DUKA LA DAWA MUHIMU

IMPROVING
ACCESS TO ESSENTIAL MEDICINES IN TANZANIA

Role of the ADDO Program

The Context

It is at the beginning of the third millennium. Tanzania emerges from decades of struggle against poverty, illiteracy and disease, with a powerful vision of quality livelihood, good governance and a strong competitive economy – the key pillars of the National Vision 2025. However, poverty remains high. About 36% of the population lives below basic needs poverty line. Over 70% of the population resides in rural areas, the majority of which depends on less than 1 US dollar a day. In a population of 34.5 million in 2002, 10 million cases of malaria are reported each year, many of which result in hospital admission and death. About 8% of the adult population is HIV positive and 107 in every 1,000 young children die before their first birthday. Access to healthcare services is constrained by long distances to health facilities especially in rural areas and widespread shortage of essential medicines in public health facilities. Fourteen percent (14%) of the population walks for more than 10km to a public facility; 6% for more than 10km to a private drug retailer. About 76% of all pharmacies in the country are located in three major urban areas (Dar es Salaam, Arusha and Mwanza). The rural populations mainly depend on Duka la Dawa Baridi (DLDB) to access medicines and the much needed pharmaceutical services. DLDBs are Part II Poison shops licensed by the Pharmacy Board to provide non-prescription medicines only. They constitute the largest segment of formally licensed outlets for basic essential medicines. They are found in all districts in the country but not evenly spread throughout the districts. Their presence is both an opportunity and threat to quality healthcare. The shops are mostly run by unqualified staff without formal training in medicine dispensing. They also lack proper storage facilities, dispense poor quality unauthorized medicines and are generally not well regulated. As the reality of the situation of the pharmaceutical sector dawns on the regulators and policy makers, all agree that something must be done to change the situation. Shutting down DLBDs is not an option given the situation in rural areas. With support from development partners led by Management Sciences for Health (MSH), the government through Tanzania Food and Drugs Authority (formerly Pharmacy Board) embarks on a long, challenging, complex but rewarding process of transforming DLDBs into Accredited Drug Dispensing Outlets (ADDOs). The process would begin in Ruvuma Region in 2003 and cover all the regions of Tanzania Mainland by 2013. The goal is increased access to quality affordable essential medicines and pharmaceutical services in the underserved rural and peri-urban areas. This publication shares the story of the ten-year journey.

Acronyms & Abbreviations

ACT	Artemisinin-based Combination Therapy
ADDO	Accredited Drug Dispensing Outlet
ADS	Accredited Drug Shop
AIDS	Acquired Immune Deficiency Syndrome
ALu	Artemether-Lumefantrine
AMFm	Affordable Medicines Facility-malaria
AMR	Antimicrobial Resistance
AMS	Accredited Medicine Shop
ARI	Acute Respiratory Infection
ARW	ADDO Restricted Wholesaler
CCHP	Comprehensive Council Health Plan
CFDC	Council Food and Drugs Committee
CHAI	Clinton Health Access Initiative
CHF	Community Health Fund
CHMT	Council Health Management Team
CSSC	Christian Social Service Commission
DANIDA	Danish International Development Agency
D-by-D	Decentralization by Devolution
DDTAC	District Drug Technical Advisory Committee
DLDB	Duka la Dawa Baridi (Retail Cold Drug Shop)
DMO	District Medical Officer
EADSI	East African Drug Seller Initiatives
GFATM	Global Fund to Fight HIV/AIDs Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
HSPS	Health Sector Program Support
HSSP	Health Sector Strategic Plan
ICT	Information and Communication Technology
IMCI	Integrated Management of Childhood Illness
ITIDO	Innovations and Technological Ideas Development Organization
LGAs	Local Government Authorities
LMHRRA	Liberian Medicines and Health Products Regulatory Authority
M&E	Monitoring and Evaluation
MDG	Millennium Development Goal
MDGs	Millennium Development Goals
MEDA	Mennonite Development Associates
MKUKUTA	Mkakati wa Kukuza Uchumi na Kupunguza Umaskini Tanzania (National Strategy for Growth and Reduction of Poverty)

MoHSW	Ministry of Health and Social Welfare
MoU	Memorandum of Understanding
mRDT	Malaria Rapid Diagnostic Testing
MSD	Medical Stores Department
MSH	Management Sciences for Health
MUHAS	Muhimbili University of Health and Allied Sciences
NACTE	National Award Council for Technical Education
NHIF	National Health Insurance Fund
NMB	National Microfinance Bank
NMCP	National Malaria Control Program
NSGRP	National Strategy for Growth and Reduction of Poverty
NTA	National Technical Award
NTLP	National TB and Leprosy Program
ORS	Oral Rehydration Salt
OTC	Over-the-Counter
PBL	Pharmacy Board of Liberia
PC	Pharmacy Council (of Tanzania)
PMI	President's Malaria Initiative
PMO-RALG	Prime Minister's Office – Regional Administration and Local Government
PPP	Public Private Partnership
RAS	Regional Administrative Secretary
RCHS	Reproductive and Child Health Services
RDTAC	Regional Drug Technical Advisory Committee
RFDC	Regional Food and Drugs Committee
RMO	Regional Medical Officer
RPM	Rational Pharmaceutical Management
SDSI	Sustainable Drug Seller Initiatives
SEAM	Strategies for Enhancing Access to Medicines
SP	Sulfadoxine-Pyrimethamine
SPS	Strengthening Pharmaceutical Systems
STGs	Standard Treatment Guidelines
SWAp	Sector-wide Approach
TB	Tuberculosis
TFDA	Tanzania Food and Drugs Authority
THMIS	Tanzania HIV/AIDS and Malaria Indicator Survey
ToT	Trainer of Trainers
TRA	Tanzania Revenue Authority
USAID	United States of Agency for International Development
VEO	Village Executive Officer
WEO	Ward Executive Officer
WHC	Ward Health Committee

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1 Introduction

1.1 Background

Prior to introduction of the Accredited Drug Dispensing Outlets (ADDO) program in 2003, the majority of Tanzanians especially those in rural and peri-urban areas mainly relied on Part II drug stores commonly known in Swahili language as Duka la Dawa Baridi (DLDB) as their source of medicines and pharmaceutical services. Part I drug shops (pharmacies) were almost exclusively located in major urban areas, with nearly 60% of the pharmacies operating in Dar es Salaam City. This made DLDBs the most accessible sources of medicines for the nearly 75 percent of the population living in rural and peri-urban areas.

Factors such as distance to health facility, seriousness of illness, cost of treatment, perceptions of privacy and quality of health care services, as well as queuing in public health facilities, were among the reasons why citizens tended to self-diagnose common medical problems such as malaria and diarrhoea and visit DLDBs for medicines before attending a health facility. In addition, high stock-out rates of 20 to 30 percent in public primary health care facilities pushed patients to the DLDBs to obtain medicines and supplies prescribed by the public health facility providers.

Despite their popularity and preference, DLDBs posed a major public health threat. The 2001 pharmaceutical sector assessment and inspection reports by the then Pharmacy Board revealed major problems with DLDBs. Since most DLDBs operated at a small scale, they were run by unqualified staff without formal training in medicine dispensing. Most outlets lacked adequate and proper storage facilities for medicines. They dispensed poor quality Part I medicines which they were prohibited to sell under the Pharmacy Board rules.

> The 2001 comprehensive assessment of Tanzania's pharmaceutical sector revealed major access gaps in respect to drug availability primarily in the public sector and issues related to quality and affordability of products and services especially in the private retail outlets.

Each of these problems was exacerbated by inadequate enforcement of regulations, difficulty in finding reliable and legal sources of drugs and supplies, and a limited list of authorized medicines in the Part II drug outlets. The challenges, together with the increasing demand for affordable quality medicines led to the introduction of the ADDO program. The innovative program was developed by TFDA with technical assistance from the MSH's Strategies for Enhancing Access to Medicines (SEAM) program funded by the Bill and Melinda Gates Foundation.

Since inception in 2003, the program worked to improve access to affordable quality medicines and pharmaceutical services by transforming the existing DLDBs into ADDOs and accrediting new retail drug outlets to provide ADDO services. The goal is to increase access to essential medicines and pharmaceutical services in the underserved rural and peri-urban areas.

The program idea has been achieved through a combination of strategies. An all-inclusive implementation approach has been used. It involves changing the behaviour and expectations of individuals and groups that use, own, regulate or work in retail drug shops. From the piloting, ADDOs were provided with financial incentives and tailor-made training programs to address different capacity needs. All ADDOs are required by law to adhere to standards related to product and service quality in order to achieve and maintain government accreditation as well as meet client demands and expectations for quality products and services.

Within one year of piloting the program in Ruvuma Region, notable changes were observed. Two hundred and two (202) shops were accredited by TFDA in Ruvuma alone. This remarkably improved access to quality medicines and pharmaceutical services in the region. The successes of the pilot program led the Ministry of Health to approve a plan to roll out the ADDO program to three additional regions in Tanzania Mainland, beginning 2005. By June 2014, the program reached all regions on the mainland and 9,226 drug shops mapped, out of which 6,086 shops were accredited and 3,140 shops were in application process. The program had also trained over 19,140 dispensers and 3,262 drug shop inspectors.

The program represents a successful case and evidence to support Private-Public Partnerships (PPP) in delivering health related services. To enable a broader and clearer understanding of how the program evolved and worked, this publication is an attempt to capture the ADDO story, a decade old journey, how it evolved from its inception, successes and challenges but more importantly how continuous learning and adopting to new challenges and opportunities allowed the program to achieve national coverage, remain truly participatory and formally link private sector providers at the community level to primary health care facilities. The publication was produced through analysis of reports and documents as well as collection of information through field visits and interviews with key program stakeholders.

1.2 Health Sector

Over the past decade, Tanzania has made some important progress in addressing major public health needs including the control of malaria, HIV/AIDS, tuberculosis (TB) and improving reproductive and child health services. Despite the progress, there remain major challenges in sustaining and advancing the health system. Severe shortage of qualified health personnel as well as inadequate capacity to train and retain health professionals limit the quality of both public and private health services. The government still faces substantial barriers in adequate provision of quality health services especially to the 74 percent of the population living in rural areas. The health sector budget is highly dependent on external donor funding, thus threatening the government's ability to provide health care services in the absence of such support.

Ongoing national efforts to reduce these health burdens have been significant. Health remains a major priority in key development policies and strategies. Tanzania Development Vision 2025 provides direction and a philosophy for the country's long-term development. Vision 2025 identifies health as one of the priority sectors contributing to a higher quality livelihood for all Tanzanians. It outlines access to primary health care for all, reducing infant and child mortality and increasing life expectancy, as the key health goals. The 2005 National Strategy for Growth and Reduction of Poverty (NSGRP) popularly known by its Swahili acronym, MKUKUTA, is the successor to the 2000 national Poverty Reduction Strategy Paper (PRSP, 2000). The MKUKUTA is informed by the Vision 2025 and provides strategic direction for the achievement of the Millennium Development Goals (MDGs). Health falls under MKUKUTA's third cluster which focuses on improving the quality of life and social well-being of all Tanzanians. The 2007 National Health Policy provides the government's vision on long-term development of the health sector.

The government is currently implementing the third Health Sector Strategic Plan (HSSP III) covering the period between 2009 and 2015. The HSSP was developed in line with the MKUKUTA goals, the National Health Policy (2007) and the MDGs. The plan serves as a guiding document for the development of council and hospital strategic plans and annual work plans. It provides an overview of the priority strategic directions for the health sector.

To meet these national development goals, the government implements different interventions and programs to combat both infectious and non-infectious diseases. Such programmes include HIV/AIDS, malaria and TB control, as well as maternal and child health services, among others. The success of these programs, to a great extent, relies on the availability of safe, quality and effective medicines. The ADDO program was designed to complement the government and development partners' efforts in improving quality of life and wellbeing of Tanzanians by devising and implementing a well regulated private pharmaceuticals delivery system which reaches all population groups with affordable quality medicines and pharmaceutical services.

1.3 The Pharmaceutical Sector

Access to essential medicines constitutes a core part of primary health care services in Tanzania. The National Drug Policy (1991) specifically highlights the government's intention to ensure that quality, effective essential medicines reach all Tanzanians at an affordable price. Medicines and pharmaceutical products are produced by eight local manufacturing industries using imported Active Pharmaceutical Ingredients (APIs) from India and China. The local industry produces only 30% of national drug requirement while the remaining 70% is imported.

Imported and locally produced medicines are procured and distributed by the Medical Stores Department (MSD) and the 291 TFDA registered local private wholesalers. Wholesalers deliver to public health facilities through the MSD's competitive public tendering process and to private retail pharmacies and health facilities through direct private procurement processes. Manufacturers, wholesalers, sub-wholesalers, donors, and MSD are the main distributors of pharmaceuticals and medical supplies. The MSD is the predominant distributor of pharmaceuticals and medical supplies. 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 faith-based organizations. In addition to supplying government facilities, MSD has the country's most advanced pharmaceutical distribution system.

Operations of the pharmaceutical sector in Tanzania are regulated by the Tanzania Food, Drugs and Cosmetics Act which established the TFDA in 2003, and Pharmacy Act (repealed in 2011) which established the Pharmacy Council of Tanzania (PC) in 2002. Both acts replaced the Pharmaceuticals and Poisons Act No. 9 of 1978 and the related enforcement agency, the Pharmacy Board; giving way to TFDA and PC are the key regulatory authorities.

The Food, Drugs and Cosmetics Act (2003) demands registration of all pharmaceutical products in the country. The TFDA approves the registration of medicines if it considers that availability of the medicine is in the public interest, and it may authorize the sale of unregistered medicines for specified purposes. The authority grants licenses for importing, exporting, manufacturing and selling medicines under specified conditions. The Act also mandates the TFDA to regulate medicine quality, efficacy and safety; while the Pharmacy Act (2011) mandates the Pharmacy Council to oversee the training and registration of pharmaceutical personnel as well as regulation of pharmaceutical practice.

1.4 Access to Essential Medicines

Consumers access medicines from public health facilities, private and NGO facilities, pharmacies and retail drug outlets. The retail drug outlets are categorized as Part I and Part II poison shops. Part I shops (pharmacies) sell both prescription and over-the-counter (OTC) medicines. These must be owned and operated or supervised by a registered pharmacist. Exemptions are granted to dentists, veterinary surgeons, medical practitioners in the treatment of their patients, and staff members of hospital, dispensary, or similar institution, or by special exemption. Prior to the introduction of the ADDO program, Part II poison shops (DLDBs) were allowed to sell OTC medicines only and operated without supervision by a pharmacist.

> The combined turnover of DLDBs was much higher than the Ministry of Health's expenditure on essential medicines in primary health care facilities.

The DLDBs formed the largest segment of formally licensed outlets for basic essential medicines in the country. They were found in all districts though not evenly spread out in their catchment areas. They were mostly found in highly populated areas and market centres. In 2003, there were about 9000 DLDBs in the country. This figure was over 50 percent higher than equivalent figure for all public health facilities, and higher than all public, voluntary and religious facilities combined. It was estimated that the combined inventory turnover of DLDBs was higher than the Ministry of Health's expenditures on essential medicines in primary health care facilities.

1.5 The ADDO Concept

The ADDO concept originated from the 2001 comprehensive assessment of the pharmaceutical sector, conducted by the then Pharmacy Board with support from MSH through the Strategies for Enhancing Access to Essential Medicines (SEAM) program. The study focused on three key areas: (i) the population's access to essential medicines and health commodities, with emphasis on geographical accessibility, availability, quality, affordability and acceptability; (ii) opportunities for the private sector to participate in improving access to essential medicines and health commodities; and (iii) feasibility of implementing public-private sector strategies to improve access to medicines.

Since inception, the ADDO program has worked to improve access to affordable quality medicines and pharmaceutical services in the underserved rural and peri-urban areas.

The assessment revealed major access gaps in respect to drug availability, primarily in the public sector, and issues related to quality and affordability of products and services, especially in the private retail outlets. The findings showed that availability of drugs was a problem at the Medical Stores Department, especially, but not exclusively, at zonal stores outside of the Dar es Salaam zone. Availability issues also existed in public primary health care facilities and also in many hospitals, though was minimal in mission hospitals. Regarding quality of medicines and services, the study revealed that the public could not be assured of product quality for a significant proportion of medicines available in the Tanzanian market.

In light of the findings, the TFDA in collaboration with MSH identified strategies to improve the availability and quality of medicines in the public and private sectors. The strategies included: (i) converting DLDBs into accredited drug dispensing outlets to provide an increased range of products under closer regulatory monitoring and control; (ii) establishing a tiered pharmaceutical product quality assurance program; and (iii) establishing an alternative, private sector supply system to augment the MSD supply system for the public sector, other MSD clients and possibly rural retail drug outlets by providing quality, competitively priced health commodities. Priority was given to implementation of the ADDO program.

1.5.1 Description

The ADDO concept primarily focuses on changing the behaviour of the shop owners and dispensing staff by providing education, incentives and regulatory coercion. The concept also focuses on influencing client demands and expectations in terms of quality of products and services. The concept was structured around interactions that occur from the time a client decides to seek care at the drug shop.

As depicted in figure 1 below, the process begins with a decision by a client with illness to seek care. The care seeking decision is dependent on a number of factors including cultural beliefs about what type of treatment is needed for a particular illness or health condition (traditional, spiritual, modern, etc.), distance to care providers, seriousness of the illness, financial means or availability of cash, failure of previous treatments, drug availability in public facilities, perceived quality of local care providers, and provider referrals.

Thus, when a client visits an ADDO, an interaction with the drug shop dispenser begins. The dispenser is expected to listen to the client's request or description of symptoms of illness and advise him/her appropriately. Advice might include recommending and providing medicine together with an appropriate dosage 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 provider for care beyond the scope of the drug shop services. To achieve this, the dispenser requires relevant knowledge, skills and client-centred attitude that meets with the ethics in delivering quality dispensing services.

The above interactions would occur in the context of an ADDO that may also provide other products and services and is generally owned by a different individual. Owners of shops are business people and would have to be willing to invest in raising the standards of the drug shop as well as quality of pharmaceutical products and services. This would require identifying what would serve as incentives and potential returns on these investments. Owners' attitudes toward the dispenser and clients would also have to meet ethical standards for operating the business.

In order provide sustainable quality services, ADDOs require a broad support system which includes reliable sources of supplies with competitively priced products whose quality can be guaranteed. Opening up access to such sources of supply may require developing an ADDO purchasing group, facilitating access to a prime vendor or creating wholesale suppliers specifically for ADDOs but located within easily accessible centres in rural areas. Additionally, training and refresher trainings to dispensers would be critical to ensuring that the dispenser gain the necessary dispensing knowledge and skills and adhere to ethics in providing services.

