Accredited Drug Seller Initiatives

Background: The Start of the ADDO Program

From 2000 to 2005, the Bill & Melinda Gates Foundation funded MSH's Center for Pharmaceutical Management (CPM) to improve access to quality medicines and services at outlets that provide first-line health care for many people, especially those living in remote, underserved areas. Many people in rural Tanzania seek health care and medicines from retail drug shops, called *duka la dawa baridi*, for reasons such as convenience and drug availability. Historically, the Tanzania Food and Drugs Authority (TFDA) authorized *duka la dawa baridi* to provide nonprescription medicines. However, a 2001 assessment showed that many shops sold prescription drugs illegally and that the drug sellers were generally unqualified and untrained. In response, this program, Strategies for Enhancing Access to Medicines (SEAM), worked with TFDA to develop and launch the accredited drug dispensing outlet (ADDO) program in 2003 and pilot it in one region—Ruvuma. The goal was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in areas where few or no registered pharmacies exist.

To improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets, a holistic approach is needed that combines changing the behavior and expectations of those who use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this can be achieved by combining training, incentives, and regulatory enforcement with efforts to affect customer demand for and expectations of quality products and services. Major program activities that contribute to this strategy include—

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

By the end of the SEAM Program in 2005, the TFDA had accredited more than 150 shops in Ruvuma. Results of the pilot provided evidence that ADDOs could improve access to quality pharmaceutical products and services. The next year, the Danish Agency for International Development Assistance (Danida) funded an independent evaluation of the program and confirmed SEAM's findings. Based on those evaluations, the Ministry of Health and Social Welfare approved roll out of the ADDO concept to mainland Tanzania. Then the government signaled its embrace of the ADDO program by announcing phase-out of all unaccredited shops by 2011.

Refining the ADDO Model and Facilitating Its Scale-Up

SEAM demonstrated that private-sector drug seller initiatives based on an accreditation and regulation model were feasible and improved access to medicines, but the model did not address scaling-up issues. In addition, the lessons from SEAM showed that countries need greater efficiencies in implementation and some changes to the models to institutionalize and sustain the initiatives. To address these issues, the Gates Foundation funded the East African Drug Seller Initiative (EADSI) in 2007 to facilitate faster and more cost-effective scale-up and create a strategy to adapt and replicate initiatives in other countries. The final report for EADSI summarizes findings of our work. EADSI worked with Tanzania to decentralize ADDO scale-up, allowing multiple regions to concurrently initiate implementation, and to support sustainability. While it took Tanzania six years to roll out ADDOs in four regions using the original model, an additional 17 regions completed implementation since 2009 using the new decentralized approach. As of July 2013, ADDOs have been scaled up in all regions of Tanzania. The figure below presents a map showing ADDO coverage country-wide.

The figure in Appendix A illustrates how our drug seller initiative implementation model has evolved since the original SEAM work in Ruvuma through EADSI-generated revisions designed to make scale-up faster and less expensive. The primary change in the revised model was to decentralize implementation by using district-level teams that work simultaneously in multiple regions, rather than one national team that can only cover one region at a time. To further increase efficiency and reduce costs, the new model includes a reorganized dispenser training schedule, reduced from 45 to 26 days, and a merge of mapping and preliminary inspection activities to identify which *duka la dawa baridi* meet basic standards for converting to accredited shop status. Using the revised model has decreased rollout time from an estimated 18 months to less than 12 months per region. As a result, the estimated implementation cost reduction for donors or the government is 55% (US$ 126,000 per district compared with US$ 57,000 per district). Additional savings have resulted from a shift in program costs to the owners and dispensers, who now contribute over 40% of training and branding costs compared with

nothing in the original pilot, in addition to paying all costs associated with shop renovations and increased inventories. As the Tanzania program continues to mature, more and more of the costs, especially for training, are shifting to the private sector. For example, in 2012, over 2,000 shop owners and dispensers in Dar es Salaam fully paid for their training.

