useful course that was not pharmacy-based. It covered skills such as maintaining books and other records, inventory management, marketing, and pricing for profit.** Based on MEDA’s follow-up assessment of 23 ADDOs, the owners had greatly improved their record-keeping practices—96 percent were keeping regular business records, compared to less than half before the training. In addition, ADDO owners reported using new marketing practices to attract and keep customers as well as abandoning old strategies that were not working so well. Another finding was that although ADDO owners were regularly supervising their shops, the frequency was somewhat less than before the training; therefore, this is an area that may need more emphasis in future business training sessions. Overall, 96 percent of ADDO owners rated “access to business training” as a benefit of joining the ADDO program.
- Given the problems with garnering the resources to provide supportive supervision and regulatory monitoring by the TFDA and local government, the ADDO program sought to train ADDO/pharmacy ethics to dispensers and owners to provide a platform for self-regulation. The SEAM experience was that dispensers especially took this very seriously and worked hard to follow the guidelines. The training gave them a professional pride that was shared by their families and communities. The graduation ceremonies sealed their newfound status in the community; their adherence to ADDO dispensing ethics was a way of bolstering and advertising this pride and status. In this regard, **having nurse assistants as dispensers might have been helpful, as they took a pride in their work and newly gained knowledge that might have been missing in more highly qualified individuals.** This pride in being a respected professional in the community did not always produce the desired results (e.g., too many referrals for malaria), but it arguably was the bedrock for maintaining dispensing standards in the presence of weak regulation and supervision.
- The central problem with training is how to cover all the ground necessary in a reasonable time scale at an affordable cost. SEAM paid for all training costs during project time, but this is not sustainable. **How to minimize costs and then share or pass them on to the students remains an important issue to address—especially with a large-scale rollout.**

Advocacy and Development of Ownership

- Primarily, the owners were engaged by (1) the prospect of making more money through selling prescription drugs, and (2) not wanting to miss the bandwagon once the ADDOs were

up and running. Additionally, in interviews, ADDO owners ranked the increase in customers, the free advertising as part of the *Duka la Dawa Muhimu* marketing campaign, and the ability to provide better advice and guidance to customers as the greatest benefits of accreditation.

- Because there were no financial institutions willing to offer loans to these shops at the start of the program (e.g., larger banks required collateral and microlending groups in Ruvuma were lacking), SEAM persuaded the Summa Foundation to provide seed money for loans and contracted with MEDA for administration. Without this support, the program would not have been able to offer a loan product, which would have made it difficult, if not impossible, for some shops to become ADDOs. Nevertheless, the management and administration of the Summa/MEDA loans was onerous and not replicable on a large scale. It was therefore vital to use the success of the lending as a means of introducing ADDO shop owners to established finance institutions (National Microfinance Bank, for example) and persuading the National Microfinance Bank to accept ADDO owners as customers, which MEDA was able to achieve successfully. SEAM had anticipated that access to loans would be more of a vital incentive for shop owners, but although 41 shops did take out loans, and some more than one loan, most instead drew on private resources to make the necessary investments. This loan incentive was not as much in demand as thought during the planning and design of the program. However, for those owners who did take loans, their repayment performance was excellent. **By the end of the program, most ADDO owners were able to access financial services from local service providers. Improved business performance and increased access to credit decreases ADDO dependence on family, friends, and savings.** This is an important lesson in terms of judging the financial responsibility of these types of small businesses.
- The costs of transition from DLDB to ADDO appear not to have affected the price of drugs. Because there are many shops, competition was probably a limiting factor. **The SEAM Program opted not to try to control prices because of the difficulty in such an environment, and allowing the market to set prices appears to have been a successful strategy for maintaining broad affordability.** Based on the evaluation results, prices in Ruvuma did increase over the baseline, but generally, baseline prices on many products had been well below general market prices in the rest of the country. By legalizing prescription drugs for the ADDO market, owners then bought stock from licensed wholesalers, which meant they paid normal market prices and passed them on to customers. That the number of customers coming to ADDOs did not decline over the life of the project is a further indicator that the increase in prices in Ruvuma did not adversely affect affordability.

Regulation and Monitoring

- Regulation is vital for a number of reasons, including ensuring the adherence to standards and—just as importantly—making sure shops that are not ADDOs do not continue illegal activities that provides unfair competition, such as selling prescription drugs. **A multi-pronged approach is needed for effective regulation: central and local government, if possible; self-regulation; professional bodies; and other sources that were not part of the SEAM Program, such as local NGOs.** The regulatory system must be designed to fit with national and local conditions. However, if the existing regulatory system is weak and lacks resources to improve, a combination of basic training, professional pride, continuing

education, and supportive supervision may be enough to ensure good service in retail drug shops, even without effective government regulation and inspection. This situation might benefit from a franchise-type of a system to provide adequate supervision.