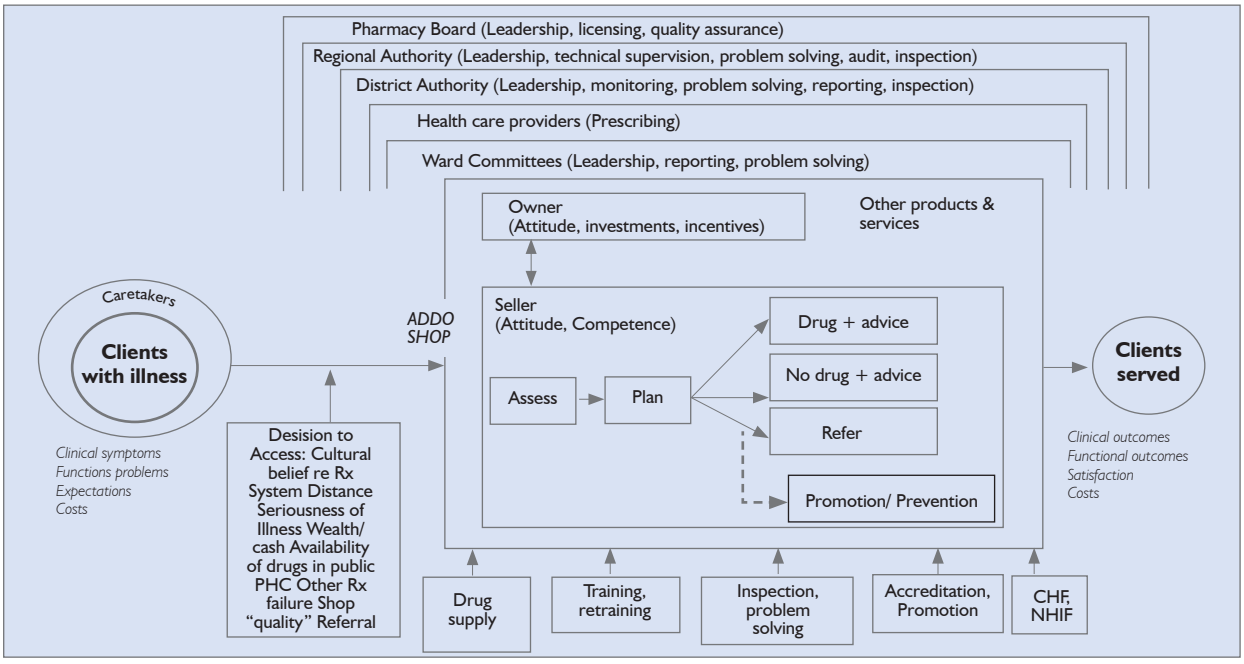
In visualizing how ADDOs would be inspected and supervised to ensure adherence to regulations and standards, it was realized that staffing levels at the then Pharmacy Board and the capacity of the then regional drug committees were insufficient to effectively perform the tasks. In light of the realities, the program design team thought an extended regulatory framework that easily reached community would be an option for more efficient regulatory monitoring and control of ADDO operations.

A new system of inspection and regulatory monitoring that engaged local government authorities at the council and wards levels, as well as regional authorities and the Pharmacy Board, would then be instituted. The system would draw upon human and financial resources already available in the councils, and align its functionality with the major local government reforms which had kicked off in Tanzania, in which financing and responsibility for social service delivery including health, were being decentralized to local authorities.

The inspection system would contribute to overall accreditation, licensing and operation of ADDOs in the community. The new system would require a significant change from the existing system of part II poisons shop licensing and regulation. Accordingly, a social marketing campaign would be rolled out to inform and educate consumers as well as political and government leaderships about the changes in the ADDO era.

The ADDO "microsystem" would be embedded in divisions and wards. For the system to function well, it was expected that divisional and ward leadership would be willing to serve as champions for its implementation. The leaderships would work through the village and ward committees to monitor operations of ADDOs and report major problems including malpractices and violation of regulations to council authorities as appropriate. Similarly, the District Medical Officer (DMO as the head of the council health department was expected to be an ADDO champion at the district level, while other council officials including members of the Council Health Management Team (CHMT), would support implementation activities, monitor ADDO operations, provide supportive supervision and report to the relevant authorities.

Figure 1. The AD D O Conceptual Framework



1.5.2 Initial Program Elements

Based on the conceptual framework, key program elements were identified in the early stages of the program development. These were exhaustively discussed by the program team which included the Pharmacy Board leadership and technical experts from MSH. At that time it was difficult to predict which elements would work best for the program. However, the team was very much encouraged by the interest the Ministry of Health led by the then Chief Medical Officer, Dr. Gabriel Upunda had shown in the initiative. The Chief Medical Officer was at the same time the Chairman of the Pharmacy Board. The Pharmacy Board Registrar, Mrs. Margareth Ndomondo Sigonda also showed unwavering support for the many proposals discussed during the initial stages. The process involved the following key steps.

A key priority in developing the ADDO standards was striking a balance between the program's objectives and optimal regulatory control without deterring the DLDB owners from participating in the program.

(a) Development of regulatory standards

This element included development of minimum but enforceable standards which could provide guidance on key issues such as buildings, drugs list, drug quality, personnel, record keeping and shop location. One of the key priorities in developing the ADDO standards was to strike a balance between the program's objectives and achieving optimal regulatory control without deterring the DLDB owners from participating in the program. Thus, care was taken to not make the standards too high nor too prescriptive to a point that the stakeholders would find them unreasonable and difficult to comply with, while still ensuring the public's health

(b) Training and continuing education

This element included the design and initiation of an ADDO dispenser training course offered either by the Pharmacy Board or an approved institution. The course was a means to equipping the dispensers with basic dispensing knowledge and skills.

(c) Development of incentives for drug shop owners

Incentives were needed to attract DLDB owners and others interested in operating an ADDO to participate in the accreditation scheme. The most attractive incentives to DLDB owners were those which focused on stimulating the growth and development of the business. Discussions with different groups of DLDB owners were helpful in identifying potential incentives.

(d) Regulatory monitoring

This element addressed the need for regulation and monitoring of ADDOs to ensure adherence to the established standards after accreditation. It also addressed regulation of non-accredited outlets which continued to exist until the ADDO system was fully established in each district. Since the Pharmacy Board had limited resources to regulate all outlets, Local Government Authorities (LGAs) were given the mandate to perform routine inspection and reporting on ADDOs and DLDBs in their areas. However, the Pharmacy Board retained overall responsibility for regulation.

To guard against abuse of their positions, lower level inspectors were not given decision-making powers. Instead, they reported to an appropriate local committee, such as the village/ward health committees and ward development committees which, in turn, were answerable to council authorities. The component also addressed issues of sanctions and penalties against ADDOs and DLDBs which went against the established regulations. The component also included procedures for appeals by owners as well as channels for processing consumer complaints against drug retailers, mainly ADDOs and DLDBs.

(e) Advocacy and marketing

The fifth element focused on the need for an effective communications and marketing strategy to convince consumers, shop owners and sellers, local government, and community leaders to participate in the program.

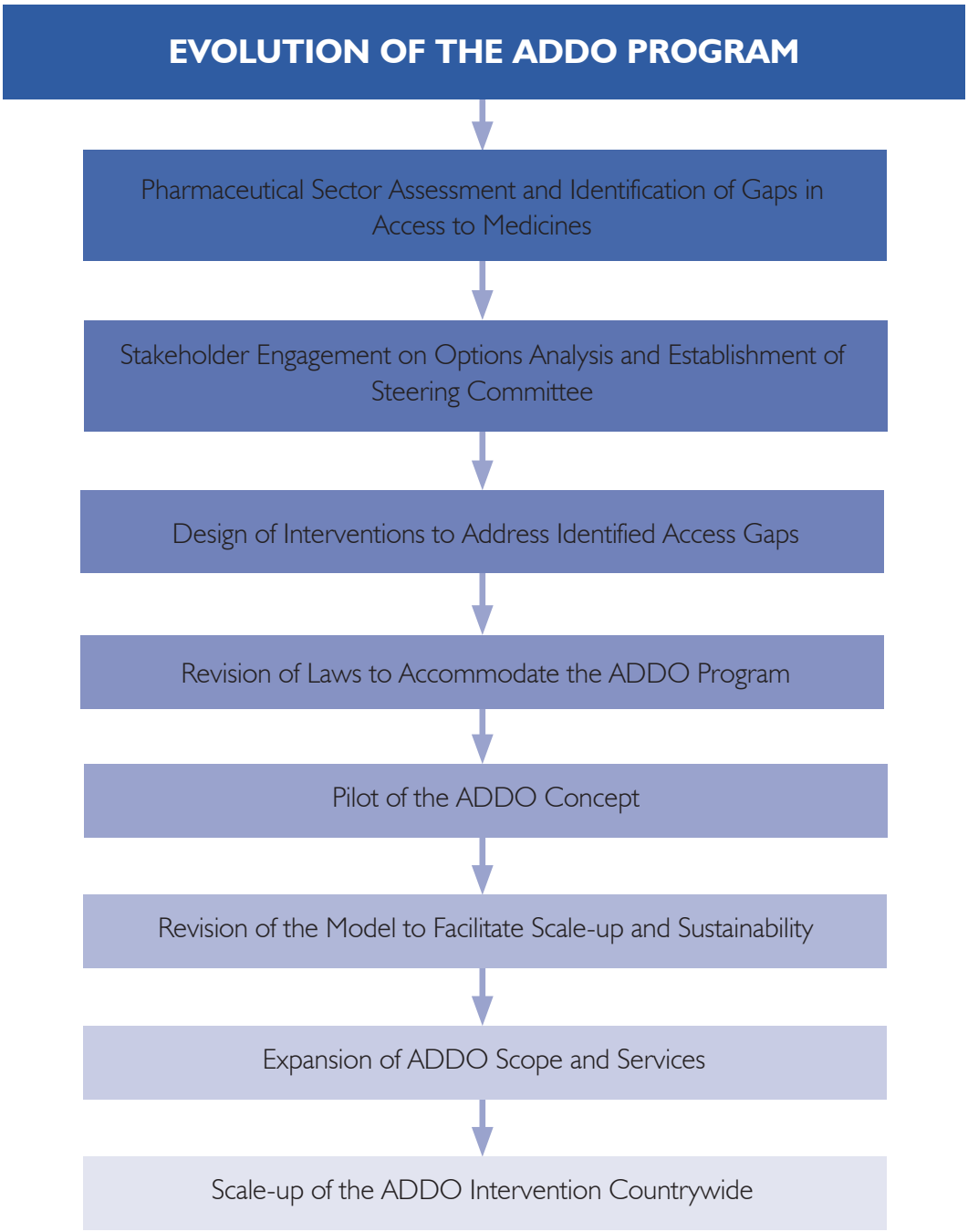
(f) Phasing out DLDBs

The final element focused on systematic phasing out of DLDBs after establishment of the ADDO system in each district. The element was designed to attract DLDBs to become accredited, persuade customers to buy drugs from ADDOs since their product and service quality could be guaranteed, and use local authorities to persuade DLDB owners to upgrade their shops to ADDOs. These efforts shifted much of the business to ADDOs and forced many DLDB owners to join the program.

1.5.3 Expected Outcome

> Successful implementation of the program was envisaged to create a large network of accredited, commercially viable and properly regulated drug shops providing a wider range of products and services which meet minimum acceptable standards, and provide a model for managing non-pharmacy retail drug shops, which could be showcased and replicated on a wider scale.

Figure 2


EVOLUTION OF THE ADDO PROGRAM
Pharmaceutical Sector Assessment and Identification of Gaps in Access to Medicines
Stakeholder Engagement on Options Analysis and Establishment of Steering Committee
Design of Interventions to Address Identified Access Gaps
Revision of Laws to Accommodate the ADDO Program
Pilot of the ADDO Concept
Revision of the Model to Facilitate Scale-up and Sustainability
Expansion of ADDO Scope and Services
Scale-up of the ADDO Intervention Countrywide

2 Implementation Process

2.1 Setting the Stage

DLDB provider attending to a patient

Prior to introduction of the ADDO program, a number of preliminary but vital activities took place. They included the 2001 comprehensive assessment of the pharmaceutical sector, dissemination of the assessment results at the national level and wide consultations on strategies for improving medicines access and quality of pharmaceutical services, and presentation of the results including the ADDO concept at the first SEAM Conference in held Washington (November 2001). After the conference, Tanzania Ghana and El Salvador were selected for continued SEAM program support to implement the identified strategies for improving medicines access. In Tanzania, priority was given to implementation of the ADDO program.

Consequently, the Government of Tanzania through the Ministry of Health signed a memorandum of understanding with MSH to pilot the ADDO program. A steering committee was established at the central level for advisory support and policy guidance to the program. The Committee was chaired by the Chief Medical Officer, and included representatives from the Ministry of Health, the Prime Minister's Office Regional Administration and Local Government (PMO-RALG), TFDA, MSH and Christian Social Services Commission (CSSC). The steering committee met on a quarterly basis and whenever need arose.

The detailed sector assessment was necessary to build a case for the Tanzanian government to support a private-public intervention to improve access to essential medicines. The assessment results were also shared with top officials of the Ministry of Health to enlighten them about the situation of the pharmaceutical sector and to engage them in finding sustainable solutions to the inherent challenges. The results were thoroughly discussed by other key stakeholders which included the Pharmacy Board leadership and staff, and technical experts from MSH.

During the discussions, different ideas on how to solve the pharmaceutical sector challenges specifically those in the private retail drug outlets, were identified. All stakeholders agreed that eliminating DLDBs was not a suitable option due to the risk of creating more problems in medicines access. There were concerns that drastic shutdown of DLDBs could result in emergence of a black-market with more serious public health consequences.

The popular proposition among most stakeholders was to improve the operations of DLDBs and strengthen regulatory monitoring. Upon this agreement, focus shifted to development of the ADDO program. The following key questions were addressed by the designers of the program: (i) what could be the appropriate name for the improved outlets to differentiate them from DLDBs? (ii) what term should be used to describe the process of upgrading the DLBDs? (iii) what requirements should the existing outlets meet to attain the desired standards? (iv) are there enough personnel with relevant knowledge and skills in medicines dispensing to enable the upgrading process to be realistic? These and many more questions came up as the team conceptualized the program. Some of the questions had immediate answers while others were addressed in the course of the program's implementation. It was agreed that the improved outlets be called Accredited Drug Dispensing Outlets (ADDOs).

The Presentation that Shaped ADDO's Future

It was at 1.45pm on the 28th day of November 2001. Tanzania's delegation had just arrived in Washington DC, two days earlier, to attend the first SEAM Conference convened by MSH with support from the Bill and Melinda Gates Foundation.

Themed, "Targeting Improved Access", the conference brought together delegates from six selected countries, donors and internationally recognized health systems experts, to explore ways of addressing the limited access to essential medicines, vaccines and other health commodities in developing countries. Apart from Tanzania, other countries represented were Ghana, Cambodia, El Salvador, India (State of Rajasthan) and Brazil (State of Minas Gerais).

These countries had been supported by the SEAM program to carry out a comprehensive assessment of their respective pharmaceutical sectors and come up with strategies for improving medicines access. Two or three countries with the most convincing long term strategies would be funded by the Gates Foundation through SEAM to implement their plans.

Tanzania's presentation was made by Dr. Gabriel Upunda, the then government's Chief Medical Officer. He was flanked by Ms. Margareth Ndomondo Sigonda, the registrar of the then Pharmacy Board, and Dr. Romauld Mbwasi, the MSH local consultant who led the country SEAM assessment. The team was supported by Keith Johnson, the SEAM Program Director and Malcolm Clark who later became the SEAM Tanzania Country Director.

Now the defining moment was at hand and Gabriel had to take to the podium. In his characteristic style, he adjusted his spectacles and called out the presentation on a projector screen. It was a seventeen-slide PowerPoint presentation that discussed the country's context including the situation of pharmaceutical services and ways of strengthening the system. It dwelt at length on the ADDO concept and its feasibility in the Tanzanian context. It was a powerful pitch that knocked off donors' socks, not only for the way it was made but more so for the vision in the ADDO concept, its potential and early signs of government "ownership".

In March 2002, Keith Johnson arrived in Tanzania to bring the good news that Tanzania, alongside Ghana and El Salvador, had won the pitch. This was followed by signing of a Memorandum of Understanding between the Ministry of Health and MSH to pilot the ADDO program. For nearly a complete decade after successful piloting, the gate of the Gates' benevolence remained open to the ADDO program, allowing millions of Tanzanians especially those in the traditionally underserved rural and peri-urban areas to access quality essential medicines.

2.2 The Initial Steps

2.2.1 Identifying the Pilot Region

Selection of the region and districts to pilot the ADDO program was carried out by a small committee consisting of the Pharmacy Board personnel and MSH/SEAM staff. The team developed a set of criteria and prepared a shortlist of the potential pilot districts. The selection criteria included presence of community health fund activities, health sector and local government reforms, strong local leadership, number of part II outlets, number of pharmacies, donor activity, urban-rural composition and economic situation determined by per capita income.

Six regions and 16 districts were shortlisted for the selection. They included Manyara (Hanang District); Mbeya (Mbeya Urban, Mbeya Rural and Rungwe districts); Tabora (Nzega and Igunga districts); Shinyanga (Shinyanga Urban, Shinyanga Rural, Kahama and Bukombe districts); Singida (Singida Urban, Singida Rural and Iramba districts); and Ruvuma (Songea Urban, Songea Rural and Mbinga districts). The selection criteria were applied indiscriminately to all the shortlisted regions. Three regions (Mbeya, Shinyanga and Ruvuma) met the selection criteria and were subjected to a second level selection process which involved site visits. The rationale for the final selection was discussed with key government stakeholders. Observations from the site visits were rated by the following yardsticks:

- *Critical:* essential for program success
- *Important:* valuable for program success
- *Helpful:* supportive of the program, but not essential for success

The selection team unanimously recommended Ruvuma Region upon review of the final selection results. Consequently, Songea Rural, Songea Urban and Mbinga districts were chosen as the first pilot areas. In the course of the piloting, Songea Rural was subdivided to create Namtumbo District. Tunduru District (also in Ruvuma) was left out in the initial planning of the pilot due to its remoteness, difficulty in reaching the area during the rainy seasons and a small number of DLDBs operating in the district. However, both Tunduru and Namtumbo districts were included at a later stage due to high demand from local leaders and DLDB owners who were eager to join the program. It was also realized that leaving out both districts could have a negative impact on the other three implementing the ADDO program.

Singida Region was selected as a control area to support evaluation of the pilot project Although Shinyanga Urban and Shinyanga Rural districts scored highly during the selection process, insecurity was so significant in Shinyanga Region at the time that the team thought it could affect smooth implementation of the project activities. Mbeya Region also scored highly but the number of pharmacies located in Mbeya Urban presented an obstacle. Most pharmacists were not very receptive to the ADDO idea, largely because of personal business interests.

2.2.2 Understanding the Pilot Area

After selection of the pilot region, the pilot team consisting of two representatives from TFDA (Emmanuel Alphonce and Yona Hebron) and another two from MSH (Dr. Romauld Mbwasi and Rogastian Shirima), visited the selected districts in Ruvuma Region. Each of the districts was visited at least twice. The field visits were helpful in identifying DLDBs and gathering basic information to inform development of the ADDO program. The visits involved consultations with local officials at the divisional, ward and village levels, and discussions with DLDB users to understand their perceptions of the drug shops and what could be done to improve the services. The team's composition in terms of expertise, commitment and cohesiveness was instrumental to the successful accomplishment of the task.

> *"This was one of the most dedicated teams I ever worked with in the program. The team surprised many local residents by visiting the remotest villages of Ruvuma Region where the residents had not even seen a motor vehicle in a long time,"* **Dr. Romauld Mbwasi, Pharmacy Council Chairman.**

2.2.3 Introducing the Program in Ruvuma

Having completed the fact-finding visits in Ruvuma, a special central level delegation led by Ms. Margareth Ndomondo Sigonda, the Pharmacy Board Registrar and Malcolm Clark, the SEAM Tanzania Project Director, visited the region to officially introduce the ADDO concept to the regional and council authorities. The delegation was received by the then Ruvuma Regional Commissioner, Retired Major General Said Said Kalembo, and held discussions with the leaderships of all the three districts selected to pilot the program (Songea Urban, Songea Rural and Mbinga). Both technical and political leaders participated in the discussions. The choice of Ruvuma as the pilot region was very well received by the local leaders. The regional commissioner was particularly excited about the program and became one of its key champions in the region and beyond.

The visit coincided with a "Full Council" meeting in Songea Urban, a planning forum which brings together technical experts in the district and community leaders to discuss the council's development plan. The visiting delegation seized the opportunity to share the ADDO concept with ward councillors in attendance and get the ADDO message out to the local residents. The visit marked the beginning of a series of sensitization and advocacy activities in the region, which would later be instrumental in creating awareness about the program and gaining community support for its implementation.

The program's outreach efforts centred on generating interest among DLDB owners towards transforming their shops into ADDOs and gaining their long term commitment towards sustainable implementation of the program.

The subsequent sensitization and advocacy meetings targeted key stakeholder at all levels (regional, district, division, ward and village). Among the stakeholders reached were government officials, local government leaders, DLDB owners and community members. Over 20 workshops were conducted in the pilot region to engage the key stakeholders on the development of the program. The major outcome of the sensitization and advocacy activities was the strong support the program received from all stakeholder groups. Much of the program's outreach efforts centred on generating interest among DLDB owners towards transforming their shops into ADDOs and gaining their long term commitment to sustainable implementation of the program.