As the accredited drug seller program has taken off, many have recognized the potential of these shops to not only increase access to essential medicines, but also to serve as a platform for community-based public health interventions; for example, a child health training module for dispensers includes danger signs of pneumonia in children and the appropriate action (co-trimoxazole treatment or referral), depending on the situation presented. As a result of the increasing interest in the concept, numerous organizations and programs have played a role in expanding both the services that ADDOs provide and their geographic reach—over 9,000 ADDOs are currently serving 21 regions—covering 100% of the population. And improvements have been sustained: in 2010, 63% of malaria encounters in Ruvuma were treated according to the treatment guideline, compared to 24% in 2004 (end of Ruvuma pilot under the SEAM program), and 6% before the ADDO program started—a 950% improvement.

To be successful, efforts of this magnitude require creative partnerships and solid commitment to productive collaboration. Appendix B includes a timeline that illustrates the range of partners and donors who have contributed to the success of the ADDO program.

Replicating Accredited Drug Seller Initiatives

Under EADSI, we worked with Uganda's National Drug Authority (NDA) to adapt and replicate the ADDO model in Uganda and successfully demonstrated the adapted model in Kibaale district, under the name of Accredited Drug Shops (ADS). As with the ADDOs in Tanzania, the EADSI evaluation showed that ADS improved access and services; for example, the percentage of shops offering injections, which are illegal in drug shops, fell from 74% to 0. In response to these results and the positive response of ADS owners and dispensers and Kibaale district health officials, the NDA has allowed Kibaale to continue the program post-pilot. In addition, NDA has included ADS roll out in its five-year strategic plan.

In 2011, the Bill & Melinda Gates Foundation provided MSH with a third grant to continue efforts in Africa to involve private sector drug sellers in enhancing access to essential medicines. The goal of the Sustainable Drug Seller Initiatives (SDSI) program is to ensure the maintenance and sustainability of the public-private drug seller initiatives in Tanzania and Uganda and to introduce, adapt, and roll out an initiative in Liberia.

Collaboration and leveraging are key strategies under SDSI. In partnership with MSH's USAID-funded STRIDES for Family Health project in Uganda, SDSI and the NDA are piloting the ADS initiative in four additional districts—Kyenjojo, Kamwenge, Mityana, and Kamuli—to help increase access to family planning and maternal and child health services. As such, the following additional public health interventions have been integrated into Uganda's ADS initiative—

- Integrated community case management of childhood illness (malaria, diarrhea, pneumonia)
- Counseling on family planning; initiating oral contraceptive and condom use
- Counseling mothers on newborn care and nutrition
- Access to artemisinin-based combination therapy and insecticide-treated nets

