The ADDO Program: Taking a Health Systems Approach to Build a Sustainable Program

In creating the accredited drug dispensing outlet (ADDO) program, the Tanzania Food and Drugs Authority (TFDA)[1] and the Pharmacy Council, as the program champions, and Management Sciences for Health, as the technical partner, designed the program to be sustainable. The ADDO model has to address all aspects of the drug shop enterprise effectively to ensure access[2] to quality medicines and pharmaceutical services—the physical premises, medicine inventory management, providers' capacity and interactions with consumers, and appropriateness of services provided. In addition, the larger health system in which drug shops operate needed to be strengthened, including product licensing and supply, training, and inspection. Major program components that contributed to this design included—

- Developing accreditation based on ministry of health-instituted standards and regulations
- Creating a strong public sector-based regulatory and inspection system and strengthening local regulatory processes and capacity to support central level actions on a continuing basis
- Developing drug shop owners' business skills; facilitating the availability of commercial incentives (e.g., access to loans); and authorizing the legal sale of a limited list of high-quality prescription medicines in accredited shops
- Building skills and changing behavior of dispensing staff through training, education, and supervision
- Improving customers' awareness of product and service quality and the importance of appropriate medicine use through marketing and public education.

Although private medicine retailers are key players in promoting access to medicines in low- and middle-income countries, pharmacies and drug shops are mostly missing from countries' health strategies, policies, and monitoring. This is no longer the case in Tanzania.

Policy Catalyst

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

Financial and Program Sustainability

As the ADDO program scaled up, financing concerns shifted from implementation to shop profitability—shops needed to stay in business to continue to provide access to medicines in the community, and local

[1] Until 2011, TFDA was the regulatory authority responsible for ADDOs; a regulatory change placed the ongoing responsibility with the Pharmacy Council.

[2] The key access dimensions as defined in the access framework include physical availability, affordability, geographic accessibility and acceptability (or satisfaction).

governments needed to budget for program costs, which the government now mandates. Our research[3] has shown that shops are profitable. Although the pilot program in Ruvuma linked the majority of owners with microfinance institutions to help them become accredited, few owners in other regions used that option to finance their shop renovations or operations (2%). The majority of owners (79%) reinvested their ADDO business profits, while 11% reported tapping personal savings for business financial needs; 8% used a combination of options[4].

Sustainability of the ADDO program is strengthened by two critical enhancements—institutionalization of training and establishment of ADDO associations. In addition, sustainability is linked to the ongoing quality and relevance of services that are provided by ADDOs.

Training institutionalization

The sustainability of the ADDO program depends to a large extent on the availability of well-trained and skilled dispensers. Since inception, for various reasons, a number of ADDOs have lost their trained dispensers leading to closures. Due to the attrition of trained dispensers and the need for owners to staff new ADDOs, there is increasing demand for more dispensers to be trained. In addition, ADDO dispensers who have already been trained in the earlier stages of the program require refresher training to reinforce existing knowledge and acquaint themselves with new developments in the field.

In response to this situation, the Pharmacy Council of Tanzania has committed to institutionalizing the ADDO dispenser training program, with the aim of complementing government efforts to improve access to essential medicines and quality pharmaceutical services in rural and peri-urban areas. The Sustainable Drug Seller Initiatives project has been facilitating these activities.

We have developed criteria for identifying and selecting training institutions to offer ADDO dispenser and owner training programs, and seven training institutions have been capacitated to offer the programs. The institutions are located in each of the following zones—

- Lake Zone (Zonal Health Resource Centre, Mwanza)
- Northern Zone (Kilimanjaro School of Pharmacy, Moshi)
- Central Zone (Public Health Nursing School, Morogoro)
- Southern Highlands Zone (Ruaha University College, Iringa)
- Southern Zone (Mtwara Clinical Officers Training Centre)
- Western Zone (Kigoma Clinical Officers Training Centre)
- Eastern Zone (St. Peter's College of Health Sciences, Dar es Salaam)

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[3] EADSI (East African Drug Seller Initiative). (2011). *East Africa Drug Seller Initiative (EADSI) Evaluation Report*. Arlington, VA: Management Sciences for Health.

[4] EADSI (East African Drug Seller Initiative). (2008). ADDO *Tanzania Situation Analysis Report: Field Data Collection Results from Morogoro, Mtwara, Rukwa, and Ruvuma*. Dar es Salaam: Management Sciences for Health.

Although a majority of ADDO trainings will be delivered by these institutions, an alternative exists for districts that are remotely located; District Health Teams can collaborate with PC to organize within-district ADDO trainings, which prevents trainees from having to travel excessively long distances.

PC oversees all training. The goal is to have enough institutions offering ADDO training opportunities across Tanzania to meet demand fully and prevent the need for district-organized trainings for remote areas. Costs of training, whether institution or district based, are now being covered completely by drug shop owners and dispensers.

Establishment of ADDO associations

In addition to the government's role in overseeing ADDO operations, MSH has been working to strengthen existing ADDO owner/dispenser professional associations and facilitate the formation of new provider associations to serve as a governance resource and a professional "voice." This work has resulted in an association toolkit that was developed through a consultative stakeholder workshop[5]. It includes operational and management tools, which are available in English and Kiswahili, that guide ADDO personnel on to how to form and register an association, mobilize financial resources, and monitor and evaluate activities.