Stakeholder Suggestions

During the sensitization meetings the following suggestions came up regarding the program's development:

- **Training:** all dispensers to be trained in medicines dispensing and basic communication skills to improve quality of dispensing services and interaction with clients. Trained dispensers should be provided with certificates and uniform. Drug shop owners should also be trained in basic business management and properly oriented on regulatory requirements for operating the drug shops;
- **Regulatory control:** councils to be given the mandate to approve establishment of drugs to reduce the waiting time; the licensing process to be made easier, faster and more transparent; and supportive supervision and inspection visits conducted routinely to promote compliance with regulations and ensure delivery of quality medicines and services to the community;
- **Supporting business development:** The list of medicines authorized in Part II drug shops to be expanded to included selected prescription medicines in high demand in the community, the supply chain system to be streamlined to increase access to affordable quality medicines, and low interest rate loans provided to the drug shop owners for development of the business.
- **Stakeholder engagement:** Formation of association of drug shop owners to be supported to facilitate a more constructive

Major concerns:

- Capacity of the drug shops to employ two or more dispensers
- Capacity of the councils to effectively and transparently provide regulatory control
- Demand for clinical services in the Part II drug shops by the community

2.3 Initial Program Development

From the preparatory phase, the overall responsibility for the program development rested with the TFDA, with MSH providing technical and financial support through the SEAM program. Local government and other health sector stakeholders such as the Ministry of Health provided technical and policy guidance.

2.3.1 Development of Regulatory Standards

The first major task in the program development was the development of a set of minimum but enforceable standards, which later became known as ADDO regulations. The standards were developed in consideration of the stakeholder opinions and the program's objectives. The standards covered vital issues such as standard of buildings, medicine list, product quality, personnel, record-keeping, shop location, etc. The process was very involving, requiring broad-based participation of different stakeholders. Thus, the project team conducted a number of consultative meetings at the national level and in the pilot region. However, the process was not without challenges due to divergent views on different contentious issues.

The most controversial issues that caused heated arguments were the propositions to allow Part II drug shops to sell selected prescription only medicines, and shifting of the mandate to approve applications for establishing drug outlets from the regional drug committees to council authorities. The two issues were very sensitive for several reasons. There was a strong resistance by professionals, mainly pharmacists to idea of authorizing Part II drug shops to sell prescription medicines. This issue was strongly contested to the extent that some individuals sent threatening messages to the TFDA Director General. Thus, during discussions, care was taken not to expand the list beyond unnecessary limits.

> *"On two separate occasions, I received serious anonymous threats in writing, warning me that if I didn't stop the project, I would be wiped out of the surface of this earth together with my entire family"* **Margareth Ndomondo Sigonda.**

The second controversial issue had more to do with perceived power play than the actual prospects of decentralizing ADDO regulatory control to council authorities. The chairpersons of the regional drug committees were regional commissioners, hence the team was hesitant to take away the mandate from the regional commissioner and hand it over to a lower level. Regional commissioners were powerful political figures and there were genuine fears that any move by the program to diminish their influence would negatively impact implementation of the program. However, consultations with Ruvuma Region Commissioners proved otherwise.

> *"After arguing over the decentralization issue for some time, Malcolm Clark, the SEAM Tanzania project director and I decided to test the waters during one of the field visits in Ruvuma. We approached the regional commissioner, the retired General Said Said Kalembo, to seek his opinion on the matter. To our surprise, the regional commissioner very much welcomed the idea, citing its consistency with the national policy of decentralization by devolution whose implementation had just begun. Encouraged by that response, we reported back to the rest of the team and went ahead to develop the council -based ADDO regulatory system,"* **Dr. Romauld Mbwasi.**

Once the draft standards were finalized, a larger team that included selected regional pharmacists, district medical officers and district pharmacists, reviewed the standards. The review process took about a week, after which a meeting was held with stakeholders in Ruvuma Region to share the standards. Participants included regional decision makers, technical staff and DLDBs owners. Components of the standards discussed included accreditation and application process, incentives for owners, building and storage conditions, staff qualifications, quality of products, training and continuing education, record keeping, as well as regulation, inspection and sanctions, and establishment of ADDO Restricted Wholesalers (ARWs). Although the stakeholders did not unanimously agree on the proposed standards, DLDB owners warmly welcomed the changes especially the proposal to include selected prescription medicines in the list of products authorized in Part II drug shops.

2.3.2 Development of Training Curriculum and Materials

Training curriculum and materials for accreditation of ADDO dispensers and owners were developed simultaneously with the standards. The program contracted technical experts from the Muhimbili University School of Pharmacy to develop the materials. A six-week course was designed for ADDO dispensers and a five-day course for shop owners. However, the project team realized that the content developed by the school of pharmacy was too technical for trainees with basic education to understand. With only two weeks before training of dispensers and owners started, the project team had to revise the materials to suite the targeted trainees.

2.3.3 Development of Incentives for Business Development

Further to the various consultative meetings involving different stakeholders more so DLBD owners, the project team came up with a package of incentives to interest the shop owners in the program and encourage their long term participation in the implementation process. .

The Incentives Package

- Training of dispensers and drug shop owner
- Instituting a broader legally approved medicine list
- Marketing and advocacy for demand creation
- Linking ADDOs with financing opportunities
- Improving access to wholesale suppliers
- Reducing tax burden and license fees

2.3.4 Establishing Regulatory and Monitoring System

(i) Regulatory and monitoring system before ADDO

The overall regulation and monitoring of DLDB fell under the Pharmacy Board and later the TFDA. Nevertheless in order to support the Pharmacy Board or TFDA, a mandate was given to a regional drug committee that had the responsibility to approve new applications for establishing DLDBs, renewal of licenses and collection of annual fees from DLDBs. The committee was also responsible to receive inspection reports carried out by the regional pharmacist. The regional Commissioner was the chairperson of the committee while the Regional Pharmacist was the secretary. The committee reported to the Registrar of the Pharmacy Board (later to TFDA). This was the only committee in the region and was responsible for all shops in all the districts in the region.

The district was not recognized in the Pharmaceuticals and Poisons Act of 1978 (repealed by the Pharmacy Act of 2002 and the Tanzania Food, Drugs and Cosmetics Act of 2003) and therefore legally, district authorities did not have any mandate unless the region specifically assigned the district to carry out some activities on behalf of the regional committee or inspector. This structure had the following short-comings:

- The regional pharmacist was the only inspector legally recognized by law. Any other person carrying out inspection or related activities that had legal implication, had no mandate to take any legal action;
- Because of the many administrative responsibilities assigned to the office of the regional commissioner by the central government, conducting routine regional drug committee meetings was not a priority in many instances and therefore the committee rarely met to approve new applications or follow up on inspections;
- Since committee meetings rarely took place, some regional pharmacists took advantage of the situation and made personal decisions which favoured some new drug shop applicants over others. The inefficiencies resulted in longer waiting periods

for outlet owners, and discouraged many from following the law in establishing the drug shops. Many shops were established without the committee's approval. These factors caused extensive violations in delivery of DLDB services, as many of the shops operated at large without the necessary regulatory control.

(ii) Regulatory and monitoring system under ADDO

The program realized the importance of close regulation and monitoring of ADDO operations to ensure that the established standards are maintained after accreditation. The experience from the region-based regulatory control forced the program to restructure the regulation and monitoring system to meet the regulatory needs of the ADDO enterprise.

Involvement of the local government in regulatory monitoring was seen as a more feasible way of controlling operations of the retail drug outlets. Thus, the local authorities were made responsible for performing routine inspections and reporting on ADDOs and DLDBs activities in their areas of jurisdiction. The role of the local government was formulated to fit with its responsibilities under local government reforms, which had decentralized major decision making powers and resources for social service delivery to the local government authorities.

To guard against abuse of their position, it was agreed that village/ward level inspectors would not have decision-making powers. Rather, they would report to the appropriate local committee, such as the village or ward health committees, which, in turn, would be answerable to the council food and drugs committee. It was also agreed that sanctions must be taken against errant ADDOs and DLDBs. Local, district, and national level authorities would be required to take appropriate action and levy penalties in accordance with the established regulations. A provision was also made for an appeals procedure to allow owners to seek redress against overly severe or otherwise unusual punishments. The table below highlights components of the regulatory and monitoring system developed in the initial phase of the ADDO program.

Table 1: ADDO regulatory and monitoring structure

ADMINISTRATIVE LEVEL	REGULATION AND MONITORING MANDATE
Ward Level	Responsible committee is the Sub-Ward Health Committee chaired by the Ward Executive Officer (WEO).
	Two to three local inspectors trained by TFDA/PC carry out local inspection and monitoring and report to the Ward Health Committee.
	New applications are submitted to this committee which, using its local inspectors, carry out preliminary inspection of premise location and fitness of the premise in provision of drug services.
	Committee submits its preliminary report to the Council Food and Drug Committee (CFDC) with the application form and committee recommendations.
	The ward health committee carries out regular (quarterly) inspections, meets quarterly and submits reports to the CFDC on quarterly basis.
Council Level	A specific committee, at first named as District Drug Technical Advisory Committee (DDTAC) under the chairmanship of the District Commissioner and later changed to Council Food and Drug Committee (CFDC) chaired by the Council Director and the District medical Officer as its secretary.
	This committee has an overall responsibility of regulation and monitoring of the functioning of the pharmaceutical services within the council in close collaboration with TFDA/PC.

	The CFDC inspectorate is formed by the council pharmacist, health and veterinary officers. Other members may be co-opted. They report to the CFDC.
	The CFDC issues application forms, receives ward's preliminary reports on the new applications and routine reports, carries out final inspection of premises of new applicants and approves locations and forwards them to TFDA/PC for final issuance of accreditation if TFDA/PC is satisfied with the CFDC approval process.
	The committee carries out bi-annual inspections and submits quarterly reports to TFDA/PC on regulatory and performance status of the pharmaceutical sector within the council. Such reports are copied to the regional committee – Regional Food and Drug Committee (RFDC).
	The committee meets quarterly to deliberate on issues related to the regulation and performance of the pharmaceutical sector in the council.
Regional Level	A Regional Food and Drug Committee (RFDC) was formed under chairmanship of Regional Administrative Secretary (RAS) and Regional Medical Officer (RMO) as the secretary.
	This committee has no direct mandate on approval of applications and taking actions against those who violate regulations and poorly perform, but acts as an advisory committee to the CFDC.
	The RFDC is an appeal body for those engraved by the CFDC decisions
	The RFDC inspectors may participate in the CFDC inspection activities - joint inspections.
	The committee works collaboratively with TFDA/PC in regulation and monitoring issues of the pharmaceutical sector in the region.
National Level- TFDA/PC	The TFDA/PC has a full legal mandate over the regulation and monitoring of the pharmaceutical sector in the country.
	It can overrule decisions or withdraw accreditation if it has found that the decision of any of the committees involved in the process was erroneous.
	TFDA/PC carries out at least one annual audit inspection in all the councils.

2.4 Ruvuma Pilot Experience

2.4.1 Mapping of DLDBs

At the beginning of the pilot phase, one of the major problems encountered by the program was the uncertain number of DLDBs operating in the pilot area. According to the regional pharmacist's records, Ruvuma Region had about 80 DLDBs. The location of some of the outlets was not precisely known. Consequently, the program team began by mapping DLDBs in all the initial districts (Songea Urban, Songea Rural and Mbinga) earmarked for the program piloting. A special mapping tool was developed for the process.

The mapping exercise began at the divisional level (sub-district administrative unit) and was scaled out to all wards and villages within the districts. At the divisional level, the program team met with divisional administrative secretaries, while at the ward and village levels, the team met with ward executive officers (WEOs) and village executive officers (VEOs), respectively. During the visits, the WEOs and VEOs were requested to complete a questionnaire for collecting basic data on the existing DLDBs in the community. Information such as location, name of shop owners, contacts and size of the outlets were collected. This activity identified a total of 144 DLDBs in the regions, and confirmed that there were several DLDBs which had been established without the knowledge of the regional authorities.

The significant presence of illegally established DLDBs in the pilot area raised a major concern which had to be addressed immediately through the TFDA. By law, the outlet owners should have been taken to court. However, since they were so many, it was thought that a drastic action against them could be counterproductive to successful introduction of the program in the region. The TFDA therefore agreed to issue a special clearance for the outlets to participate in the program on condition that they take the necessary steps to acquire legal status and meet the accreditation criteria in the ADDO framework. A total of 202 retail drug outlets had been accredited in Ruvuma by the end of the ADOO pilot phase.

2.4.2 Human Resource Situation Analysis

Initially, the program team intended to set fairly high educational and training requirements for potential dispensers in the accredited shops. This included dispensers who had trained as nurses, nurse midwives, retired clinical officers, pharmaceutical technicians and assistants who have no engagement and are easily available in the pilot region. However, the move was opposed by some members of the program team who thought that such personnel were not many in rural areas and that setting very high dispenser qualifications would set up the program for failure.

Consequently a rapid assessment was conducted to understand the human resource situation in the region. The results showed that the anticipated skilled cadres were scarce in the whole region and the few who were available were already engaged in public facilities. The most common cadre which was easily available in the region and especially in rural areas was nurse assistant. These were one year-trained health support staff mostly working in hospitals and public primary health facilities. Some of them also worked as dispensers in DLDBs, while others had not secured jobs yet. Although the government had stopped training the carder, some faith-based hospitals were still training the nurse assistants for internal use. In most cases, nurse assistants were in excess of hospital requirements. This was an important finding in the process of developing standards for ADDO personnel. The nurse assistants were seen as potential candidates for the ADDO dispenser training course.

2.4.3 Advocacy Activities

Various advocacy workshops were conducted in the pilot area to mobilize the participation of different stakeholders groups in the development and implementation of the program. The workshops were conducted at the regional and district levels. The regional level process targeted key decision makers including the regional commissioner, regional administrative secretary (RAS) and other technical staff drawn from different departments such as health, community development, social welfare, planning, etc. At the district level, the advocacy activities targeted senior officials such as district commissioners, district executive directors, district medical officers, district pharmacists, trade officers, cooperatives officers, community development officers and agricultural and livestock development officers. Other participants in the district level process were drawn from the community and included ward councillors, ward executive officers, village executive officers and DLDB owners. In total, 20 workshops were conducted in the pilot phase. The workshops were helpful in understanding the stakeholder expectation and opinions on different aspects of the program especially what they thought could work or not work.

2.4.4 Developing the ADDO Legal System

(i) Ward Level Regulatory Structure

The inability of the central and regional level regulatory authorities to closely monitor the operations of drug outlets in the community, was a major consideration in developing the ADDO regulatory system. A regulatory structure which readily reaches the community was deemed necessary in meeting The ADDO regulatory needs. Thus, responsibilities were assigned to the ward health committee to ensure regular inspections and monitoring of ADDO operations. Accordingly, the ward became the lowest level of the legal system for pharmaceutical services regulation.

However, a number of challenges came along with the establishment of the ward level regulatory structure. There was scarcity of people with relevant pharmaceutical background and technical know-how at ward level who can act as local inspectors for ADDOs. Only medical personnel working in primary health care facilities and the ward health officer had basic public health background. Moreover, staff at this level was constantly changing through transfers from one ward to another. This would have meant that even in cases where staff were trained to become local inspectors, there would have been a need for constant retraining every time a staff member is transferred. There were also complications on which authority will be responsible for certifying staff who were inspectors. Practically, staff at ward level work under the council director and therefore fall under the PMO-RALG and MoHSW. Staff that were identified as inspectors were appointed by the TFDA/Pharmacy Board.

With the above issues in mind, the program through TFDA negotiated with the local government. It was agreed that TFDA would appoint local inspectors and issue inspector's identity cards during the pilot phase with the intention that other issues will be handled when the programme is rolled out. To prevent the loss of trained inspectors due to transfers, the program trained three inspectors per ward. This ensured that not all three inspectors will be transferred at the same time. In case of a transfer of an inspector, the rest would have ample time to train new staff. It should be noted that at this level, inspectors had limited authority. They mainly acted as watchdogs and reported on serious violations to the council inspector who had a stronger mandate to take action.

(ii) District Drug Technical Committee (DDTC)

At the beginning of the program in each district, a special committee was appointed and worked in collaboration with program team in the ADDO accreditation process. Once final inspections for each outlet were completed, MSH/TFDA/DDTC inspectors prepared an inspection report for all premises indicating the outcome of the inspection. Inspectors would put in their recommendations and submit reports to the committee to approve request for accreditation. Premises which were approved by this committee were issued with accreditation by TFDA. Collaboration between program inspectors and district committee built ownership of the program to local authorities and transferred inspectorate skills that were necessary for sustainability of the system.

(iii) Regional Drug Technical Committee (RDTC)

Many arguments were raised regarding the role of the region in the program. This was ignited by the removal of the regional mandate to approve establishment of drug outlets. Some members argued that there was no need of having a regional committee since there was no specific role for it in the program. However, not recognizing the region was not an option for the program. The regions still had the central government mandate to monitor service delivery in the districts. Therefore program decided to establish the Regional Drug Technical Committee (RDTC), guide by the principle of monitoring activities within districts and providing guidance where necessary. The regional committee worked in close collaboration with TFDA and Pharmacy Council and would at times carry out audit inspections on behalf of the regulatory bodies. The committee also acted as an appeal forum where disenchanted ADDO appellants could take their concerns. The regional inspector was also tasked to participate in council inspections as well as being an observer at councils' committee meetings. This was done to enable the inspector to know the operations of the system at the lower level and provide feedback to the regional committee.

(iv) Central Level Regulatory Authorities

The laws establishing the TFDA and the Pharmacy Council gave both central level regulatory authorities oversight regulatory mandate in delivery of all pharmaceutical services in the country. In the ADDO context, the TFDA had the final decision-making powers on the accreditation process and other law enforcement decisions. It was the only body which could issue accreditation certificates to successful applicants. The regulatory body also addressed all appeals which the regional and council committees could not resolve. It carried out inspections whenever necessary but also delegated such activities to the regional committee, as appropriate. It was under this mandate that all the inspection activities conducted during the pilot period were fully controlled by the TFDA.

2.4.5 Establishing the Accreditation System

(i) Inspection of Premises

Accreditation during the pilot period had several requirements which a drug shop owner was required to fulfil before being allowed to operate an ADDO. The following were key steps and conditions towards accreditation:

- The owner would willingly show interest to join the program;
- All owners interested to join the program would be listed according to the locations of their drug shops. The owners would be informed through their ward or village executive officers, of the date that the ADDO team would visit to conduct preliminary premise inspection;
- On the scheduled date, the accreditation team would travel to each of the listed premises to carry out preliminary inspection using a checklist developed on the basis of the ADDO standards. During the preliminary inspection, three situations could be encountered. The current premises could meet most of the requirements such as size, had a store or could be made within the room, but would need basic renovations and installation of shelves as per required standards; or the premise did not meet the basic standards, for example it was small with no possibility of having a store. In such a situation, two alternatives happened. If the premise is rented, the owner would agree to provide an additional room and renovate to meet ADDO standards. In case the owner of the rented premise did not permit modifications, DLDB owners were asked to look for alternative premises. This was not easy in rural areas. In many cases, DLDB owners decided to build new premises.
- In all above cases, the DLDB owner would be left with full written instructions on what they were required to do before the final inspections in order to meet accreditation requirements. Owners were also required to submit two names of dispensers to undergo the six-week dispenser training course. Owners were required to take a five-day business management course. The estimated period given for the premise renovation was about three months.
- The final accreditation inspection was conducted towards the end of the dispensers and owners course. This was necessary so that all premises which finally met the basic accreditation requirements would have the two dispensers ready, and during the district program launch the owner would receive his/her accreditation certificate and start operating the ADDO business.
- Owners who did not manage to meet requirements by the time of the program launch were given more time to finalize renovations and were accredited once final inspection results showed that all basic requirements were met.