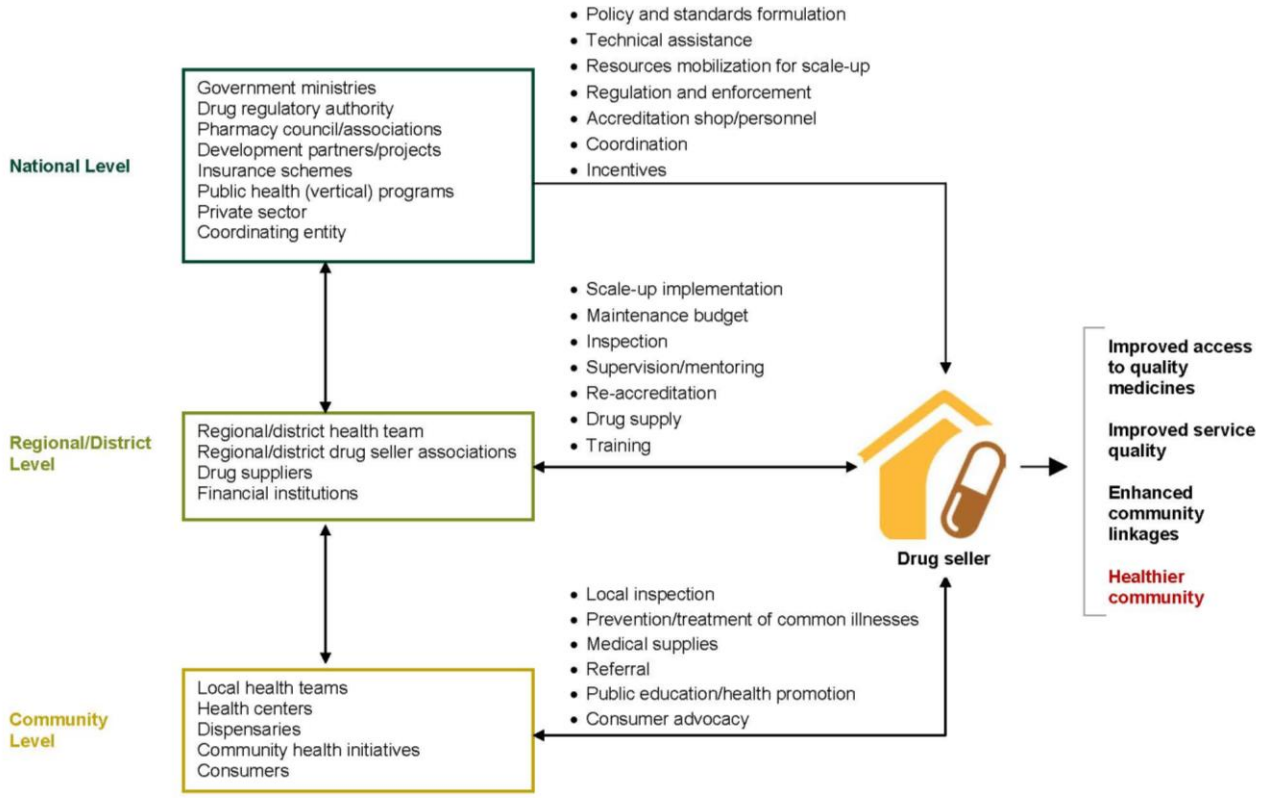
The enhanced Ugandan program was successfully launched in Mityana district on November 8, 2012 and then in Kyenjojo, Kamwenge, and Kamuli districts by year's end.

In Liberia, SDSI has worked with the Ministry of Health and Social Welfare and the Liberian Medicines and Health Products Regulatory Authority to create the Accredited Medicines Stores (AMS) program. Laws and regulations have been changed to recognize AMS, and standards have been established for both personnel and physical facilities. The focus of implementation has been Montserrado County, which includes close to 40% of the entire country's population and the majority of its drug shops. The AMS program was officially launched on February 12, 2013.

Sustaining Accredited Drug Seller Initiatives

The sustainability of a public-private model such as accreditation of drug sellers relies on an in-country, public sector "champion" to embrace the model initially, and then on the institutionalization of the model at both national and local levels. In Tanzania, for example, the TFDA took ownership of the ADDO program early on. The evolution of the program involved the development of a number of new policies that entrenched the initiative within the country's existing health structure. For example, Tanzania's National Malaria Control Programme adopted the ADDO platform as part of its national strategy to increase access to malaria treatment in the private sector, paving the way for distribution of subsidized artemisinin-based combination therapy through ADDOs and the award of a Global Fund grant to scale up the program in eight additional regions. Other significant new policies include the National Health Insurance Fund's decision to allow members to fill prescriptions at ADDOs; revision of the model to decentralized implementation at the district level; a national government mandate requiring local government incorporation of ADDO implementation and maintenance in planning and budgeting; and the Ministry of Health and Social Welfare's decision to phase out all unaccredited drug shops by 2011. All of these policies have strengthened the position of ADDOs as an important component of the country's strategy to ensure access to medicines in all areas of the country.

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



Although a national-level champion is key to a successful model launch, a mature program relies on the commitment of local officials to support inspection and supervision. In Tanzania, the decentralization of the program now requires regional and district officials to be involved from the beginning, which increases their stake in the process. In Uganda, district health officials are the focal point of implementation and maintenance, and local monitors provide ongoing review of ADS performance. Wide-ranging participation contributes to acceptance and sustainability. In terms of individual shop sustainability, our qualitative research under the EADSI program showed that ADDO and ADS owners now keep business transaction records, their shops are profitable, and they use their profits to put money back into the business. Owners cite dispenser training and their ability to sell from an expanded drug list as the biggest benefits to converting their shops to ADDOs or ADS.

