

Background

The ADDO (accredited drug dispensing outlet) program was established in 2003 through a collaboration between the US-based nonprofit organization Management Sciences for Health (MSH) and the Tanzania Food and Drug Authority (TFDA). The program was created in response to a 2001 country assessment conducted by MSH's Strategies for Enhancing Access to Medicines (SEAM) Program, a Gates-Foundation-funded group that fosters public-private partnerships in the developing world. This assessment revealed substantial gaps in both the availability and quality of essential medicines, especially in the rural areas that account for 75% of Tanzania's population. People in these areas accessed medicines primarily through private retail shops known as *duka la dawa baridi* (DLDB), which the TFDA authorized to carry only a small list of nonprescription medications. SEAM's assessment revealed widespread illegal dispensing of essential prescription medications, many of which were of dubious quality due to the lack of oversight and unregulated channels used for distribution (SEAM 2005). Recognizing that these findings were indicative of significant unmet medical needs, the Tanzanian government worked with MSH to develop a solution that prioritized public health goals over strict regulatory compliance (Goodman et al. 2007). Rather than shut down DLDBs or remove stocks of medicines, the ADDO program focused on training DLDB employees to bring supplies and services in line with best practices, so that the shops could then be reclassified and authorized to dispense prescription medicines (CPM 2008).

Following a pilot in the Ruvuma region in 2003, the ADDO program was evaluated by SEAM in 2005 and the Danish Agency for International Development Assistance in 2006. Based on the results, the TFDA approved the program for rollout to the whole country in 2006 (MSH 2009). As of 2009, ADDO rollout was funded and initiated in 18 regions of Tanzania (Rutta 2009), and a law had been passed to decertify all DLDBs and mandate their phase out (MSH 2009). There were plans to complete rollout to all 30 regions by the end of 2012 (MSH 2012), but rollout is so far incomplete and has been slower than planned because of the "huge costs involved" (MOHSW 2009:43).

Business Model

The ADDO program is based on a public-private partnership model, with direct collaboration between the Tanzanian government and various private organizations that provide logistical and financial support. Importantly, the ADDO program does not operate on a franchise model: while shop owners and dispensers are encouraged to form regional associations in order to share best practices and improve buying power, this process is voluntary, and individual ADDO owners are private, independent entities that are solely responsible for operating their own shops (MSH 2010). A 2008 survey of shop owners revealed that profitability varied widely, with monthly revenues ranging from TZS 10,000 to TZS 500,000 (SEAM 2008). The initial training provided to shop owners and dispensers is nationally standardized, and routine oversight, including biannual inspections, is directed by the TFDA through a network of local representatives (CPM 2008). Funding is provided by the government as well as several nonprofits, including the Gates Foundation, the Rockefeller Foundation, the United States Agency for International Development, and the Global Fund (PMI 2013).

Value Delivery & Metrics

The ADDO program was designed to improve healthcare delivery for rural and peri-urban populations through four specific goals (CPM 2008:9). The first is to improve the *quality of medicines* distributed by providing access to drugs through official channels and training dispensers to recognize counterfeits. The second is to increase the *availability of medicines* by improving record keeping and providing reliable supply chains. The third is to improve the *quality of dispensing services* by training dispensers to recognize common symptoms and apply best practices for treatment. The fourth is to ensure the *affordability of medicines* by increasing shop profitability and purchasing power, and providing opportunities for subsidy partnerships. Progress toward these goals is evaluated by survey of consumer satisfaction, as well as by common quantitative metrics from routine inspections – percentage of expired or counterfeit drugs, number of drug stock outs, frequency of improper prescriptions, and median drug prices. Within the care delivery value chain (CDVC) for a given disease, the ADDO program has direct impact on the diagnosis, preparation, and therapy segments. Because ADDO trained dispensers are embedded within communities and able to interact regularly with patients to share knowledge, there is also substantial collateral impact on the monitoring and managing segments of the CDVC.