Transforming DLDB into ADDO

(ii) Training of ADDO Dispensers and Owners

ADDO dispensers were trained on basic dispensing knowledge. The training covered such topics as ADDO-approved medicines, common health problems and their basic symptoms, common indications and contraindications, common dosages, side effects, patient information, ADDO-regulations and ethics, and effective communication skills. Training for owners also provided an understanding of the laws governing dispensing practices, skills in management and record-keeping and discussed pharmacy practice ethics.

(a) Training of dispensers

The selection of potential ADDO dispensers had two main stages. All potential dispensers submitted by DLDB owners who had applied for accreditation got the first priority in the selection process. Independent training candidates were allowed into the program provided that they met the selection criteria. These included submission of a copy of certificate of nurse assistant from a TFDA recognized institution and presentation of original certificates during personal interviews. Candidates were also required to write essays and attain a pass-mark of not less than 50% and score about 25 points from interviews. If candidates presented by the DLDBs owners failed to meet these requirements, individual candidates were asked to negotiate with DLDB owners for recruitment.

Assigning dispensers to a shop before admission into the course had two important reasons. It ensured that each shop that met accreditation criteria had a qualified dispenser to start operations, and that the newly graduated dispenser had a place to practice his/her knowledge and skills, and could be easily reached for follow up after training. Nevertheless, with these advantages, there were still some problems that came up.

(b) Identification of trainers

Trainee dispensers sitting a test

Dispensing trainees had very low educational background - mostly standard seven leavers. The program therefore needed well experienced trainers to effectively train the groups. The program recruited different experts to conduct the dispenser trainings. The first group trainers included Mr. S. Senya, a principal pharmacist who for several years headed the Muhimbili School of Pharmaceutical Technicians and served as the director for allied health sciences; Mr. Sospeter Magambo, a principal pharmacist and regional pharmacist for Iringa with wide experience in training lower cadres; Mr. Tibaijuka, the Head of the School of Pharmaceutical Technicians at Bugando Referral Hospital with wide experience in training candidates with lower education levels; Mr. J. Kejo, a senior pharmacist and former regional pharmacist for Mbeya; Kejo initiated a training of DLDB dispensers in his region and therefore had substantial experience in training similar cadres; Ms. Rose. J. Marwa, a senior pharmacist and tutor at the school of Pharmaceutical Technicians at Muhimbili National Hospital; Mr. W. Singano, also a tutor at the same school and Dr. Romuald Mbwasi with extensive experiencing in teaching cadres with similar background of education; also joined the training team.

(c) The dispenser training process

Initially about 23 shops were identified for accreditation in Songea Urban. Therefore the minimum number of dispensers to be trained was 46 (two per shop). Trainees were divided into two groups each with about 23 trainees. The training was conducted over a six-week period. Trainees had to sit a test every Saturday - a minimum of four tests before the final examination. Continuous assessment tests carried 50% to the final evaluation result. Trainees and trainers worked very hard together and the results were high. We had 100 percent pass for all candidates. At the end of the course all trainees that passed were awarded a Dispensing Certificated by TFDA.

(d) Training of owners

The training of shop owners was conducted for six days only. Two days were allocated for orientation of owners to ADDO regulations, related laws and application, and inspection procedures. The remaining four days were used by Mennonite Development Associates (MEDA), commissioned by the program to conduct the business skills and management training. At the end of the training, each trainee was awarded a certificate of attendance by MEDA.

(iii) Shop Accreditation

Three weeks prior to the completion of the owner and dispenser trainings, the program team visited shops which had applied for accreditation to carry out final accreditation inspection. Using the previous inspection checklist report, a copy of which was left with the owner of the shop, the inspectors would go through each item to ascertain that all accreditation requirements were met. At the end of inspection, the team made an inspection summary report for each shop, recommending shops which had met all the requirements for accreditation.

Shops which did not meet requirements were identified and inspectors indicated each of the unfulfilled requirements as well as the time allocated for its fulfilment. The inspection summary report was submitted to the DDTAC chaired by the District Commissioner for approval of DLDBs that met all accreditation requirements. Additional time was always provided to allow those who had not yet met the requirements to finish the process. Special committee meetings were conducted on rolling basis to approve such applications upon meeting the accreditation requirements.

(iv) Program Launch

Once trainings and accreditation of shops were completed, new ADDO shops were inaugurated at a special district launch event. Every dispensers who had successfully completed the course and passed the final examination received a dispensing certificate from TFDA, a white dispensing coat and a T-shirt, all branded with the ADDO logo. The ADDO owners also received their accreditation certificates, certificate of attendances of the owners' course, patient registers, and an ABS with ADDO logo ADDO to fix in front of the accredited shop.

The program launch and accreditation day was a colourful event with participation of political figures and senior government officials. It included entertainment such as traditional dances, special songs about the the ADDO program, drama performed by the dispensers themselves depicting the problems of DLDBs and the services the community should expect from ADDOs. Details of the launch are described under marketing activities.

Procession by the first batch of trained ADDO dispensers on the program launch day.

(v) Supervision and Follow-up after Accreditation

Supervision of dispensers was conducted after the training and accreditation. Supervision was done through a contracted team of pharmacists from the Pharmaceutical Society of Tanzania and experienced nurses who were also trainers. The first follow up was done one month after the training and operations of the outlet. Subsequent supervisions were conducted every two to three months. A supervision check-list was prepared and supervisors stayed with the dispensers in the shop for up to six hours to see how they were working and provided guidance where they seemed to have difficulties. The supportive supervision activities were instrumental in building the dispensers' confidence. At the end of every supervision visit, the supervisors discussed their observations from the field with the program team. Challenges related to training were immediately reviewed to improve training quality.

2.4.6 Promoting Local Program Ownership and Public Awareness

(i) Social Marketing

In an effort to raise community awareness about ADDO services, influence consumer behaviour change and stimulate demand for the services, the program supported various social marketing and promotional activities. The efforts also targeted gaining wider stakeholder support and participation in implementation of the program. To achieve these, a marketing and communication strategy was necessary. Consequently, the SEAM program supported a formative research towards development of the strategy.

The qualitative study for behaviour change was conducted in the initial three intervention districts (Songea Urban, Songea Rural and Mbinga). It focused on understanding the behaviours and preferences of consumers, shop owners, dispensers, and local government and community leaders regarding DLDB services, and the stakeholders' expectations of the ADDO program. Thus, the exercise was helpful in understanding the stakeholders' opinions and recommendations on how the ADDO program should function. Data was collected through focus group discussions and in-depth key informant interviews.

Results from the study indicated major community concerns about the quality and origin of medicines sold by DLDBs. All stakeholders wanted trained dispensers who could provide quality medicines at a reasonable price, but the shop owners preferred limited government regulation. Despite the reservations about DLDB services, the community still emphasized the important role the drug shops had in providing essential medicines. They wanted the services to be improved.

The findings provided useful insights in the development of the communication and marketing strategy. Based on the recommendations in the communication strategy, the program hired a professional advertising company to develop selected marketing materials and promotional tools including radio spots and billboards. The central theme in the marketing and promotional materials was TRUST, as detailed below.

Radios spots

Radio spots played a very important role in improving public awareness about the benefits of the program and particularly behaviour change. The radio spots included conversations between two people about the problems encountered at DLDB and the improved services experienced in ADDO. Others spots directed clients to seek ADDO services whenever needed because of their improved quality of medicines and services. Radio spots also addressed inappropriate client behaviours such as demanding half doses of medicines from drug shops and self-administration of medicines without seeking medical advice.The radio spots became very popular in Ruvuma Region and led to nicknaming of ADDOs as *"maduka ya dozi kamili"* (full dose drug outlets).

ADDO billboards and logo

Twenty seven billboards of varying sizes were produced and put up in strategic locations within the pilot area. They were placed at major junctions, bus stations, and along roads leading to major hospitals including regional and mission hospitals, health centres and market places. The billboards were of the highest quality in the region. Some of them can still be seen in parts of Ruvuma region. They depicted the high quality of services provided by ADDOs, and included visuals of a mother and child visiting ADDO. The billboards became a powerful symbol of the ADDO program in Ruvuma. People visiting the region left with exciting stories about ADDO.

A special logo and an appropriate Swahili name also had to be created for branding of ADDOs. This was another exciting task in the program's development process. A tender was issued for designers to come up with a Swahili name and logo for the ADDO program. Seven bidders participated in the process. The name and logo concepts generated by the bidders were sent to local communities in Songea Urban, Songea Rural and Mbinga districts for pre-testing. A social scientist was contracted to lead the exercise. A special team consisting of senior staff from TFDA and MSH's SEAM program reviewed the pre-test results to come up with a catchy name and logo for the program.

> *"After several interpretations of the pre-test results, Ms. Margareth Ndomondo Sigonda, the then TFDA Director General suggested that the probable Swahili name for the outlets was Duka la Dawa Muhimu (DLDM). The team could not agree more with her on the suggestion and the name was unanimously adopted,"* **Dr. Romauld Mbwasi.**

ADDO billboard at the main entrance of Songea main bus stand

Launch Events

The program launch events were an important part of the ADDO marketing strategy. Two types of launches were conducted in the pilot region. The first "mega" launch was regarded as the "national launch" of the program in Tanzania. It officially ushered in ADDOs in Ruvuma Region. The mega launch was followed by district-based launch events which went hand in hand with introduction of the program in the initial intervention districts. The events pulled huge crowd from the local communities due to their uniqueness.

The mega launch took place in Songea Urban on August 11, 2003. The event was given the highest possible profile and officiated by the then Health Minister, Hon. Dr. Anna Abdallah. The event was punctuated with a colourful procession by the trained ADDO dispensers, presentation of certificates to the dispensers and ADDO owners, rich entertainment by local performing arts groups, and speeches by the Guest of Honour and other senior government official including Ms. Margareth Ndomondo Sigonda, the TFDA Director General and the retired General Said Said Kalembo, the Ruvuma Regional Commissioner; as well as a speech by Keith Johnson, the SEAM Program Director. Most of the entertainments (song, dance, and drama) had specific messages about ADDO, with emphasis on their improved quality of medicines and services.

"This was the most memorable event in the history of the pilot project. I still can remember the excitement among the local residents, the pride in the trained dispensers as they matched in white dispensing coats and caps, the strong feeling of achievement among the local leaders and the program team, and the plenty of singing and dancing which not even the dignitaries at the launch ceremony could resist. The pharmaceutical sector was never going to be the same again with the advent of ADDO," **Emmanuel Alphonce, the first ADDO program coordinator.**

Dr. Anna Abdallah (extreme left), Margareth Ndomondo (2nd left) and Keith Johnson (3rd left) acknowledging cheers from participants of the national launch of the ADDO program in Songea.

Furthermore, the program hired one of the most popular performing arts groups in the country, the Tanzania One Theatre (TOT) to tour all the initial intervention districts (Songea Urban, Songea Rural and Mbinga) in the entire week after the mega launch, to deliver specific messages about ADDO through its unique music which combined contemporary tunes with the popular Swahili *Taarab* genre. The group pulled huge crowds wherever they performed in the pilot region. The launch and post-launch activities had a major marketing impact on the local communities including stakeholders who were not yet convinced about the potential of the program.

The launch events also attracted active participation of local leaders especially ward councillors who saw the activities as an opportunity to advance their political careers. In every district, the leaders wanted to demonstrate that they were capable of championing implementation of the ADDO program. This strong sense of local ownership served the program well in scaling up the implementation within the pilot region. However, the launch events were resource intensive and could not be conducted in the same scale as the first "mega" launch, in the subsequently intervention districts.

(ii) Linking ADDOs with Financing Opportunities

As part of the efforts to support ADDOs to become sustainable businesses, the program contracted Mennonite Development Associates (MEDA) to conduct a needs assessment, prove basic business management skills training to ADDO owners and identify potential partners in the microfinance sector to provide the necessary financial services to the accredited drug shops. Through these efforts, the program managed to secure about US$ 50,000 funding from Summa Foundation for soft loans to ADDOs.

The loans were provided for procurement of medicines only and not for renovation of premises. The duration of the loan was one year. MEDA was appointed to manage the scheme. All ADDO owners who received the loans were able to pay back within the scheduled repayment period. Unfortunately the fund was not allowed to revolve so that new ADDOs could benefit from it. This scheme was limited to the pilot phase and for a short period of time.

Based on the experience, MEDA recommended linking of ADDO with local financing opportunities for more sustainable access to credit. The project again assigned MEDA to facilitate the process. The National Microfinance Bank (NMB) responded positively by providing a number of ADDO owners in Ruvuma Region with loans. Even ADDOs in remote rural areas, located way outside 30km radius from the lending branch, benefited from the credit facilities. This was a major breakthrough by the program, with the bank agreeing to bend its regulation which prohibited lending to small businesses operating outside 30km radius from the lending branch.

> The decision by the National Microfinance Bank to provide loans to ADDOs operating outside 30km radius from the lending branch was a major breakthrough in the efforts to increase ADDOs' access to credit.

Efforts were also made to link ADDOs with the Community Health Fund (CHF), unfortunately the fund's coverage in rural areas was still very small. The program then persuaded the National Health Insurance Fund (NHIF) to accredit some ADDOs to provide services to their members in rural areas whenever they were unable to access medicines from health facilities. The accreditation of ADDOs by health insurance institutions was a vital step in improving quality of services and adherence to ADDO regulations especially the use of legal prescription for the dispensation of prescription medicines. Although these efforts began in the pilot phase, actual NHIF engagement happened much later during the scale-up phase in Morogoro and Ruvuma regions.

(iii) Improving Access to Wholesale Supplies

ADDO regulations required the drug shop to purchase their supplies from registered suppliers only. However, during planning it was established that most of the districts in which most ADDOs would be operating did not have wholesaling pharmacies. Existing dug outlets had to order their supplies from the major cities which were far from their locations. The situation was more complicated for rural drug outlets. Nonexistence of registered wholesalers encouraged illegal practices whereby some retail shops would also provide wholesaler services.

Consequently, the program met with various nation wholesalers to encourage them to establish branches in the pilot areas. It was through this effort that Songea Urban got its first wholesale pharmacy named Southern Highlands Pharmacy, a subsidiary of the Dar es Salaam based Pyramid Pharmacy. To alleviate the problem of unregulated wholesalers, a provision was made in the ADDO regulations to allow establishment of ADDO Restricted Wholesalers (ARWs) to sell only ADDO permitted medicines. However, the establishment of the ARWs was not realized to the extent that the program had envisaged. The main obstacle to the realization of this undertaking was the requirement of having a pharmaceutical technician to supervise such outlets. Such technicians were not easily available in rural areas.

(iv) Reducing Tax Burden

High taxation by revenue authorities, multiple fees and forced contributions were among the major concerns raised by DLDB owners during the first stages of program development. This made it necessary for the program team to analyse the taxation system. Tanzania Revenue Authority (TRA) was contacted to gain insights into the taxation procedures and fees for small businesses. It was learnt the TRA had an established taxation system for small businesses like DLBs. However, the key challenge was availability of transparent sales and procurement records in the DLDBs. Thus, taxation was purely based on estimations which depended on the evaluating officer. To deal with this challenge, it was agreed that all ADDOs would keep records of sales and procurement to ease taxation calculations.

2.4.7 Scaling up Implementation in the Pilot Region

After the successful accreditation of the first 23 drug outlet in Songea Urban, the program started to experience an increased demand from DLDB owners who wanted to join the program. The number of applicants from Songea Urban almost doubled the original number of shops. All owners wanted to be included in the accreditation process in the next set of intervention districts (Songea Rural and Namtumbo). Due to the high demand, the program had to accommodate all the applications including those from Songea Urban. The increase in number of applications for accreditation meant that the number of dispensers to be trained would also increase. This created challenges since the training capacity at the initial training venue (Songea Clinical School) was unable to accommodate a big number of trainees. However, the program managed to get a larger central training facility.

By the end of the piloting process, Ruvuma Region had a total of 202 ADDOs. This was approximately 4 times the planned number of drug shops for accreditation and 2.5 times the number of DLDBs documented by the regional authority at the start of the intervention.

After Songea Rural and Namtumbo, the accreditation process was scaled out to Mbinga and Tunduru districts. Although Tunduru was not originally included in the pilot plan, demand for the program forced the project team to cover the district. Since the accreditation process was very transparent, there were no complains of unfair treatment by ADDO owners. This increased trust in the system and encouraged DLDB owners to transform their shops into ADDO status.

Despite the fact that there was no legal order to close DLDBs after launching ADDOs in pilot districts, experience showed that by the time the pilot was completed, the region had no DLDB in operation. All outlets had converted to ADDOs voluntarily or closed due to lack of business, as consumers had more trust ADDO services. This was a clear result of the marketing and advocacy activities.

2.4.8 The Ruvuma Pilot Evaluation

Upon completion of the pilot phase, an internal evaluation was conducted by the SEAM program while an external evaluation was conducted by an independent organization (Health Research for Action [HERA] with support from DANIDA). The SEAM evaluation process began with a baseline assessment in 2003 which covered a set of key indicators and gathered information necessary for the project planning. The program developed the indicators and survey instruments based on those used in the 2001 assessment of the country's pharmaceutical sector. A local contractor (HealthScope International) was hired to manage the data collection process. The contractor collected the baseline data in both Ruvuma and Singida (control region). The SEAM program staff analyzed the data and prepared a summary report in June 2003.

As a follow-up to the baseline survey, an endline evaluation was conducted in 2004 to assess the impact of the ADDO intervention. This was done at the end of the Ruvuma pilot. HealthScope International was again contracted to manage the data collection process. The endline data was collected between October 28 and November 19 2004. The evaluation incorporated most of the indicators assessed in the baseline survey. Additional areas of study were assessed in the endline survey. Some of the survey tools used in the baseline were not applied at endline because they were intended to inform the program's design instead of evaluation. The endline survey included the following five areas of study: stock availability and price, client exit interview (to assess satisfaction), malaria simulated client, simulated client visit for upper respiratory tract infection (URTI) and product registration status survey. Data was analysed by the SEAM program staff and the evaluation results compiled and shared with stakeholders at all levels.

Major Achievement of the Pilot

Program achievements were measured in terms of the following access dimensions:-

Quality of service in terms of clients getting appropriate recommendation for treatment measured through a combination of simulated client and client exit interviews.

Quality of services in terms of dispensing communication

Quality of products

Affordability

Availability

Acceptability/satisfaction

The program achieved all its objectives. It addressed the major access gaps especially in the rural, peri-urban and other disadvantaged settings.

The overall assessment of the ADDO Program by the TFDA, MoHSW, and local and regional government representatives who participated in the February 2005 ADDO evaluation workshop, revealed that the program contributed significantly to improving both access to essential medicines and rational medicine use in the Ruvuma Region. The program's approach created a model for private sector pharmaceutical delivery that can be used in other developing countries.

Stakeholders at the evaluation workshop agreed that the ADDO Program provided a multidimensional approach with the following benefits:

(a) Improved basic access to essential prescription and non-prescription medicines and pharmacy services in the retail sector.

(b) Improved private pharmaceutical sector regulatory control without jeopardizing essential services.

(c) Stimulated economic development and incomes for shop owners, wholesalers as well as the delivery infrastructure for pharmaceutical products.

(d) Created new avenues for other public health interventions for instance delivery of artemisinin-based combination therapy for malaria, child health, and HIV/AIDS programs.

(e) Diminished the scope of illegal activity in the pharmaceutical market.

(f) Expanded legitimate availability of important groups of prescription medicines in a way that reduced potential inappropriate use.

(g) Built on local government and health sector reform to strengthen local government, build better links between the central and local governments, and empower grassroots structures.

(h) The ADDO experience deepened the MoHSW's understanding of the nature and importance of the private sector, which contributes directly to an important MoHSW strategy for improving access to public health services through development of public-private partnerships.

2.5 Program Expansion through the Centralized Approach

2.5.1 Rationale

After the successful ADDO piloting in Ruvuma, the government and other ADDO stakeholders unanimously agreed on the need to rollout the implementation to other regions. The decision was informed by the results of the pilot and findings from the 2001 countrywide assessment of the pharmaceutical sector which revealed major medicines access gaps and systems challenges which could be addressed through a program such as ADDO. A visit by the Parliament's Health and Social Welfare Committee to the pilot region added great impetus to the push towards the proposed scale-up. The members of parliament were greatly impressed with the results of pilot and strongly recommended expansion of the program to other regions of Tanzania.