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

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

Likewise, dispensers mentioned that the associations will—

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

[5] MSH (Management Sciences for Health). (2010). Using Associations to Assure Sustainability in Private Sector Drug Seller Initiatives in Tanzania: Final Report. Submitted to the Rockefeller Foundation. Arlington, VA: MSH.

Ensuring service delivery quality

Sustainability is linked to the ongoing quality of services that are provided by ADDOs, which needs to be ensured by regular inspections and supportive supervision, and to the relevance of services provided, which requires routine data collection to inform policy decisions.

Developing the accreditation standards was a critical part of the model design and led to the overhaul of regulations governing drug shop operations. The law requires all ADDO owners and dispensers to have a thorough understanding of standards and ethics[6]. It was amended in 2009 to accommodate the revision of the model to reflect decentralized implementation and operations—most notably, inspections.[7] As the program expanded, it quickly became clear that relying on a centralized regulatory body would not provide the capacity to conduct regular inspections. Therefore, an important aspect of revising the model was to decentralize the monitoring and inspection responsibility to the local level, with TFDA conducting inspector training and taking any regulatory actions based on local inspection input. This is now embedded in the ADDO program.

Although inspection is a critical aspect of the program, it was clear that the level of supportive supervision to owners and dispensers needed to increase. Having inspectors who have the power to close down shops for legal infractions play a dual role as supportive supervisors is obviously not ideal, but a lack of government personnel who could take over a supervisory role left a gap. MSH is now exploring how associations can provide that support through a peer supervision model that we are testing in Uganda and will adapt for Tanzanian ADDO associations to use pending Uganda's results.

People were accessing medicines from drug shops in Tanzania long before ADDOs were developed. What is different now is that whereas prescription drugs, such as antibiotics, previously were sold illicitly by

[6] The Tanzania Food, Drug and Cosmetics Act (standard and code of Ethics for Duka la Dawa Muhimu Regulation 2004.
[7] The Tanzania Food, Drug and Cosmetics Act (standard and code of Ethics for Duka la Dawa Muhimu (Amendments) Regulation 2009.

untrained shop staff, licensed ADDO dispensers are now doing so legally. Accreditation standards have broadened the list of medicines ADDOs can legally dispense to include high-quality essential prescription and nonprescription medicines that are supplied by registered distributors. Coupled with a dispenser training program on appropriate medicine use and referral, quality of care in ADDOs has improved. In addition, product quality is better; for example, during the pilot evaluation in Ruvuma, registration status of medicines was used as the indicator of the quality of drugs being sold in stores. After ADDOs were introduced, the proportion of unregistered medicines in Ruvuma was reduced by a factor of 13, from 26% to 2%[8]. In evaluations in other regions since then, very few unregistered products have been found in ADDOs. Furthermore, SDSI Objective 3 assessments in 2013 found very limited evidence of poor quality products in ADDOs, with nearly 95% of products meeting quality standards. ADDO dispensers also receive training on the importance of not selling drugs that have expired, and expiry has not been identified as a problem.

As the ADDO program has taken off, many have recognized the potential of these shops to not only increase access to essential medicines, but also to serve as a platform for community-based public health interventions, thereby increasing their relevance to the communities they serve. For example, a child health training module for dispensers includes danger signs of pneumonia in children and the appropriate action to take (co-trimoxazole[9] treatment or referral), depending on the situation presented. Other programs currently being integrated include tuberculosis case identification and referrals and reproductive health commodities and services. The SDSI mobile technology initiative, which allows for periodic ADDO reporting on select indicators, will offer Pharmacy Council and other stakeholders information on which to make policy decisions that address ADDO practices and community needs.

Stakeholder Engagement: The Linchpin of Success and Sustainability

The one critical element that has been essential to the ADDO program's success is stakeholder engagement—the successful buy-in and sustained commitment came directly from the effort, time, and resources spent to fully connect with all vital stakeholders at all levels. Involvement ranged from publicly stating support for the concept to working closely on all aspects of the program design and implementation. At the end of the pilot in Ruvuma, regional and district stakeholders reported the following program strengths—

- Use of a participatory approach that involved all stakeholders from the beginning—owners, dispensers, consumers, political leaders
- A fair and transparent process for permit application and approvals
- The dispenser training component
- Respecting and valuing community-level inputs

One major result of full stakeholder engagement was the decentralization of the implementation model; in 2008, the MOHSW mandated that local governments incorporate ADDO implementation and maintenance into their regular planning and budgeting. Another result was the development of a 2009 strategy to introduce ADDOs to urban areas, which defined the conditions under which ADDOs can be licensed to open in underserved areas of urban populations.

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[8] SEAM (Strategies for Enhancing Access to Medicines Program). (2007). Tanzania: Accredited Drug Dispensing Outlets—Duka la Dawa Muhimu. Arlington, VA: Management Sciences for Health. http://www.msh.org/seam/reports/SEAM_Final_Report_Summary-Tanzania_ADDOs.pdf

[9] Now replaced with amoxicillin.