- Effective regulation will be an ongoing matter of importance for any drug shop improvement project, whether it is an ADDO-style accreditation or franchise model. In the latter model, regulation is done in-house by the franchisor (a real advantage of franchises over ADDOs), but with accreditation, government authorities need to be involved in regulatory activities, such as the development of standards and licensing. **However, in places where government resources are limited, monitoring and inspection can be decentralized.** It was clear from the beginning that the TFDA, working in their traditional, centralized fashion, would not be able to conduct the regular inspections that would be needed for the ADDO program. During the initial mapping work, SEAM discovered a number of subdistrict-level officials who were already visiting drug shops in their areas and taking actions based on obvious regulation violations. This opened the possibility for TFDA to work through local government channels and led to the development of a decentralized model for inspection and licensing overseen by TFDA. TFDA had some problems with initiating the decentralized inspection program; for example, training was done late in the process; TFDA support to local governments was not as readily available as it needed to be; and local inspectors were hesitant to do inspections without an accompanying TFDA official. Local governments were more likely to take their own initiative if they had strong leadership from district commissioners or district medical officers, but these initiatives tended to be ad hoc and uncoordinated.
- **A lack of human resources and financing for the inspection activities were problematic, both obtaining the actual money for inspections and developing a secure mechanism for getting the money to inspectors and ensuring it was not diverted for other purposes.** SEAM agreed to pay for the inspections and set up an arrangement to send the money to TFDA, who was supposed to channel it to District Councils who oversaw local inspectors. However, this arrangement collapsed when TFDA was unable to (1) establish a secure mechanism for channeling funds to local government beyond an informal arrangement for the first tranche, and (2) meet the reporting requirements for accounting for the first tranche.
- Resource constraints at TFDA meant that they were constantly unable to provide adequate staffing for the ADDO work. Although initially two people were dedicated to ADDO work, for the last few years of the program, TFDA had only one person dedicated. **Involved and active leadership, adequate staffing, financing for travel, and effective mechanisms for providing financial and technical support to local governments are essential if governments are to provide effective regulation and oversee shop activities.**
- **Even where government is doing what it can, forms of self-regulation are likely to be important, but no less difficult to achieve. One mechanism that has potential is to work through trade and/or commercial groups, such as shop owners' associations,** for example. Unfortunately, the Ruvuma Drug Shop Owners Association (RUDOAA) did not get off the ground due to internal friction among members, administrative weaknesses, and poor leadership, in spite of substantial support from SEAM. A second association was beginning to operate in Mbinga towards the end of the SEAM Program that showed more promise.

Recognizing the importance of regulation as well as the difficulty in making regulation effective is worth building into the program from the beginning. Pharmaceutical societies could, in principle, also play a role, but in Tanzania (and in many developing countries), these professional societies are too small and weak to provide substantial help with ongoing supervision or regulation.

- **An important regulatory advance was TFDA’s authorization of a new level of wholesaler, called the ADDO Restricted Wholesaler.** This wholesaling business opened up the potential for legitimate wholesalers to start operations in more remote areas that had not previously had easy access to these important drug sources. By improving availability, this type of innovation helps the development of the pharmaceutical market to support upgraded drug shops.

Marketing and Promotion

- **A marketing strategy is essential if consumers are to recognize the ADDO program’s quality brand and purchase their medicines through such “branded” shops.** Customers can be educated on what constitutes quality in retail drug shops and why visiting an ADDO can make a difference to their health. A communications plan for the brand includes performing a market analysis, developing key communications messages for different groups of customers, and identifying and implementing communications activities using print and other media, such as radio announcements.
- **Developing a marketing strategy requires marketing expertise,** and SEAM benefited from contracting with a professional consultant with a social marketing background. The consultant was able to lead SEAM step-by-step through the various stages to the final marketing plan. SEAM hired a local advertising company to develop the marketing campaign. However, the company did not have the creative expertise to carry this out, so in practice, they took care of practicalities, such as taking photos for posters and billboards, managing the placement of newspaper ads, and recording and broadcasting radio spots. TFDA and program managers ended up being more involved than anticipated with developing the creative ideas, such as the branding and logo creation..
- **The evaluation of the SEAM Program did not include the impact of the marketing program, but program managers are convinced that the marketing campaign was a vital part of the work,** which was substantiated by anecdotal evidence. Research, especially at the household level, would have provided more information on the exact nature of its impact. However, even with a lack of formal research, it was clear that not all parts of the marketing campaign were effective. In particular, the newspaper ads were not very useful, because the strategy relied on national newspapers to advertise a regionalized intervention in a place where few read the newspaper. Radio spots seemed to have been the most effective at raising public understanding of basic drug use issues. In an informal poll conducted by the Chief Medical Officer in Songea, people referred to radio spots when asked about how they knew about ADDOs. It was the “take the full dose” radio spot that earned the ADDOs their nickname in Songea—*duka la dose kamili* or “full dose shops.”

CONCLUSIONS

This is an ethical professional service. Those who are hungry for riches should not venture into it.

These shops have greatly helped people. I believe many peoples' health have improved through the *Duka la Dawu Muhimu* service. Good health encourages a person to work well and productively. This approach should be replicated throughout the nation.

The ADDO program has brought about remarkable change and great reform. Services are of good quality, presentable, and appreciated by the community.