Among the outstanding achievements of the pilot were a significant drop in availability of unregistered medicines in the pilot area (from 26% at baseline to 2% at endline), increased availability of quality medicines and improved rational use of medicines (39% of dispensers recommended antibiotics for acute respiratory tract infection at baseline compared to 14% at endline). Moreover, prices of medicines were reported to have stabilized following improvements in the pharmaceuticals supply chain system and closer regulation and monitoring of the drug outlets.

2.5.2 The Scale-up Process

(i) The Initial Scale-up Regions

Although the rationale for the program expansion to other regions was very clear, the program team and other stakeholders were uncertain on how exactly to proceed with the recommended expansion. The initial thinking was to roll out the program to all regions in just five years (2005-2010). The idea was to start with 2 regions in the first fiscal year (FY2005/2006), 3 regions in FY2006/2007, 5 regions in FY2007/2008, 5 more regions in 2008/2009 and another 5 regions in 2009/2010. However, the feasibility of the plan was put into question given the enormous financial and human resource needs of the program.

As stakeholders pondered on the issue, two suggestions came up. The first one was to start the expansion in selected hard-to-reach regions where access to medicines was most difficult and scale up gradually to regions with relatively better access. The second suggestion was to follow the seven geographic zones on the Mainland in picking the regions to start the expansion and later scale up within the zones. After long deliberations, it was agreed that the process should started in two selected hard-to-reach regions (Mtwara and Rukwa) and one region with relatively better access (Morogoro). The USAID through the President's Emergency Plan for AIDS Relief (PEPFAR) agreed to fund the expansion activities in Morogoro Region under MSH's technical leadership, while the Government of Tanzania funded the expansion process in Mtwara and Rukwa regions under TFDA's leadership. Accordingly TFDA included the initial program implementation activities in Mtwara and Rukwa in its FY2005/2006 budget.

The expansion approach was similar to the model use in Ruvuma whereby most of the implementation activities were centrally managed. However, some modifications were made to minimize costs and improve efficiency in the implementation process. The TFDA had the overall oversight role in all the regions including Morogoro where MSH had been allowed to lead the process. Therefore, MSH involved TFDA in most of the implementation activities in Morogoro although TFDA did not involve MSH in the Mtwara and Rukwa processes.

Being one of the first expansion regions, Morogoro was used as a learning ground to test new initiatives in ADDO. Among the changes was active involvement of the council technical staff and committees in the implementation process. Every step was completed with local staff to transfer skills and knowledge even though the program leadership was centralized. Efforts were also made to integrate other public health interventions in the ADDO system.

Unlike the pilot Ruvuma Region, the ADDO implementation process was much faster in Morogoro. This was mainly due to the experience gained from the pilot phase. The implementation process began in October 2006 in Ulanga District and by November 2007, MSH had covered four other vast districts in the region (Kilombero, Kilosa, Mvomero and Morogoro Rural). Morogoro Urban was not immediately covered since it was an urban setting where the program had not yet established procedures for working

with urban retail pharmacies. However, the district had to be covered in the course of the expansion process. Consequently, MSH developed a concept note describing how the rollout would take place in urban settings. The concept was submitted to TFDA and later approved after wide consultations. The approval paved the way for the program to experiment ADDO implementation in urban areas. The experience was very useful in developing a standard approach for ADDO implementation in major cities.

(ii) Development of the Countrywide Rollout Strategy

Soon after agreeing on the initial program scale-up regions (Mtwara, Rukwa and Morogoro), the TFDA with support from MSH, developed a comprehensive five-year national rollout strategy (2006 - 2012) which addressed various needs of the program during the scale-up. Among the issues address in the strategy were the program implementation approach, the sequence, the scope, rollout costs, financing options, program management, institutional frameworks, stakeholder roles, and local "ownership" and sustainability of the program.

Another major output from the process was development of an implementation plan that outlined a clear timeframe for the program rollout and the major implementation costs. The plan envisaged that by July 2012, a total of 8,160 ADDO shops would have been established in the 17 targeted regions and 16,320 dispenser and 6,120 inspectors trained in the regions, and that 80% of the rural, peri-urban, and other underserved populations on the Tanzania mainland would be accessing quality, safe, efficacious and affordable medicines and quality pharmaceutical services.

(iii) Measures to Reduce Implementation Costs

Although the benefits of the ADDO program were highly appreciated based on the Ruvuma pilot results, the high cost of implementation was one of the most criticized aspects of the pilot by external evaluations. Development partners including potential donors were adamant that measures had to be taken to make the intervention more cost-effective. Stakeholders were of the opinion that costs could be reduced significantly through changes to the implementation approach (e.g. using new training approaches, combining certain activities such as mapping and pre-inspection) and eliminating or drastically cutting back on certain program elements which were not very necessary (e.g. elaborate regional and district program launch events).

Revising the ADDO dispenser training approach as a cost-cutting measure was a contentious issue. While reducing the duration of the course appeared a popular view among most development partners, the TFDA and MSH had some reservations on the ground that it could compromise the quality of the training given the educational background of the potential trainees. A decision was finally taken to reduce the duration of the course from six to five weeks, amidst complaints from dispensers that the five weeks were not enough for the training.

To augment the changes, it was also decided that both drug shops owner and dispensers would meet part of the training costs through a cost-sharing mechanism as a way of leveraging resources for sustainable delivery of the training component. However caution was taken not to make the course too expensive to these primary program stakeholders, as doing otherwise would have discouraged their participating and jeopardized implementation of the program. Thus, it was decided that the program would only cater for trainers' costs, training materials, the training venue and half board costs during training, while the trainees (owners and dispensers) met the cost for transport, stationery, accommodation and past of the meals (breakfast and dinner) for the five weeks. The dispensers were also responsible for purchasing dispensing coats from TFDA. As the program evolved, the trainees have been able to cover all training costs except the cost of training materials.

Based on the experience from Ruvuma and the initial cost-cutting approaches implemented in Morogoro, Mtwara, and Rukwa, the TFDA estimated that the total cost of rolling out the program to the 17 regions (including 5% for monitoring and evaluation) would be Tsh.16,868,761,875, or an average of Tsh.992,280,110 ($760,177) per region. If 10% overhead and 15% (average over 5 years) technical assistance costs were included, the total program cost would be Tsh.21,085,952,344, or an average of Tsh.1,240,350,138 ($942,530) per region. Overhead costs were logically considered part of the existing government contributions through TFDA's regular operating budget, and the costs of technical assistance, if needed, would be covered through development partner support. This per region estimate of rollout costs was approximately half of what was required for Ruvuma. It must be kept in mind, however, that the pilot costs covered creation of the model, getting key stakeholder agreement, and the one-time costs of developing processes and materials to support implementing and evaluating the model.

(iv) Development of Legal Instruments to Facilitate Scale-up

Another strategic measure considered was recognition of the need for enhanced local inspections. This was among the options discussed in the ADDO Countrywide Rollout Strategy meeting (April 2006). The discussions informed the development of the Tanzania Food, Drugs and Cosmetics Delegation of Powers Order (2006), as a legal instrument which enabled the TFDA to delegate some of its core regulatory functions (especially inspection, supervision and monitoring of drug outlets) to all LGAs (including those not yet implementing the ADDO program) based on the experiences gained from Ruvuma Region during the development of the ADDO regulatory system. In 2007, the TFDA amended the Delegation of Powers Order through Government Notice (GN) Number 165, to give councils more responsibilities and authority in the implementation of the ADDO program. These changes were supported by the national policy of Decentralization by Devolution (D-by-D) which focused on empowering LGAs (the custodians of development process at the grassroots level) through provision of responsibility, authority, and resources.

2.5.3 Expanding the Program's Scope

Throughout the ADDO piloting and regional expansion phases, the program demonstrated enormous potential to deliver other public health interventions to the underserved rural and peri-urban communities. This realization led to the expansion of the program's scope to integrate other community-based health interventions such as reproductive and child health services, malaria control using Artemisinin-based Combination Therapies (ACTs), and linking of ADDOs with the National Health Insurance Fund (NHIF) to help increase access to essential medicines.

(i) Integrating Child Health Interventions

Incorporation of the Integrated Management of Childhood Illness (IMCI) strategy in the ADDO program was the first major step towards opening up ADDOs for wider public health use and benefit. Through implementation of the IMCI strategy in public health facilities, Tanzania had realized considerable improvements in managing the common causes of childhood illness and death, such as malaria, acute respiratory infections (ARI) and diarrhoea. However, these improvements had not been extended to the private sector where a significant proportion of the population turned to for care.

To help address the gap, the USAID through the MSH's Rational Pharmaceutical Management (RPM) Plus Program selected Tanzania to explore the feasibility of using the private sector to improve access to treatments for common childhood illnesses. The ADDO platform was identified as a potential delivery mechanism for the intervention. Consequently, MSH hired an experienced paediatrician and a national champion of the IMCI strategy, Dr. Suleiman Kimatta, to lead the efforts to integrate IMCI in ADDO. He was instrumental in convincing the Ministry of Health and Social Welfare (MoHSW) to approve the initiative. The process was hastened by Dr. Gabriel Upunda, the then Chief Medical Officer, who used his position as the Acting MoHSW Permanent Secretary, to grant the approval.

> *"When you look at IMCI and ADDO, both have high impact at the lowest level of the healthcare system where the majority of the population seeks care. Integrating IMCI in ADDO made perfect sense because a lot of children were dying in the community without contact with the public health facilities where the IMCI strategy had demonstrated great impact on child survival. I did not see the need for another pilot to show that integrating IMCI in ADDO would help to save more lives of children,"* **Dr. Gabriel Upunda.**

Immediately after the approval, TFDA in collaboration with MSH invited a small technical group of stakeholders to a workshop in Bagamoyo to develop IMCI-in-ADDO training materials. The training was designed to take four days as a separate module in the ADDO dispenser training curriculum. The training covers management of the major causes of childhood illness (malaria, diarrhea, acute respiratory infections) using the common medicines authorized in ADDO, counselling of caregiver on danger signs of illness in children and appropriate care seeking behavior, referral of sick children whose conditions cannot be managed in ADDO, and documentation of referrals for follow-up.

The course was later integrated in the ADDO dispenser training manual, as the sixth module, and delivered for the first time during ADDO dispenser trainings in Kilosa, Morogoro Rural and Mvomero districts of Morogoro Region. Refresher trainings were organized for ADDO dispensers in the other districts in the region (Kilombero and Ulanga) where the regular dispenser training had been conducted prior to the introduction of IMCI in ADDO. Similar fresher trainings were conducted in all the districts of Ruvuma Region to quip ADDO dispensers with the necessary knowledge and skills on the IMCI strategy.

To facilitate follow-up and supportive supervision after the dispenser trainings in IMCI, at least three health officials were trained in each district on the IMCI-in-ADDO initiative. During the follow-up and supportive supervision visits, various information, education and communication (IEC) materials on child health, family planning, and HIV/AIDS, were also distributed to the dispensers. These efforts were backed up with a powerful mass media campaign (radio spots, jingles and talk shows) on the local radio stations in Morogoro Region, to enlighten the population about the common causes of childhood illness, as well as general signs and danger signs of illness in children.

> *"The radio jingles especially the one danger signs became so popular in Morogoro that people kept calling the radio stations to ask for it even after the campaign had ended. The campaign was very successful in increasing the population's knowledge of both the general and danger signs of illness in children,"* **Dr. Suleiman Kimatta, MSH Tanzania Country Director.**

The campaign was run for a period of two months (April and May 2009) on Radio Abood and Radio Ukweli. A follow up survey conducted by MSH in collaboration with TFDA in August 2009 to determine the effectiveness of the campaign, revealed that 95% of the radio listeners who participated in the survey heard the campaign messages, and about 88% of child caregivers who heard the messages reported taking various actions for the benefit of their children. Among the actions mentioned were: early care seeking upon noticing signs of illness (40.6%), use of ITN for protection against malaria (28.1%), boiling drinking water (12.5%), using ALu for malaria treatment (9.4%), keeping the environment clean (6.3%), and hand-washing before feeding a child (3.1%).

(ii) Increasing Access to Malaria Treatment

Malaria is a major public health problem in Tanzania. About 93% of the population lives in malaria transmission areas. The disease is the leading cause of health facility attendance, admission and deaths. One of the key strategies for malaria control is timely treatment using an efficacious antimalarial. When the ADDO program was introduced in 2003, Sulfadoxine-Pyrimethamine (SP) was the recommended first-line treatment for uncomplicated malaria. However, following widespread resistance to SP in the country, the government changed the malaria treatment policy to recommend Artemisinin-based Combination Therapies (ACT) as the standard treatment for uncomplicated malaria. The process of the policy change coincided with the expansion of the ADDO program to Morogoro, Rukwa and Mtwara regions.

Due to the high cost of ACTs, the government received support from the Global Fund and the United States of America President's Malaria Initiative (PMI) to subsidize the treatments in public health facilities. The government settled on Artemether + Lumefantrine (ALu) as the ACT of choice for use in public health facilities. However, the cost of ACTs remained high in the private sector where a significant proportion of the population sought malaria treatment. This was a major impediment to the population's access to the efficacious treatments with potential to delay malaria parasite resistance. Making ACTs affordable and accessible in the private sector became an urgent health priority.

With financial support from the PMI, the MSH's Rational Pharmaceutical Management (RPM) Plus Program, in partnership with the National Malaria Control Program (NMCP) and TFDA designed a plan to distribute subsidized ALu through ADDOs in Morogoro and Ruvuma regions. The plan was immediately approved by the Ministry of Health and Social Welfare. The TFDA also responded fast to facilitate implementation of the intervention by reviewing the ADDO regulations to include ACTs in the list of medicines authorized in ADDOs. This development also necessitated review of the ADDO dispenser training manual to update the malaria treatment guidelines. Refresher trainings were later conducted to all ADDO dispensers to update them on the new malaria treatment policy.

The next major task was to develop a mechanism for distributing the subsidized ALu to ADDOs in the selected regions. The program had to deal with several logistics issues such as quantification of the needed doses, pricing, packaging and branding to differentiate the products from the ALu distributed in the public sector, distribution of the medicines, as well as monitoring the product's availability and use in the target communities. The biggest challenge, however, was ensuring the product's security.

From the very onset, the donor wanted to be sure that the subsidized ALu would not land in unintended outlets. One of the options the program had was to request the manufacturer, Novartis, to print the ADDO logo on the ALu strips. The manufacturer indicated that the option had major legal implications since it would require changing the registered packing by the approving authorities. The next option was to contract a local company to manually stick the ADDO adhesive logo label on each ALu pack. The branding was perfectly done but at additional higher cost to the program.

On the issue of distribution, the program identified a private company (Pyramid Pharma) to handle the process. An agreement was signed between MSH and the company to distribute the subsidized ALu to all ADDOs in Morogoro and Ruvuma regions. The contract was unique because MSH did not directly pay the distributor. The PMI paid for the cost of the products importation up to the port entry. Pyramid received the products at a zero cost but was allowed to recover its distribution management costs (clearance, storage, distribution, administration, etc) from the product sales to ADDOs. The distributor was also allowed include a modest mark-up (profit). After determining the distributor's price for the product, the USAID/PMI directed that a 25% mark-up be added to determine the final selling price to ADDOs. The 25% mark-up was meant for establishing a revolving fund to enhance sustainability of the scheme. The selling price to ADDO ranged between TZS. 1,000 - 1,500, depending on the distribution costs. Based on that, the program established the product's retail price for ADDOs in both Ruvuma and Morogoro regions.

With the delivery mechanism fully in place, the scheme was launched on November 17 2007 at colourful ceremony near Mikumi National Park in Kilosa District. The event was combined with official launching of the ADDO program in Morogoro Rural and Kilosa districts. The ceremony was officiated by the then USAID Tanzania Mission Director, Ms. Pamela White, accompanied by the then MoHSW Director of Preventive Services, Dr. Donan Mmbando.

Pamela White and Dr. Donan Mmbando officially launching subsidized ACT distribution in Morogoro

Although the scheme was implemented over a short period of time, it provided useful lessons for implementation of the longer term Affordable Medicines Facility for Malaria (AMFm) through which the government has been able to facilitate successful distribution subsidized ACTs in the private sector, with financial support from the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria (GFATM). ADDOs constitute a major part of the AMFm delivery mechanism.

(iii) Linking with health insurance schemes

ADDOs' scope was further expanded in 2007 when the National Health Insurance Fund (NHIF) allowed its members to fill prescriptions at selected ADDOs in areas without pharmacies. Integration of NHIF services. Between 2007 and 2012 the NHIF accredited over 700 ADDOs in 20 regions to provide services to its members, mostly civil servants the rural areas.

2.5.4 Lessons from the Centralized Regional Expansion Phase

The regional expansion process provided the TFDA and MSH with an opportunity to develop the ADDO program further. It was during this time that the ADDO training curriculum and materials were reviewed. New components such as those discussed above were introduced and tested at a much smaller scale. The introduction of the child health component in ADDO, the subsidized ACT distribution and integration with the National Health Insurance Scheme, were among the initiatives which encouraged the Global Fund to support ADDO rollout activities in Tanzania.

The transition period demonstrated that for efficiency and fast implementation of the programme to be realized, collaboration between implementing partners at all level is essential. The expansion period provided an opportunity to devise practical approaches to dealing with emerging needs such as accreditation of ADDOs in urban areas. Cost-sharing approaches for the ADDO trainings were also developed and implemented during the expansion phase. Although most ADDO implementation activities were handled by the central level teams during the regional expansion phase, the transition period demonstrated that most councils had limited technical and financial resources to effectively implement the program without close support from the central level. The experiences shaped the implementation approach for the countrywide rollout.

2.6 National Rollout Through Decentralized Approach

2.6.1 The Momentum towards Decentralization

> The national rollout process had to move fast to meet the huge demand for the program and also tap the goodwill and funding potential among different development partners.

Having gained experience from Ruvuma and the initial expansion regions, the country was set for a rapid rollout of the ADDO program to the remaining 17 regions, at the time . By early 2008, the demand for the program had grown significantly in many parts of the country and national health programs such as the Reproductive and Child Health Services (RCHS) and the NMCP were increasingly showing interest in using ADDO as a platform for reaching rural communities with both preventive and curative interventions. The IMCI strategy had just been introduced in the ADDO platform, and so was the distribution of subsidized ACTs through ADDO piloted in Morogoro Region. Moreover, the government through the NMCP's National Insecticide Treated Nets (NATNETs) program had rolled out a unique national discount voucher scheme *(Hati Punguzo)* for distribution of subsidized insecticide treated bed nets (ITNs) and retreatment kits to the groups most vulnerable to malaria (pregnant women and under-five children) through the private sector, and ADDOs were increasingly becoming attractive as distribution points due to their quality of services and documentation practices. The number of development partners willing to support the program had also increased.

Although simultaneous rollout to all the remaining regions was a desirable option, challenges existed. The TFDA did not have enough staff to effectively manage such a large-scale implementation process. Neither was there a large enough pool of trainers at the central level to conduct the ADDO trainings. Furthermore, experience had shown that the centralized implementation

[1]Currently there are 25 regions in Tanzania Mainland, following the creation of Njombe Region out of Iringa, Simiyu Region out of Shinyanga, Katavi Region out of Rukwa, and Geita Region out of Mwanza.

approach applied in Ruvuma and the initial scale-up regions was resource-intensive and would take a long time to cover all the remaining regions. Moreover, availability of funds to cover the pending regions was also not guaranteed despite the goodwill among the development partners and other program stakeholders. Many donor thought that the cost of implementing the program was still high. This situation called for re-engineering of the ADDO implementation model to be able meet the high demand for the program, reduce costs and make efficient use of the available limited resources.