Through our SDSI work in Tanzania, Uganda, and Liberia, we expect not only to expand access to medicines and treatment in an expanded population base, but to solidify the global view that initiatives to strengthen the quality of pharmaceutical products and services provided by private sector drug sellers are feasible, effective, and sustainable in multiple settings.

To assist other countries in conceptualizing and implementing an accredited drug seller initiative, planning documents and reports from our work in Tanzania and Uganda are available on the Drug Seller Initiative website. To access these documents, go to the Toolkit.

Lessons Learned and Challenges

Expanding the accredited drug seller program to other countries presents significant challenges. Although other countries express considerable interest when they learn about the program, moving forward with program development and implementation is a major decision. For example, in addition to the need for stakeholder consensus, a number of components must be successfully completed, including—

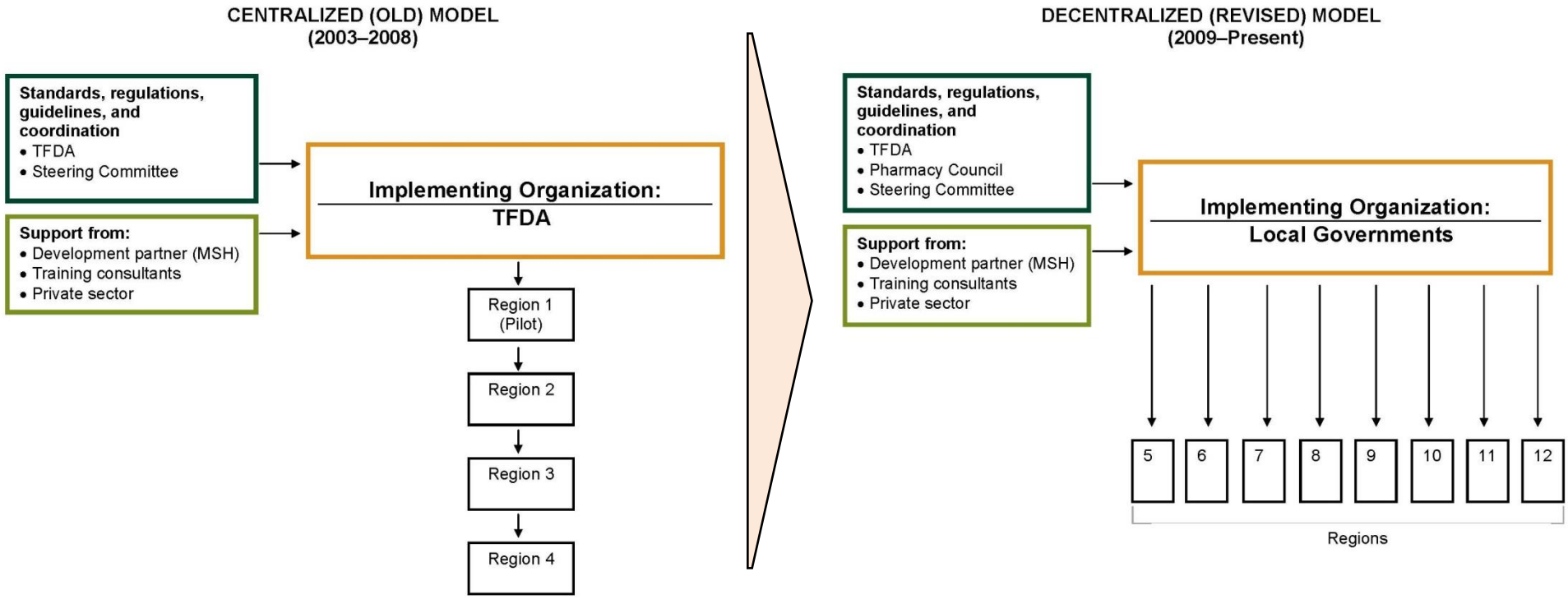
- Development of a funding strategy and mobilization of funding
- Development of standards
- Change of laws and regulations
- Development or adaptation of training and other materials
- Revamp of inspection and monitoring strategy
- Assurance of quality drug supply
- Initiation of implementation
- Sensitization of consumers
- Creation of scale-up strategy
- Development of maintenance strategy, including reaccreditation and continuing education

The process is complex, with political, legal, regulatory, professional practice, and economic challenges that must be addressed. Appendix B provides information about the number of players and time that it took to get the Tanzanian ADDO program developed and scaled up.