Challenges to Scale

There is little evaluation of the ADDO program from sources not affiliated with MSH and its subsidiaries. The SEAM Program produced their final report on the ADDO program in 2008 (CPM 2008). The report offered an evaluation of the ADDO program based on the quality, availability and affordability of medicines and dispensing services in participating regions. The ADDO business plan was also assessed on the basis of sustainability and support to small businesses. The

report concluded that the ADDO program reduced the percentage of unregistered medicines, increased availability of both prescription and nonprescription medicines, and improved the clients' opinion on quality of services and medicine availability. ADDOs dispensed medicines more rationally and were better at communicating facts about medicines and their use than DLDBs. The sustainability assessment found a dramatic increase in the number of store owners keeping accurate financial records after joining the ADDO program, and reported that owners experienced increased profits, better access to financial services, and diversification of medicine suppliers.

Despite these positive evaluation results for ADDO stores, a recent independent analysis concluded that there was no significant difference between ADDOs and DLDBs in terms of adherence to dispensing regulations and best practices for antibiotics (Minzi and Manyilizu 2013). The authors found that both types of drug outlets had a poor knowledge of the basic pharmacology of antibiotics, while a larger proportion of ADDOs dispensed antibiotics without prescription and did not refer patients to health facilities. A number of ADDO stores had been converted to food stores or other businesses, or had simply become inactive. The authors further identified a potential conflict of interest for the TFDA, which serves both as a training and managing agency for ADDOs and as a drug-regulatory body. This was emphasized by the observation that no ADDO store had been shut down by the TFDA due to infringement of drug regulation. The lack of supervision of the ADDOs by an external regulatory body may be the source of significant limitations for the sustainability and growth of the program.

Funding for the majority of program establishment and expansion activities came from external donors and nonprofits, while costs for program maintenance and continuous improvement were primarily the responsibility of the government. In both cases, funding limitations hampered plans (MOHSW 2009). Although SEAM has emphasized the sustainability of the ADDO business model due to increased profits and business skills of shop owners (CPM 2008), the program's heavy dependence on external funds is troubling. The business model does not appear to be as sustainable or profitable as would be needed to ensure its future survival and pragmatic expansion (MOHSW 2009).

Yet another indication of the lack of sustainability for the ADDO program is the low retention rate of drug dispensers at the program's stores. In a 2009 refresher training report, SEAM discussed a shortage of accredited drug dispensers and recommended increased dispenser training to meet the demand (SEAM 2009); this shortage was especially troubling as more than 13,000 drug dispensers have been trained as of 2012 (IPP Media 2012). Still, in 2013 an independent survey revealed dispenser dropout rate of up to 40% in ADDO stores. The high attrition rate was compensated by employing untrained individuals, thus negating a major benefit of the ADDO program. This led to improper dispensing practices and inaccurate communication of dosing or other drug-related information (Minzi and Manyilizu 2013).

Solutions & Recommendations

We have identified three aspects of the ADDO program that should be carefully addressed in order for the program to expand sustainably and reach scale. While all three areas are critical, we have prioritized them as follows:

Dependence on external funding: if external funds are no longer available for ADDO, the program does not seem able to continue. In order to address this limitation of its selling model, we recommend that ADDO: (1) partner with more multi-national organizations and local companies to strengthen its fundraising base; (2) implement more rigorous business training for shop owners; and (3) adopt a tiered price model for its services beyond medicine dispensing. Specifically, we advise that ADDO will reduce the risk of fund drying by diversifying its donor base, while it will empower business owners to increase profit by improving their management skills and diversifying revenue sources. In the latter scenario, we expect that ADDO will be in a position to support distribution of goods other than medicines to store owners who stock various essential goods alongside drugs and create a one-stop-and-shop store model.

Lack of third-party oversight: the closed feedback loop of supervision and training both conducted by the TFDA has given rise to doubts about the transparency and efficacy of ADDO inspection. We recommend that ADDO prioritize the movement of training responsibilities to the Pharmacy Council of Tanzania, which was planned in 2011 (PC 2013) but has seen little progress (IPP Media 2012). Licensure should remain the purview of the TFDA; failures of dispensing or quality regulations should result in the loss of access to subsidized prescription medicines for the noncompliant store.

Low dispenser retention rate: to tackle the loss of accredited ADDO dispensers to urban centers and private pharmacies, we recommend the creation of incentive programs in partnership with the PC, to offer dispensers the potential of store ownership and other career development opportunities. We further suggest the training of ADDO store owners toward dispenser accreditation, thus meeting the demand for dispensers despite high trainee dropout rates.

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