Consequently, on 5th July 2008, the TFDA with support from the MSH's EADSI project, convened a major national ADDO stakeholders meeting at St. Gaspers Conference Centre in Dodoma, where a decision was taken to change the program's implementation approach to a decentralized model. The aim was to speed up the national rollout process, reduce implementation costs and promote local ownership for sustainability. The meeting was officiated by the then Minister of State in the Prime Minister's Office, Regional Administration and Local Government (PMO-RALG), Hon. Celina Ompeshi Kombani (MP), together with the then Minister for Health and Social Welfare, Hon. Professor David H. Mwakyusa (MP). The meeting was attended by 83 participants from different parts of the country and was preceded by a two-day technical working session which discussed various challenges in the implementation of the program and options to address them. The discussions largely focused on the scalability and sustainability of the program, with emphasis on issues of policy, funding, human resource, institutional frameworks and roles of different stakeholders; all of which were central to the decentralization decision.

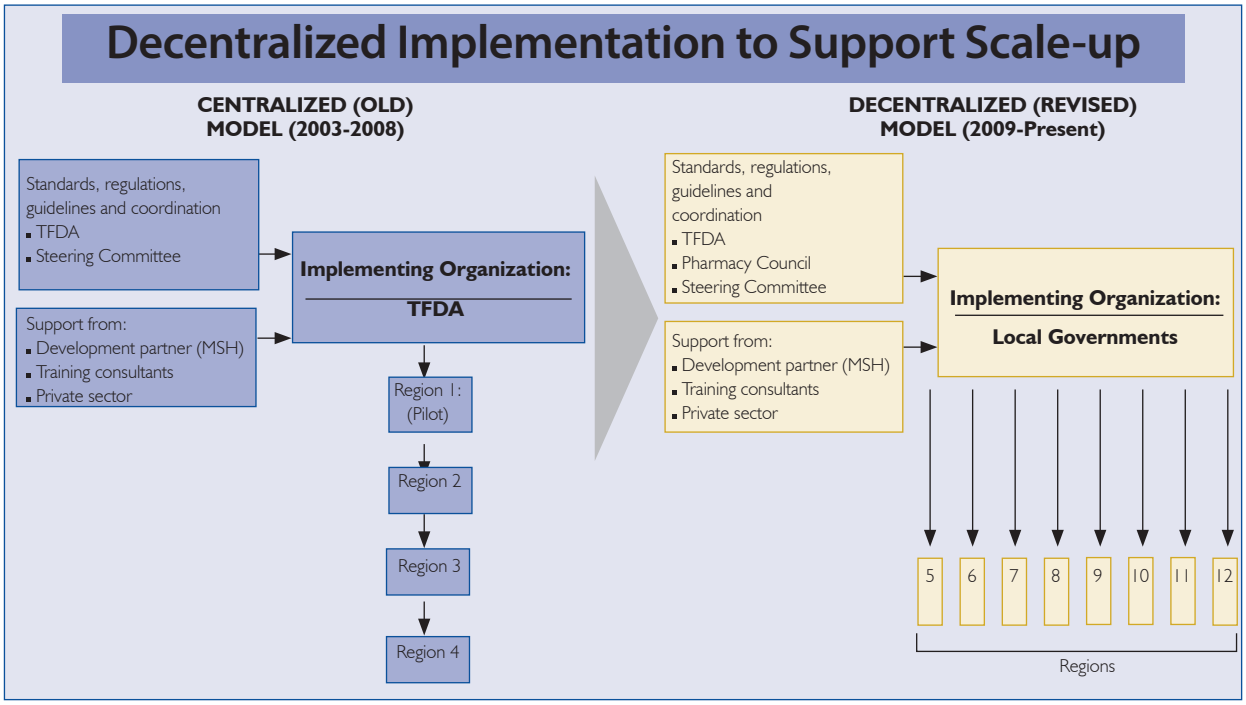
2.6.2 The Design

The decentralized implementation meant putting the Local Government Authorities (LGAs) at the centre of the key program activities including mapping of DLDBs, sensitization of key stakeholders, conducting, preliminary inspections, selecting candidates for dispenser trainings, conducting the ADDO trainings, handling pre-accreditation activities, providing supportive supervision to ADDOs, conducting routine inspections, collecting regulatory fees, coordinating re-accreditation components such as continuing education, and managing general program activities including reporting to the central level. Thus, the decentralized implementation required a close working relation between the TFDA and the councils to ensure smooth implementation of the program. Senior council officials and technical personnel in the council health department were considerably relied upon as key resource persons.

However, the TFDA maintained the following core functions: (i) overall regulatory oversight, guidance and control; (ii) overall management of the national rollout, implementation and evaluation; (iii) follow-up plans for post-accreditation follow-up and inspections with support to districts through TFDA zone offices; (iv) development of modalities/mechanisms for re-accreditation and how to link inspection, supervision, monitoring and continuing education for ADDO to that process; and (v) on-going management and coordination of the ADDO programme on a routine basis once roll out to a region has been completed.

In line with the decentralization plan, the authority moved to strengthen its inspectorate services by establishing inspection committees at the ward, council and regional levels. Committee members were appointed from the respective local government staff. They were responsible for conducting inspections and taking actions within their legal mandates. The inspectorate structure also included zonal offices and regional drug technical committees which were legally formed to deal mainly with appeals from the lower levels and advise the TFDA central office on matters pertaining to the ADDO programme. Funds for the decentralized rollout were centrally managed by TFDA until the overall program management was transferred to the Pharmacy Council, following the promulgation of the Pharmacy Act 2011.

Figure 3



2.6.3 Preparations for the National Rollout

Prior to the countrywide rollout, a number of strategic activities took place. They included mobilization of financial resources, countrywide sensitization of LGAs and training of ADDO trainers and inspectors, and restructuring of the TFDA to improve efficiency.

(i) Resource Mobilization

Having developed the countrywide rollout strategy and implementation plan, the next major task for the TFDA was mobilization of the necessary financial resources to support the rollout. The TFDA under the leadership of Ms. Margareth Ndomondo Sigonda, approached several stakeholders to seek support for the ADDO program. A major achievement for the TFDA immediately after the Ruvuma pilot was the decision by the government to support the expansion of the program to Mtwara and Rukwa Regions. However, getting support for the program rollout to the remaining 17 regions was a major challenge.

Although a number potential donors which had traditionally supported the health sector in Tanzania had shown interest in the ADDO program, most of them were already channelling their support through the national health sector basket (Basket Fund) following establishment of the sector-wipe approach (SWAp) as a mechanism for aid delivery. It was therefore not easy to secure their direct support for the program rollout outside the SWAp framework. Moreover, due to the many competing health priorities at the time largely associated with the major health sector reforms which peaked in the early-to-mid 2000, it was not easy get support through the Basket Fund for an intervention such as ADDO which mainly targeted the private sector.

However, DANIDA was able to support the program through its Health Sector Program Support (HSPS) initiative. It first supported the 2006 Health Research for Action (HERA) independent evaluation of the Ruvuma pilot which also recommended some of the measures (discussed above) to reduce ADDO implementation costs. Following the revision of the ADDO dispenser course duration and consideration of the other recommended cost-cutting measures in the development of the ADOO five-year rollout strategy, DANIDA provided the TFDA with Tsh.578,006,400 in FY2007/2008 towards the review of ADDO dispenser training manuals and printing of several copies in readiness for the rollout. The funds also supported ADDO sensitization seminars for all LGAs in the targeted rollout regions as well as training of ADDO trainers of trainers (ToTs) and district inspectors. In the subsequent fiscal year (FY2008/2009), DANIDA again provided the TFDA with Tsh.250,000,000 to start the initial rollout activities

in Lindi, Pwani and Mbeya regions, as the TFDA continued to look for more funds to complete the process in the regions and rollout the program to other regions of the country.

> The support from DANIDA was instrumental in setting into motion the countrywide ADDO rollout process.

While the resource mobilization efforts for accreditation processes were on-going, donors also demonstrated interest to support revision of the ADDO implementation approach to increase efficiency and cost-effectiveness and also open up the ADDO platform for integrating other public health interventions The Bill and Melinda Gates Foundation provided support through the MSH's East African Drug Sellers Initiatives (EADSI) project towards the revision of the ADDO implementation model to make it more efficient, cost-effective and sustainable and to determine whether the decentralized model provided results that were equivalent to or better than the centralized model.. The USAID-supported child health interventions and subsidized ACTs distribution in ADDOs opened up a golden opportunity for funding from the Global Fund towards completion of the rollout; while the EADSI grant enabled MSH to provide the much needed technical support toward successful review of the ADDO implementation model. The EADSI also supported monitoring and evaluation efforts (with a focus on sustainability, scalability and replicability of ADDO) and replication of the program in Kibaale District of Western Uganda, with a great degree of success.

> *"Facilitating decentralization which allowed for faster and more efficient implementation and the resulting nationwide scale-up of the ADDO initiative are probably the most significant of MSH's contributions. Although conceptualization of the ADDO model and its piloting in Ruvuma was critical, all too often projects end after that stage has been completed,"* **Keith Johnson, Director, Private Sector Programs, MSH-USA.**

In a bid to broaden the resource mobilization efforts, the TFDA decided to seek support from the Global Fund Round 6 towards the planned ADDO rollout. A technical team consisting of senior TFDA and MSH staff (from both Tanzania Country Office and Head Office in USA) met for a couple of days in Bagamoyo to develop the proposal. Considerable efforts were made by the team to demonstrate ADDO's potential to support the delivery of other health interventions such as malaria prevention and treatment, reproductive and child health services, and components of HIV/AIDS prevention and control, among others. However, the bid was not successful.

In 2008, Tanzania got another opportunity to apply for Global Fund Round 7 to support the national efforts to increase access to ACTs. The TFDA saw this as an opportunity to make another attempt to seek support for ADDO rollout by positioning the drug shops as a potential avenue for increasing access to the malaria treatments especially in the underserved rural and peri-urban areas where there were few or no pharmacies, and access to public primary health care facilities was also difficult. With technical support from MSH and CHAI, the TFDA partnered with the NMCP to develop a joint proposal to the Global Fund Round 7. However, the partnership did not come easy. Differences in approach emerged from the very initial stages of the proposal development.

The NMCP had proposed a three-day training for dispensers in all Part II Poison shops, as part of the process of delivering quality assured ACTs through the private sector. The TFDA took a strong stand against the proposal on the grounds that unlike ADDOs, regulations did not allow DLDBs to dispense prescription medicines including ACT. The TFDA used this opportunity to push for inclusion of ADDO rollout in the proposal by insisting that the support should not just focus on ACTs dispensing but changing the entire dispenser behaviour and operations of the drug shops. Moreover, the new malaria treatment policy had already been integrated in the ADDO dispenser training curriculum. The Global Fund saw the logic in the TFDA's position but questioned how the ADDO program would support the NMCP's objectives in the event that the rollout process took too long to be completed. After a series of discussions, a compromise was reached. The TFDA agreed that it would allow outlets with fully trained dispensers to start dispensing ACTs, as the process of accrediting the outlets continued. With those clarifications made, the Global Fund approved the Tanzania proposal which included ADDO rollout in 6 selected regions.

In November 2008 (FY2008/2009), the TFDA received the first disbursement of the funds (phase 1) amounting to Tsh.1,500,096,713 to carry initial ADDO rollout activities in selected six regions namely Lindi, Pwani, Kigoma, Singida, Mbeya and Tanga. The second disbursement amount to Tsh.2,709,795,670 was made in FY2009/2010 to continue the rollout activities. As the rollout process gained momentum, the Global Fund launched the Affordable Medicine Facility-malaria (AMFm) – a global a global subsidy to make ACTs available and affordable to all malaria patients in both public and private sectors. The AMFm was not a new funding round but a tool to help meet the Round 7 objectives. Tanzania was one of the countries eligible to apply for the first phase of the AMFm planned to operate for 18 months. Again, the TFDA and NMCP, with technical support from MSH and CHAI, put together a joint proposal for the AMFm in October 2009. The proposal was approved, allowing Tanzania to access more funds

to increase access to quality assured ACTs and complete the ADDO rollout. The final disbursement of Tsh.3,015,797,285 was made in FY 2010/2011. Thus, the TFDA received a total of Tsh.7,225,690,208 from the Global Fund towards ADDO rollout – thanks to the AMFm initiative.

However, the introduction of AMFm considerably delayed the second GF Round 7 disbursement. As the country was waiting for the Phase II funds, some LGAs in Shinyanga, Tabora, Iringa, Arusha and Kilimanjaro regions took initiative to mobilize funds to introduce ADDO. In the same period (2009), CHAI also obtained Tsh.606,639,500 from USAID through TSMP to support initial ADDO rollout activities in Shinyanga and Dodoma Regions. When the program was introduced in Dar es Salaam City in 2011, drug shop owners and dispensers, because of their big number (~1,300 dispensers and ~1,700 owners) also made significant financial contributions towards training activities during the rollout.

(ii) Sensitization of Regional and Local Government Authorities

Sensitization of key decision-makers at the regional and council levels was one of the key activities that set the stage for the rapid national rollout of the ADDO program. With financial support from DANIDA, TFDA was able to cover all the 17 rollout regions with specific messages about the ADDO. The aim was to raise their awareness of the program and enlighten them about their envisaged roles in the implement process once the planned rollout began. The sensitization activities were very instrument in gaining the support of the regions and councils towards a smooth national rollout of the program.

(iii) Training Trainers of Trainers

Training trainers of trainers (ToTs) was undertaken to address the problem of scarcity of ADDO trainers. The trainees were drawn from different regions and districts countrywide. The aim was to make the trainers readily available in the councils and help to reduce training costs in terms of per-diem and travel allowances for the trainers. The strategy also made it possible to conduct multiple ADDO trainings in different districts and regions simultaneously. The trainees had different educational backgrounds, and were drawn from both public and private sectors. The majority were pharmacists, trained and experienced nurses, medical and clinical officers. Those picked from the public sector were mostly regional and district pharmacists, senior medical personal in both government of faith-based hospitals, and tutors from various health training institutions. The first ToT training was held in Iringa, organized by TFDA and funded by DANIDA. More trainings took place in Morogoro and Dodoma, with support from different funding sources. By the time the rapid national rollout process began, TFDA had trained over 200 ToTs in different parts of the country.

2.6.4 Multi-regional Rollout

During the development of the five-year National ADDO Rollout Strategy (2006 – 2011), the 17 targeted regions were grouped into five implementation groups (Table 2). However, during the actual implementation, some changes were made to accommodate interest of other stakeholders and also make effective use of the available funds for the process.

Table 2: ADDO Rollout Plan

Implementation Groups	Regions	Timeframe
Group 1	Lindi, Pwani, Singida and Dodoma	FY2007/2008
Group 2	Mbeya, Kigoma, Tabora and Iringa	FY2008/2009
Group 3	Kagera, Mwanza and Mara	FY2009/2010
Group 4	Manyara, Shinyanga and Tanga	FY2010/2011
Group 5	Arusha, Kilimanjaro and Dar es Salaam	FY2011/2012

Note: *Ruvuma, Morogoro, Rukwa and Mtwara regions were excluded because they were already implementing the program.*

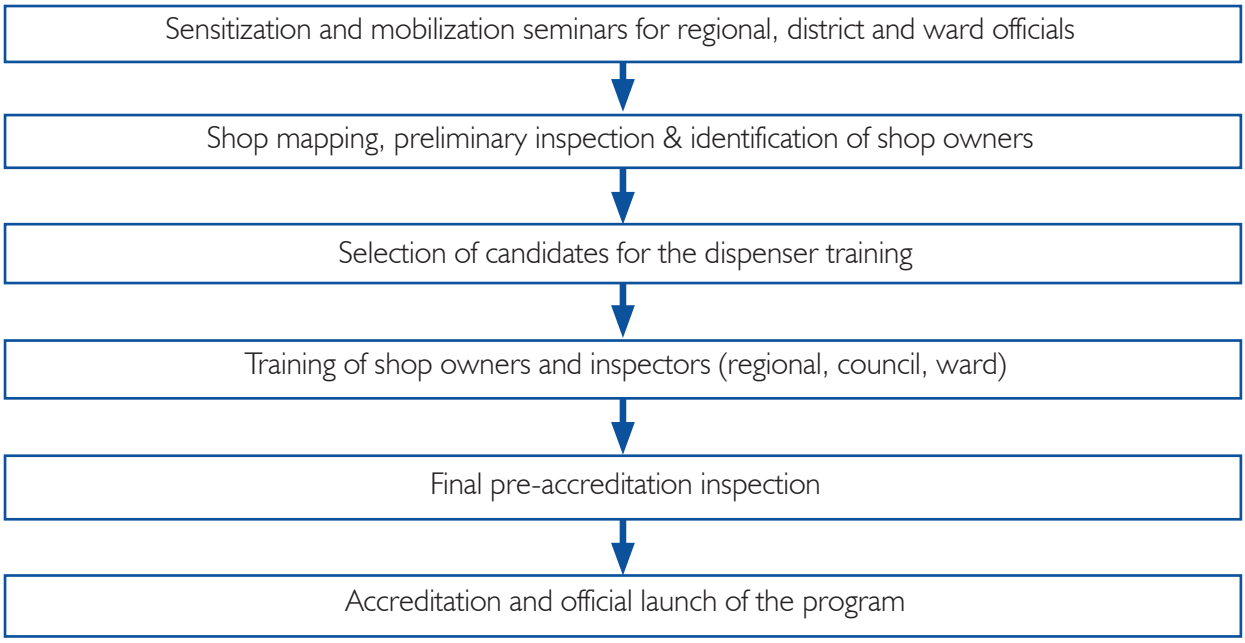
Initially the Global Fund had agreed to support ADDO rollout in 6 regions proposed by the TFDA in consultation with the NMCP. The regions were Lindi, Pwani, Singida, Kigoma, Mbeya and Tanga. Thus, when the TFDA received the first disbursement of the GF Round 7 funds in November 2008 for FY2008/2009, it immediately initiated the initial ADDO rollout activities in all the six regions. These regions became commonly known as "Phase I regions". However, when Tanzania qualified for additional funding under the AMFm as a tool for meeting the GF Round 7 objectives, all the remaining 11 regions were supported to implement the ADDO program. They became commonly known as "Phase II regions".

Due to late disbursement of the Round 7 funds to support rollout activities in the fiscal years 2009/2010, some LGAs in Shinyanga, Tabora, Iringa, Arusha, Kagera and Kilimanjaro regions took initiative to introduce the ADDO program using their own funds. It was at this point that CHAI also intervened to support the initial program rollout activities in Shinyanga and Dodoma regions. In July 2010, the program was introduced in Dar es Salaam followed by training of drug shops owners and dispensers in the region in 2011. Manyara and Mara regions were also covered in FY2010/2011. Mwanza was the last regions to introduce the program in 2013.

As the TFDA was gearing up to complete the rollout process, the Pharmacy Act 2011 was promulgated and the overall program management had to be transferred to the Pharmacy Council. During the transitional period in 2012, the TFDA worked in collaboration with the Pharmacy Council to complete ADDO implementation activities in the Phase II regions, using the Funds from the Global Fund. The transition partly contributed to the delay to introduce the program in Mwanza, the only region in which the Pharmacy council managed the ADDO rollout process without direct involvement of the TFDA.

By June 2014, all the 21 regions of Tanzania Mainland were implementing the program. A total 9,226 retail drug outlets had been mapped, out of which 6,086 shops were accredited and 3,140 were in the accreditation process. The program had also trained over 19,140 dispensers and 3,262 drug shop inspectors. The implementation process in all the regions followed a standard sequence of activities carried out in every district/council in the regions (Figure 4).

Figure 4: Implementation Components and Sequence



2.6.5 Major Lessons from the Decentralized Rollout

Decentralization increased program ownership at the local levels, facilitated rapid scale-up, and reduced implementation costs. For instance, it took the TFDA 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model. In comparison, 10 regions completed implementation within 3 years using the new decentralized approach. Furthermore, TFDA estimated that the savings were greater than 50%. For example, in a district with 100 outlets to be accredited and 120 dispensers to be trained, the decentralized implementation model cost Tsh.73 million (~USD 49,000) compared to Tsh.163 million (~USD 109,000) under the centralized implementation model.