This project saves people. The Ministry of Health should continue it. Although I have seen many projects, I have yet to see one which has brought such benefits. Those who have accepted *Duka la Dawu Muhimu* have great hope in it.

—Concluding thoughts from stakeholder interviews

The ADDO program was able to achieve its goals. It addressed the major access problems identified in the 2001 Tanzania assessment, especially in rural, periurban, and other disadvantaged settings.

The overall assessment of the ADDO program by the TFDA, MOH, and local and regional government representatives who participated in the February 2005 ADDO evaluation workshop was that the project has been a very positive experience and has contributed significantly to improving both access to essential drugs and rational drug use in the Ruvuma region. However, the impact of a nationwide ADDO approach on the pharmaceutical sector—and subsequently on society as a whole—promises to provide a model framework for private-sector pharmaceutical delivery in the developing world. Stakeholders agreed that the ADDO program provides a multidimensional approach with the following anticipated benefits—

- Improving basic access to essential prescription and nonprescription medicines and pharmacy services in the retail sector
- Putting the private pharmaceutical sector under stricter regulatory control without jeopardizing essential services
- Stimulating economic development (old shops improved, new shops opened, income for owners and sellers, wholesaling market and infrastructure)
- Opening new avenues for public health interventions (artemisinin-based combination therapy for malaria, child health, HIV/AIDS programs)
- Diminishing the scope of criminal activity in the pharmaceutical market
- Expanding legitimate availability of important groups of prescription drugs in a way that reduces potential inappropriate use
- Building on local government and health sector reform to strengthen local government, build better links between the central and local governments, and empower grass roots institutions

It is these broad societal and health sector benefits that underpin the justification for the level of investment, time, and commitment that will be needed to take ADDOs nationwide.

The MOH and TFDA would like to roll out ADDOs to all regions of the country as quickly as possible and has established plans and budgets to begin that process in cooperation with their donor partners. Nevertheless, it is estimated that rolling out the ADDO program across Tanzania would possibly take up to 10 years with in-country implementation costs for an average-sized region, like Iringa, being about USD 1.9 million and an additional USD 1.5 million for microfinancing and international technical assistance (if needed—it is anticipated that these costs will decrease dramatically after several rollouts). Once mature, the estimated annual cost of maintaining the program would be approximately USD 80,000 per region (not including any microfinancing costs, if needed at all). The scale of commitment required from government and donors is therefore enormous.

The ADDO experience has also deepened the Ministry of Health's understanding of the nature and importance of the private sector, which contributes directly to an important MOH strategy for improving access to public health services, namely the development of public-private partnerships. The MOH and TFDA recognize that this is a challenging, complex, and costly program that will require significant support from government and its partners in the donor community. Major challenges to be overcome relate to training and continuing education, supervision, and regulation, as well as ensuring the full commitment of all stakeholders in each region. A fully regulated, comprehensive private sector pharmaceutical services system in Tanzania will 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 MOH and TFDA are convinced that rolling out the ADDO program to all areas of the country is warranted. While acknowledging the significant costs and time needed for a full national implementation, the broad benefits are judged to justify these. This program, when fully rolled out, will have placed Tanzania in a unique position regarding access and availability of quality drugs and pharmaceutical services to the population, at all levels and settings.

Annex I. SEAM Advisory Committee Members

MSH has convened a group of expert volunteers from around the world to provide advice in implementing and sustaining the SEAM Program.

The members of the SEAM Advisory Committee are—

Oscar Arias Sánchez, Fundación Arias para la Paz y el Progreso Humano, San José, Costa Rica

Zafrullah Chowdhury, Gonoshasthaya Kendra (the People's Health Center), Dhaka, Bangladesh

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Graham Dukes, Professor Emeritus, Drug Policy Studies, University of Groningen, the Netherlands, and Adviser, Drug Policy Studies, University of Oslo, Norway

Jaime Galvez Tan, University of the Philippines, Manila, the Philippines

Jorge Jimenez de la Jara, Former Chair, Executive Board, WHO, and Professor of Public Health, Universidad Católica, Santiago, Chile

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Annex 2. Evaluation Tracer List

Part I Drugs	Amoxicillin 250 mg caps
	Benzyl penicillin powder injection
	Co-trimoxazole 480 mg tabs
	Diclofenac 25/50 mg tabs
	Doxycycline 100 mg caps
	Metronidazole 200 mg tabs
	Nystatin suspension
	Praziquantel 600 mg tabs
	Phenoxyethyl penicillin 250 mg tabs
	Procaine penicillin fortified injection
	Quinine 300 mg tabs
	Erythromycin 250 mg tabs
	Contraceptive pill
	Indomethacin 25 mg caps
Part II Drugs	Amodiaquine 200 mg tabs
	Sulfadoxine/pyrimethamine 525 mg tabs
	Sulfamethopyrazine/pyrimethamine 525 mg tabs
	Mebendazole 100 mg tabs
	Salbutamol 4 mg tabs
	Paracetamol 500 mg tabs

Annex 3. ADDO Project Evaluation Workshop, Kunduchi, February 22–24, 2005

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