Developing and implementing an accredited drug seller initiative and bringing it to scale is an expensive venture. If limited funding is available and used to complete only discrete pieces of what is needed to create a sustainable whole, then failure results if interest wanes or the situation changes before all pieces can be completed. Our work in Zambia illustrates this point. Although we designed and proposed a broad-based sustainable private drug seller initiative, the World Bank could not justify the amount of money required and funded only inclusion of anti-malaria medicine and rapid diagnostic tests in the drug shop product list, along with over-the-counter medicines. With ability to sell only malaria medicines, the drug shops did not generate enough business, and many of the shop owners opted out of the program. Although a few shops continued to operate under the program, there is no impetus for scale-up and maintenance activities have not been initiated.

The means to success of a public-private initiative such as the ADDO program is key stakeholder “buy-in” and “ownership” The country must drive the activity, not the donor or the organization providing technical support to the initiative.

Appendix A. Evolution of the ADDO Initiative Implementation Model



Appendix B: ADDO Evolution Timeline

2003 Gates Foundation-funded SEAM Program and TFDA design and launch the ADDO program in the Ruvuma region

2005 SEAM Program and TFDA evaluate pilot program in Ruvuma

2006 Danida sponsored an independent evaluation of the ADDO program in Ruvuma

2006 Government of Tanzania, through the Ministry of Health and Social Welfare, approves TFDA plan to roll out ADDOs to Tanzanian mainland

2006 US Agency for International Development, through MSH's Rational Pharmaceutical Management (RPM) Plus Program, funds ADDO rollout in Morogoro region using resources from the President's Emergency Plan for AIDS Relief

2006 Government of Tanzania funds rollout in Mtwara and Rukwa regions

2006 RPM Plus Program collaborates with the Basic Support for Institutionalizing Child Survival Project to add a child health component to ADDO services

2006 National Malaria Control Programme adopts the ADDO concept as part of its national strategy to increase access to malaria treatment

2007 Tanzania's National Health Insurance Fund initiates plan that allows members to fill prescriptions at ADDOs

2007 MSH's SPS Program uses President's Malaria Initiative funds to provide subsidized artemisinin-based combination therapy (ACT) through ADDOs

2007 Global Fund to Fight AIDS, Tuberculosis and Malaria agrees to fund ADDO rollout in six to eight high-impact malaria regions to improve access to ACT for children under five; Danida also contributes funding for rollout

2007 Gates Foundation funds the East African Drug Seller Initiative (EADSI) to work with TFDA to review and revise the existing ADDO model to make nationwide scale-up more cost-efficient and to help ensure the long-term sustainability of ADDOs

2008 Gates Foundation provides EADSI with supplemental funding to evaluate ADDO rollout in Tanzania and long-term sustainability in existing ADDO regions

2008 The Prime Minister's Office for Regional Administration and Local Government mandates local governments to incorporate ADDO program implementation into their planning and budgets

2009 Rockefeller Foundation funds MSH to develop a strategy to promote program sustainability and quality through the establishment of ADDO owner and dispenser associations

2009 Local governments in Iringa, Manyara, and Mara took initiative on their own to mobilize funds to introduce ADDOs

2009 Government of Tanzania starts rolling out ADDOs to six of the eight Global Fund- and Danida-supported regions and developing a strategy to open ADDOs in urban areas

2009 The Clinton Foundation funds initial implementation activities in and Dodoma

2009 Government of Tanzania regulation is revised to phase out unaccredited drug shops (*duka la dawa baridi*) by 2011

2011 Gates Foundation funds MSH's Sustainable Drug Seller Initiatives to help ensure ADDO program sustainability, quality, and maintenance

2013 Scale-up of the ADDO program in all regions completed.