Savings came primarily from a reorganized dispenser training schedule that was reduced from 45 to 35 days and the merging of mapping and preliminary inspection activities that were carried out by district officials rather than centrally based TFDA staff. Evaluation of product availability and service quality in Singida compared with Mtwara showed that these changes did not have significant negative impact on implementation results. In addition, owners and dispensers paid larger proportions of their training expenses, which were formerly covered by the government or a donor.

A more recent situation assessment conducted by the MSH's Sustainable Drug Seller Initiatives (SDSI) project with technical assistance from Apotheker Consultancy (T) Ltd, demonstrated that decentralization increases regulatory monitoring at the lowest level. The assessment was conducted between July and August 2012 and covered six selected regions (Morogoro, Ruvuma, Pwani, Singida, Tanga and Mbeya). The objective was to understand the functioning of the decentralized ADDO regulatory system. It revealed that while TFDA was able to conduct only two inspections between July 2010 and June 2012 (FY2010/11 and FY2011/12) covering a total of 100 ADDOs (an equivalent of 0.33% of all registered ADDOs by June 2012), about 53% of Ward Health Committees (WHCs) covered in the assessment conducted all the 8 scheduled inspections in the same period (4 per year), with most of the inspections covering up to 100% of functioning drug outlets.

> Decentralization increases local ownership, improves efficiency and reduces implementation costs.

> While TFDA was able to conduct only 2 inspections between July 2010 and June 2012, covering 0.33% of all registered ADDOs; 53% of WHCs conducted 8 inspections each, in the same period, with most of the inspections covering up to 100% of functioning ADDOs.

The high coverage of the WHC inspections is made possible by the fact that the WHCs have much fewer outlets to inspect than other regulatory bodies. Most wards have between 1-5 drug outlets, although a few have more than 5. With availability of resources, this number of shops can be covered in one to two days. Furthermore, the assessment demonstrated that with proper planning and prioritization regulatory activities, the cost of ward inspections should be manageable to councils. In most cases, a ward inspector is paid between Tsh.5,000 and Tsh.10,000 as extra-duty allowance per inspection day. There are no additional costs since most inspectors walk or use bicycles to reach inspection sites. Thus, for the WHC to perform the 4 scheduled inspections a year, it would require between Tsh.40,000 and Tsh.80,000 as extra-duty allowance for two inspectors. Given that the average number of wards per council is about 25, the annual cost of local inspection would be about Tsh.1 million to Tsh.2 million only.

2.7 Implementation Challenges

Although the ADDO national rollout process was generally smooth, a number of constraints and challenges have been experienced in the implementation of the program. The challenges largely touch on financing, regulatory monitoring and control, human resource and practices of ADDO providers.

2.7.1 Inadequate Financing of Key Regulatory Activities

When the TFDA decentralized some of its regulatory functions and ADDO program management activities (e.g. pre-accreditation processes, supportive supervision and routine inspections) to the councils, the expectation was that the councils would allocate the necessary funds for implementation of these activities in the annual Comprehensive Council Health Plan (CCHP). To complement the CCHP, the TFDA allowed the councils to retain 40% of regulatory fee collections, to support some of the basic regulatory activities including quarterly CFDC meetings and Ward Health Committee (WHC) inspections.

However, most councils do not regularly budget for these activities, and collection of regulatory fees is generally weak. An assessment conducted by TFDA in 2011 to understand how the councils were fairing on with the delegated regulatory functions, revealed that only 14 out of the 42 councils surveyed collected regulatory fees in the fiscal years 2007/08, 2008/09 and 2009/10, and only 9 out of the 14 councils remitted the remaining 60% of the collections to TFDA as required. This also affects implementation of regulatory activities at the central level.

It was also learnt that not all councils use the 40% allocation for the intended purpose. Some CFDCs face difficulties accessing the allocation once the collections are deposited in the general health department account (or the Council Director's miscellaneous account currently in use as per the new financial regulations for LGAs). Moreover, the current system of "blanket" allocation of the 40% of regulatory fee collections is open to abuse since it is not based on the performance of the councils nor specific planned regulatory activities. These financing challenges significantly constrain effective maintenance and sustainability of the ADDO regulatory system at the local level.

2.7.2 Weak Enforcement of Regulations

Due to the inadequate prioritization and resource allocation for inspection and supportive supervision activities by council authorities, enforcement of regulations at the local level is generally varied. The July-August 2012 SDSI/Apotheker situational analysis showed that although WHCs were generally trying to carry out the delegated regulatory functions, most CFCDs neither conducted inspections regularly nor facilitated WHCs to carry out ward level inspections. For example, between July 2010 and June 2012 (FY2010/2011 and FY2011/2012) Mbinga, Morogoro Rural, Singida Urban, Korogwe and Mbarali districts conducted only 2 inspections each, out of the 8 recommended for the two-year period (4 per year). The number of quarterly CFDC meetings conducted in the assessment area also arranged between 1 and 2 per year in most of councils, and minutes of the meetings and inspection reports were widely unavailable.

Apart from the inadequate prioritization of the key regulatory activities, conflict of interest among the regulators and limited decision powers of local inspectors are among the deterrents to effective enforcement of regulations. It is estimated that more than half of ADDOs in the country are owned by health workers in the public sector, many of whom serve as drug shop inspectors. Although regulations do not allow an inspector to inspect his/her own shop, there is a potential for an inspector not to penalize a shop owned by a fellow inspector in case of violation of regulations. Moreover since the local inspectors have limited decision powers, they mostly issue verbal warnings to culpable drug shops, pending follow-up action by the district pharmacist or national level inspectors during audit or investigative inspection.

During the SDSI/Apotheker assessment, the assessment team did not come across any written warnings, closure orders, or a single shop closed by the regulatory authorities for gross violation of regulations, yet serious offenses were noticeable in the assessment area. For example, about 14% of the ADDOs visited were managed by untrained dispensers and only 33.1% of the shops had all the three legal documents required for formal operation of the business (accreditation certificate, business permit and dispenser certificate) displayed in the shop as per regulations. About 45% had an incomplete set of the documents, and 22.3% did not have any of the documents. Considering that the documents define lawful existence of the outlets, the absence of all the three should have led to immediate closure of the culpable outlets.

The other factor which has made inspections ineffective is the growing practice among ADDO providers to close shops whenever they noticed inspectors were around. The practice is fueled by leakage of information about an impending inspection visit by errant inspectors out of selfish personal interests and the widespread use of the mobile phone technology by ADDO providers. It is not uncommon for the providers to send each other SMS alerts whenever inspectors landed in a particular location. Thus, new strategies need to be devised to deal with this vice to ensure that inspections are effectively carried out as planned. In some districts, ADDO provider associations have been instrumental in advocating against this retrogressive practice.

2.7.3 Slow Process of Accreditation

Accreditation of ADDOs is an elaborate process which begins at the community level and ends at the central level. It is also a continuous process once the ADDO program has been introduced in a particular district. However, experience has shown that the process is generally slow in most councils, mainly because CFDCs are not conducting preliminary inspections as frequently as expected, CFDC meetings to review applications hardly take place and ADDO trainings take too long to be organized. Moreover, some CFDC would even forward to TFDA applications for approval without the necessary accompanying documentations such as a summary of inspection reports and minutes of CFDC meetings recommending the applications. For the period TFDA was responsible for the process, incomplete applications accounted for about 20% of all the applications retuned to the council for the due process to be followed. Some CFDCs has also formed a habit of bypassing WHCs in processing the applications, further delaying the accreditation process, if discovered. In some cases shop owners also delay to meet the established accreditation conditions. The SDSI/ Apotheker assessment showed that on the average, accreditation lead-time (from submission of an application by the prospective ADDO owner to approval by TFDA) ranged between 16 and 24 weeks in most areas.

For the period TFDA was responsible for the accreditation process, incomplete applications recommended by CFDCs accounted for about 20% of all the applications retuned to the councils for the due process to be followed.

2.7.4 Shortage of Trained Dispensers and Ward Inspectors

Even though considerable efforts have been made to train ADDO dispensers in every district in the country, shortage of these key personnel is widespread. It is instructive to note that by December 2013, the number of trained dispensers was more than twice the number of shops accredited by the same date (5,542 shops versus 13,500 dispensers), yet the shortage was still prevalent. Although regulations require each ADDO to have at least two trained dispensers, in practice, over 90% of the outlets operate with only one dispenser due to their small scale of operations. Thus, more than more half of the trained dispensers do not work in ADDOs. The question is, where do they go?

Due to the acute shortage of skilled health workers in public facilities especially in rural areas, some of the trained dispensers have been absorbed in the public sector and NGO/faith-based facilities. Others have opened their own ADDOs, while others have migrated from their districts for different economic and social reasons including marriage.

A more fundamental factor is lack of a reliable system for continuing education and training of the dispensers at the council level. Many councils tend to take a very long time to organize ADDO trainings after the initial trainings conducted during the program rollout. However, the more recent developments by the Pharmacy Council to institutionalize the 35-day dispenser training course in government zonal health training and resource centres, and the introduction of the one year pharmaceutical dispensing certificate course in both public and private training institutions are envisaged to provide a lasting solution to the challenge.

A similar challenge has been experienced in the case of the ward inspectors. Most councils have not taken initiative to conduct inspector trainings after the initial trainings conducted during the ADDO program rollout in their districts. Considering the high turnover of these key personnel and new postings at the community level, many wards have ended up with health committee

members without proper knowledge about the ADDO program and inspection procedures. The inspector and dispenser shortage, if not well managed, can greatly affect the operations and quality of ADDO services and sustainability of the program.

2.7.5 Difficult Urban Implementation of the Program

The ADDO program was originally designed for rural and peri-urban areas where access to medicines was most difficult. However, based on the Ruvuma piloting results, the government took a decision to rollout the program nationally, including the major urban areas with considerable numbers of pharmacies and high concentration of DLDBs, such as Dar es Salaam, Mwanza, Arusha and Mbeya. This was followed by a directive by the government that no DLDB permits should be renewed after January 15 2009, and that DLDB regulations should be revoked by 2011 when the national rollout of the ADDO program was scheduled for completion.

However, implementation of the program in the major urban areas (cities) has been met with some resistance from DLDB owners. The most contentious issue has been the distance provision in ADDO regulations which allows for establishment of only one ADDO within a radius of 300m. The regulations also prohibit establishment of ADDOs within the Central Business District (CBD) served by pharmacies. Thus, any DLDB which is unable to upgrade to pharmacy is required to move out of the CBD. Both regulatory requirements have been a major cause of conflict between regulatory authorities and DLDB owners.

As a compromise, TFDA agreed that only new shops established after introduction of the ADDO program in the cities would be subjected to the distance rule. The amnesty enabled DLDBs which had met accreditation requirements to upgrade to ADDO without having to move location of the business. However, an attempt to push out DLDBs and ADDOs from CBDs was still challenged in the high court by outlet owners in Dar es Salaam, leading to an injunction on the process. In Mbeya DLDB owners also took Mbeya City Council to court for the same reasons. These challenges have resulted in continued existence of DLDBs in some of the major urban areas. Dar es Salaam region leads in the number of DLDBs operating side by side ADDOs.

2.7.6 Inadequate Coordination and Reporting

Effective coordination between central level regulatory agencies (TFDA and PC) and the lower level regulatory structures (RFDCs, CFDCs and WHCs) is essential for efficient functioning of the decentralized regulatory system. Although the roles of all the structures are clearly outlined, coordination between the structures is generally weak due limited opportunities for physical interaction through meetings, poor communication and inadequate reporting at all levels. At the national level, there is no established forum which brings together the central level regulatory agencies (TFDA and PC) with the RFDC and CFDCs to discuss regulatory matters and receive feedback on the implementation of delegated functions. Likewise, at the lower levels, there is no established system for routine meetings between TFDA zonal offices and RFDCs, RFDC and CFDCs and CFDCs and WHCs. Previously, TFDA would sponsor the Association of Local Government Authorities in Tanzania (ALGAT) Annual Conference and request for a slot in one of the conference days to discuss regulatory matters. However, that opportunity was hardly enough to exhaustively address regulatory issues.

In the absence of meetings, the regulatory structures mainly depend on memos and activity reports as a way of relaying information and obtaining feedback. However, reporting is generally weak at all levels and constrain effective coordination between the various regulatory bodies. Structurally, WHCs are supposed to send quarterly activity reports including inspection reports to the CFDC. On the other hand, CFDCs are supposed to send quarterly activity and financial reports to the central level (TFDA and PC) and copy RFDC. The RFDCs are also supposed to report directly to the central level on regulatory matters. However, in practice, major gaps exist in the reporting system. For example, the SDSI/Apotheker assessment (June - August 2012) observed that out of the six CFDCs surveyed in Morogoro, Ruvuma, Singinda, Pwani, Tanga and Mbeya regions, only two CFDCs submitted reports to TFDA and copied the respective RFDC in the two-year period under review (FY2010/11 and FY2011/12). Moreover, the observed practice by some CFDCs to recommend ADDO applicants for accreditation without inputs from the WHCs, is a pointer to a major coordination and reporting problem at the local level.

Reports from CFDCs to the central level are particular critical for monitoring implementation of the ADDO program and informing central level decisions in addressing system needs and challenges. Their absence therefore creates a major gap in the coordination system and decision-making processes. The biggest challenge, however, is that structurally and legally, councils are semi-autonomous administrative units only accountable to the central government through the Prime Minister's Office, Regional Administration and Local Government (PMO-RALG), not the Ministry of Health and Social Welfare under which the TFDA and PC are established. Thus, when councils fails to send regulatory activity and financial reports to the regulatory agencies, the agencies have no direct authority to reprimand the culpable councils. They can only recommend action against the councils to PMO-RALG through the Ministry of Health and Social Welfare. Practically, this has not worked very well to ensure accountability on the part of councils.

2.7.7 Weak Monitoring and Evaluation

Although a monitoring and evaluation system for the ADDO program exists, the system is largely geared toward meeting the program scale-up needs with a limited set of outcome indicators. Moreover, routine data collection and processing is generally weak despite availability of various documentation and reporting tools. The tools include among others, the patient/drug register, inspection form, patient complaint/adverse drug reaction form, expired medicine form and patient referral form and register. Other important information sources which remain under-utilized are quarterly inspection reports, supervision reports and training reports. Going forward, a much broader M&E framework would to necessary to capture the evolving M&E needs of the program and demonstrate its potential on a wider scale.

> *"Since the information collected through the ADDO documentation tools and reporting system is relevant to both TFDA and PC in the respective regulatory mandates, I think both agencies need to work together to establish an effective M&E system through which a set of key indicators can be monitored routinely and analyzed periodically, with minimal duplication effort, to inform policy, intervention planning and decision-making at implementation levels,"* **Elizabeth Shekalaghe, the Pharmacy Council Registrar.**

> *"With the successful national rollout of the ADDO program, I think a comprehensive independent evaluation of the program is needed to demonstrate the impact of the nationwide implementation. This is an area in which TFDA and PC could work together, considering the role TFDA played in the implementation process,"* **Adam Fimbo, the TFDA Director of Medicines and Cosmetics.**

3 Implementation Gains

Evidence from various internal and independent evaluations has shown benefits of the ADDO program. Among the widely documented benefits are increased access to quality essential medicines, improved dispensing quality and enhanced regulatory control of the private retail pharmaceutical sector. Moreover, ADDOs have created a broad platform for delivery of various public health interventions and stimulated economic and social development.

Through ADDO,

We have increased access to essential medicines,

We have dispensers who are qualified,

We have shops that meet minimum regulatory standards,

We have medicines whose sources can be verified

We have drug shop owners who understand the legal and regulatory requirements for operating the business,

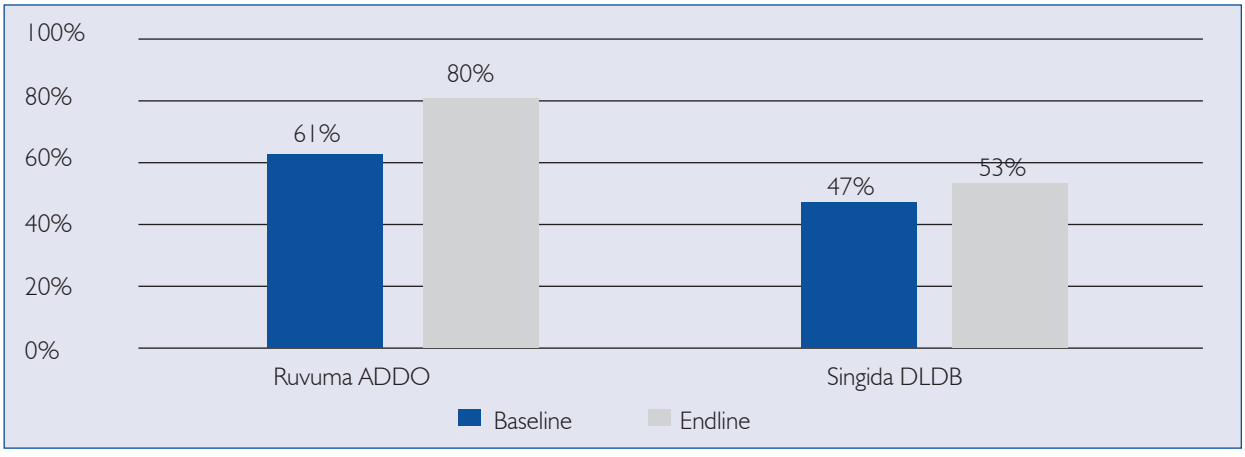
We have communities that are aware that they deserve quality services.

Hiiti Sillo, TFDA Director General

3.1 Increased Availability of Essential Medicines

The SEAM evaluation conducted at the end of ADDO piloting in Ruvuma revealed a major increase in availability of essential medicines. The evaluation used a tracer list of 20 key medicines to study the availability. It was observed that average availability of all the tracer medicines in Ruvuma had increased by 19% (from 61% at baseline to 80% at endline). The increase was much higher than in Singida which was used as a control region (Figure 5). The tracer products included both prescription (Part I) and non-prescription (Part II) medicines.

Figure 5: Comparison of average availability of Part I and Part II medicines in Ruvuma and Singida at baseline (DLDBs) and endline (ADDOS and DLDBs).



Source: SEAM Evaluation 2004/05

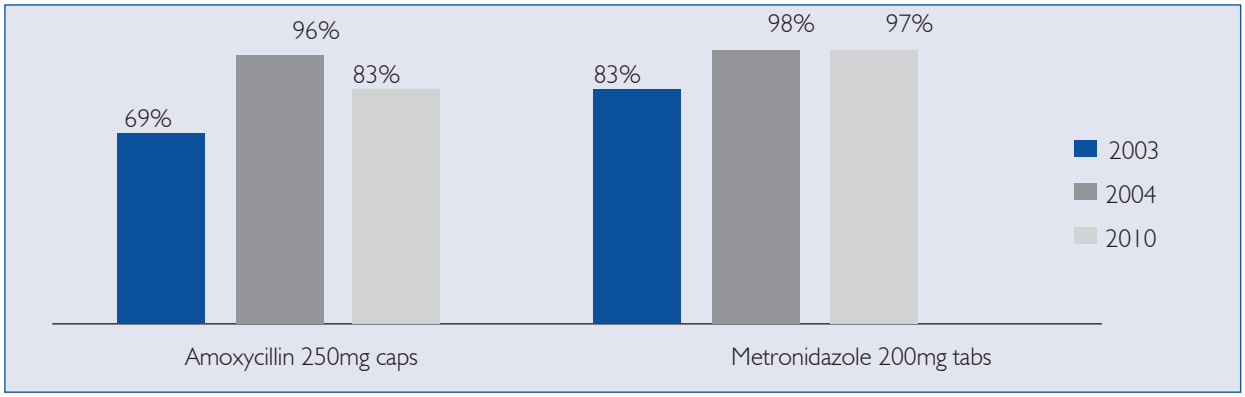
According to TFDA regulations, non-prescription medicines may be sold without a prescription by either DLDBs (Part II shops) or pharmacies (Part I shops) but Part I medicines could only be sold by pharmacies against a prescription. Review of regulations to allow ADDOs to sell selected prescription medicines was among the incentives offered to DLDB owners in Ruvuma to upgrade their shops to ADDO status. Thus, at the time of the endline survey, ADDOs in the region were legally selling all the

Part I medicines on the tracer list, unlike DLDBS in Singida which were selling the medicines contrary to regulatory provisions. As a result, availability of Part I medicines in Ruvuma increased from 56% (baseline) to 79% (endline) compared with the marginal increase observed in Singida (from 38%, baseline to 42%, endline). Average availability of Part II medicines was also relatively higher in Ruvuma (83%, endline) compared with Singida (76%, endline).

An independent evaluation conducted by Health Research for Action (HERA) in 2006, with support from DANIDA, concluded that ADDOs do increase access to quality essential medicines, which is otherwise constrained by insufficient availability of medicines in public facilities, and sometimes long distances between communities and health care providers. The study noted that life-saving medicines such as antibiotics and first-line treatment for uncomplicated malaria were widely available in ADDOs, although availability of some essential medicines for addressing maternal and child health needs (such as Ferrous Sulphate, Folic Acid and Vitamin A tablets) were not yet optimal.

The East African Drug Seller Initiatives (EADSI) evaluation completed in November 2011 demonstrated that the medicines access gains are scalable and sustainable. The study observed that eight years after completion of ADDO piloting in Ruvuma, essential medicines authorized in the drug shops were largely available. For example, in 2003 before antibiotics were allowed in Part II shops, 69% of DLDBs surveyed in the region had amoxicillin 250mg capsules. In 2004, after introduction of ADDOs, availability increased to 96%. In 2010, availability of the medicines in ADDOs was still significantly high (at 83%). For metronidazole 200mg tablets, availability was 83% in 2003, 98% in 2004 and 97% in 2010 (Figure 6).

Figure 6: Average availability of essential antibiotics in Ruvuma Region (2003-2010)

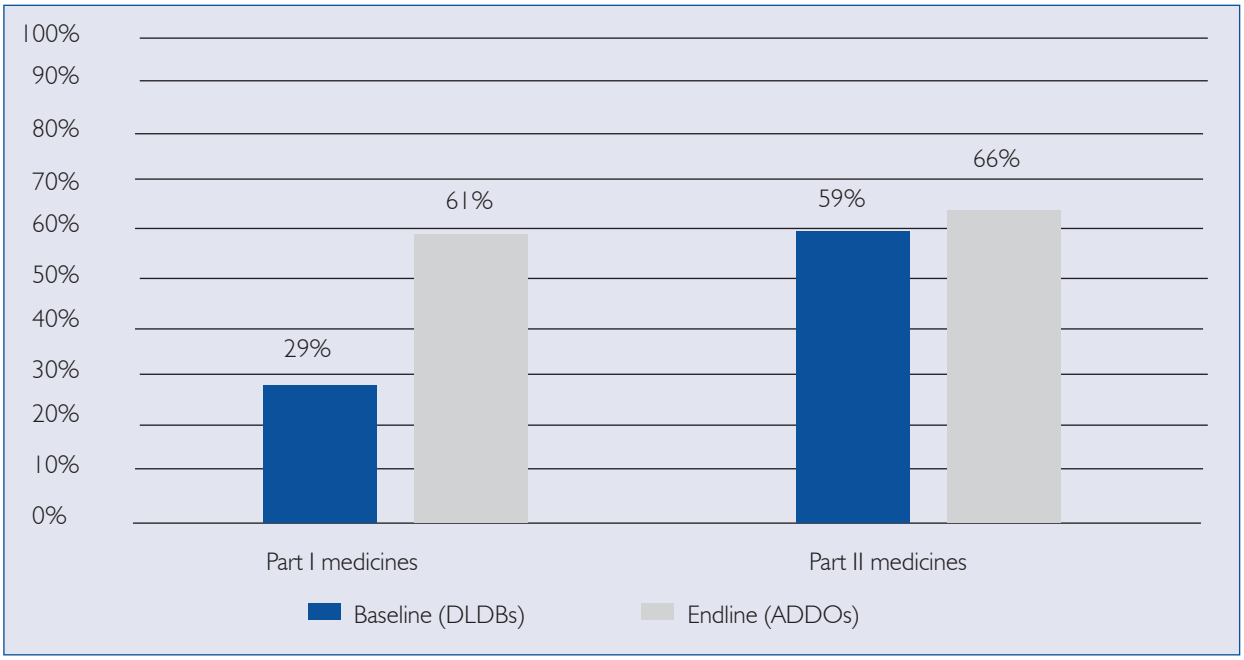


Source: EADSI Evaluation, 2011

Moreover, experiences from other regions where implementation of the program has been extended, have shown a similar trend. The EADSI evaluation revealed that in 2009, just before ADDO program was rolled out to Singida Region[2], availability of prescription and non-prescription medicines in DLDBs was at 29% and 59%, respectively. A year after implementation of the program, availability of prescription medicines increased by 32% (from 29%, baseline to 61%, endline). An increase was also observed in availability of non-prescription medicines (Figure 7). The evaluation used a tracer list of 30 products to study the availability of essential medicines in the region.

[2]Singida was the first region to implement the ADDO program through the decentralized approach. Thus, it was used as a pilot region in the context of the EADSI evaluation, and a control region in the context of the SEAM evaluation.

Figure 7: Average availability of Part I and Part II medicines in Singida Region



Data Source: EADSI Evaluation, 2011

Although the increase in medicines availability has been mainly attributed to changes in regulations to allow ADDOs to sell selected prescription medicines, improved efficiency in the ADDO supplies chain is also widely acknowledged as an important contributing factor. During the pilot in Ruvuma, deliberate efforts were made to encourage national pharmaceutical wholesalers to establish branches in the region to help increase medicines access, reduce operation costs to ADDOs, control end-market price of essential medicines and guarantee quality of medicines sold by ADDOs.

3.2 Improved Quality of Medicines

The 2005 SEAM evaluation showed that the ADDO program had improved quality of medicines available in accredited drug shops. Registration status of medicines was studied in both baseline and endline as an indicator of the quality of medicines. The study revealed that the proportion of unregistered medicines in Ruvuma had reduced by 24% (from 26%, baseline to 2%, endline). In Singida, the proportion of unregistered medicines also reduced – thanks to the broader regulatory work of the TFDA. However, the reduction (from 29%, baseline, to 10%, endline) was not as significant as the situation in Ruvuma.

The findings implied that ADDO users in Ruvuma had a 1 in 50 chance of buying an unapproved medicine, compared with a 1 in 10 chance among DLDB users in Singida. The findings were consistent with opinions expressed by ADDO users during exit interviews which were included in the pharmaceutical quality component of the endline survey. A higher proportion of consumers in Ruvuma (94%) described the quality of medicines available in ADDOs as "good" or "excellent", compared with 83% of consumers in Singida who felt the same about quality medicines in DLDBs.

The remarkable reduction in availability of illegal medicines in Ruvuma was partly attributed to improvements in the ADDO supply chain. The HERA evaluation noted that most ADDOs in Ruvuma were buying medicines from Southern Highlands Pharmacy in Songea Urban or Southern Highlands ADDO Restricted Wholesale in Mbinga District, both operating according to the TFDA regulations which include adherence to product quality requirements. Other major factors included increased regulatory oversight through local and TFDA inspections and supervision visits, confiscation of illegal products and increased transparency in operation of the accredited drug shops.

A more recent study by MUHAS School of Pharmacy *(E. Kaale, M. Chambuso, V. Manganya; January 2014, to be published)* analyzed a total of 243 samples of nine different medicines collected from ADDOs and Pharmacies randomly selected in Morogoro, Tanga, Mbeya and Singida regions. The total number of pharmacies included was significantly lower since several districts have no pharmacies at all. Procedures used in analyzing the samples involved physical examination and validated analytical techniques. The study revealed a high overall pass rate of 92.6% for products tested in meeting quality standards. The 7.4% failure rate recorded was mostly observed in samples of one product - ergometrine injection.

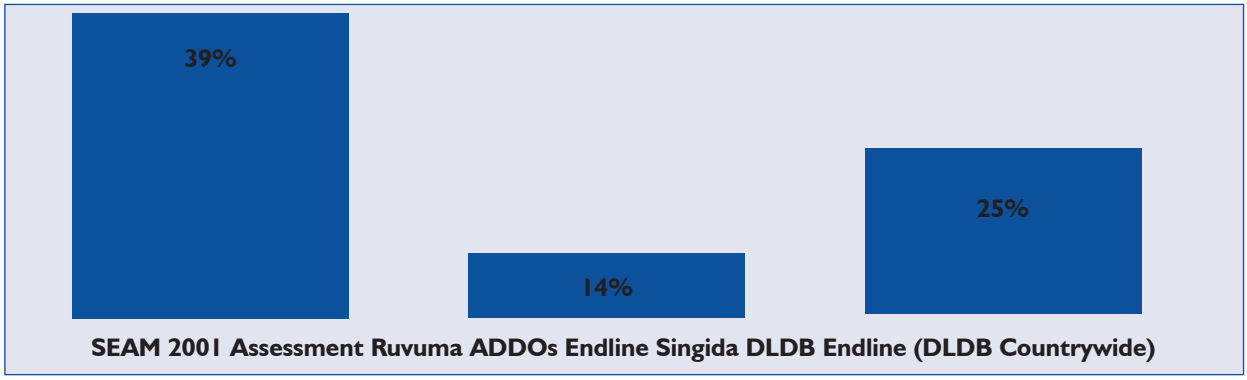
The failure of ergometrine injection samples was mainly attributed to non-adherence to good storage practices by both pharmacies and ADDOs or poor cold chain prior to delivery. The product has high sensitivity to tropical temperatures and light. Among the major recommendations made by the study were replacing ergometrine with a more temperature stable substitute in the list of medicines authorized in ADDOs and increasing awareness to all drug outlets on good storage practices including proper cold chain maintenance.

3.3 Improved Quality of Dispensing Services

One of the major components of the ADDO program is improving quality of dispensing services through dispenser training, supportive supervision and provision of essential working tools. Considerable gains have been realized in this area since piloting of the project in Ruvuma. The SEAM evaluation used simulated client (mystery shopper) approach and client exit interviews to study medicines dispensing practices. It also analyzed the drug store registers for various rational medicines use indicators. The mystery shopper approach was applied in two scenarios, one for symptoms of complicated malaria and another for symptoms of URTI. Both scenarios were for a six-year old child. On the other hand, client exit interviews focused on quality of services and communication with the client.

Results from the study showed that much fewer URTI clients in Ruvuma (14%) were given or advised to use antibiotics compared with URTI clients in Singida (25%). This was a marked improvement from the findings of the SEAM 2001 assessment which revealed that 39% of URTI clients were treated with antibiotics (Figure 8). Similarly, among malaria patients for whom no antibiotic was indicated, no antibiotics were dispensed at endline in ADDO (0%), where 5% of DLDBs in Singida dispensed an antibiotic medicine for treatment of malaria.

Figure 8: Percentage of simulated URTI clients dispensed or recommended antibiotics

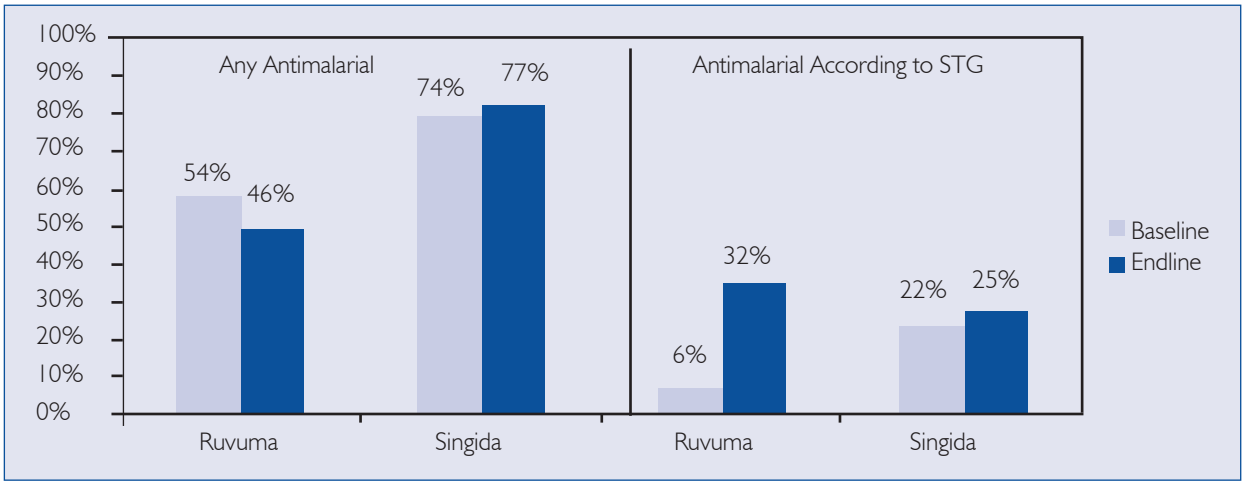


The evaluation also observed that the average number of medicines dispensed per malaria simulated client encounter dropped from baseline to endline among Ruvuma ADDOs (1.6 to 1.4) and Singida DLDBs (1.9 to 1.8). The number of medicines dispensed in the URTI scenario also showed that ADDOs in Ruvuma dispensed fewer medicines per encounter (1.5) in the endline than were documented in the DLDBs visited during the 2001 SEAM assessment (2.3). The average number of medicines dispensed is an important indicator of rational medicine use[3].

[3]Calculation of the average number of medicines dispensed in the encounters included any item that the dispenser recommended including an analgesic or even a bed net.

In overall the evaluation observed that dispensing of any antimalarial fell slightly in Ruvuma (from 54%, baseline to 46% endline) while in Singida, more shopkeepers dispensed antimalarial medicines at endline (77%) than baseline (74%). However, for all antimalarial medicines, the percentage dispensed according to national Standard Treatment Guidelines (STGs) increased in ADDOs from 6% to 32%, while in Singida the increase was not as significant (Figure 9). Moreover, a major increase was observed in the percentage of referrals without antimalarial medicines in Ruvuma (from 32% to 52%). The percentage of URTI simulated clients referred to a doctor or clinic at endline was also significantly higher in Ruvuma ADDOs (35%) than Singida DLDBs (14%).

Figure 9: Dispensing of any antimalarial medicine or treatment according STGs to simulated malaria clients in Ruvuma and Singida



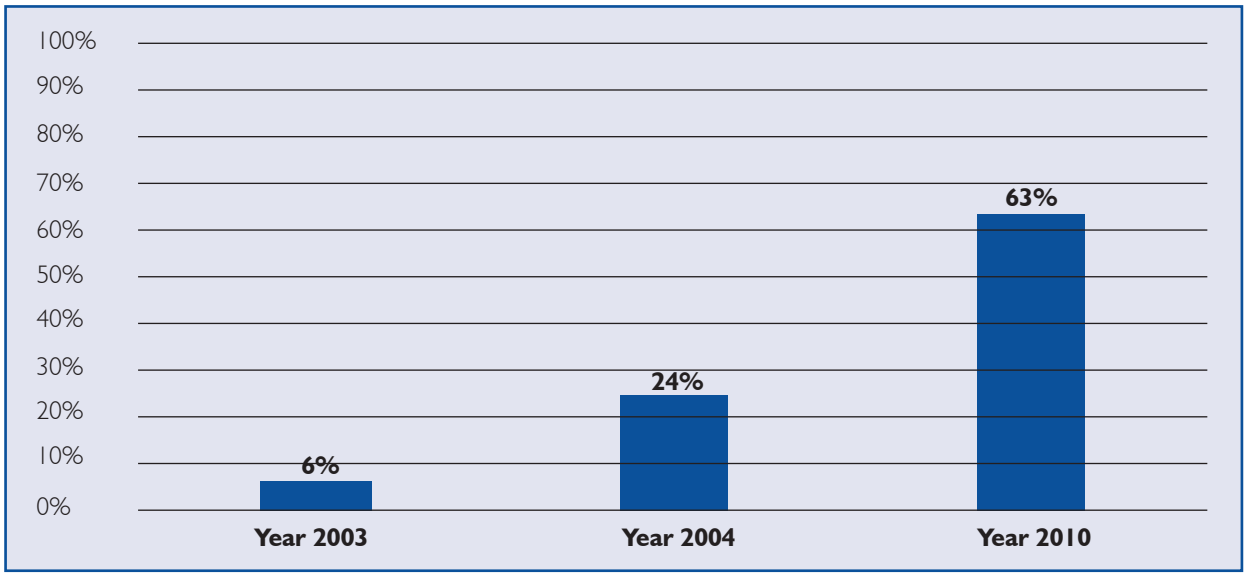
A stakeholders meeting convened in 2005 to discuss the SEAM evaluation results attributed the positive results to ADDO training which encouraged dispensers to refer clients to the next level of care in cases where they did not feel they could treat the patient. They interpreted the results as evidence of efforts by trained ADDO dispensers to conduct business in an ethical and professional manner. The observations gave credence to the argument that allowing selected prescription in ADDOs, does not necessary lead to overuse of the medicines especially antibiotics, more so if dispensers are well trained.

In addition to rational use of medicines, the SEAM evaluation also assessed quality of dispensing communication and instructions given by the attendant. Questions about systems, medication history and instructions on how to take medicine, were meant to demonstrate the attendant's dispensing skills. In the malaria simulated client scenario, the evaluation revealed a 5% increase in the proportion of ADDO dispensers in Ruvuma who asked about both symptoms and medication, while in Singida a 10% drop was recorded in this indicator among DLDB attendants. Similarly, in the URTI scenario, ADDO dispensers in Ruvuma asked about symptoms and medication more frequently (37%) than did DLDB attendants in Singida.

These observations were reinforced by feedback from client exit interviews which demonstrated that ADDO dispensers were viewed more positively by clients than DLDB attendants. Overall, 95% of ADDO clients rated the dispenser's expertise as "good" or "excellent", compared with 83% of DLDB clients. Moreover, the proportion of clients who rated dispenser skills as "average", was much higher among DLDB clients (16%) than ADDO clients (5%).

The 2011 EADSI evaluation demonstrated that the dispensing quality in ADDOs can be maintained, and even improved, for some indicators. For example, the percentage of encounters where a client received appropriate malaria treatment in Ruvuma (according to standard treatment guidelines) increased significantly between 2003 and 2010 (Figure 10). On the other hand, referral for uncomplicated malaria reduced from 52% in 2004 to 17% in 2010. This was interpreted as a sign of confidence in decision making.

Figure 10: Percentage of encounters with appropriate malaria treatment in Ruvuma Region



Source: EADSI, 2011

Regarding management of non-bloody diarrhea, the percentage of encounters in which metronidazole was dispensed declined from 53% in 2004 to 42% in 2010. Although this was an improvement in terms of the assessment, it showed that more efforts are still need to achieve appropriate management of diarrhea. Only zinc and OR are recommended for management of non-bloody diarrhea.

To assess whether ADDOs do satisfy community needs, the EADSI Evaluation included household surveys in Ruvuma, Singida and Mara regions. In Ruvuma 86% of respondent reported using ADDO services, out of which 79% said they went to drug shops because ADDO dispensers are skilled. In Singida the proportion of respondents who believed that drug shop attendants are knowledgeable increased from 48% (baseline) to 77% (endline). These perceptions about ADDO dispensing quality are noticeable in other areas where the program has been rolled out, as captured in the story of Neema Wagenge, the ADDO user in Mbarali District of Mbeya Region.

Building Trust through Quality Dispensing Services

Neema Wagenge is a mother of two, residing in Rujewa ward of Mbarali district. Although she does not live far from the district hospital, she mostly depends on a particular ADDO for health care services whenever her child is sick. She prefers to use the drug shop because it is only a few minutes-walk from her house and does not have to queue for services. Most importantly, she is happy with the quality of services she gets from the ADDO and trusts advice she gets from the drug shop dispenser.

She has become the best of friends with Famieta Mlambia, the dispenser and owner of the shop. She recalls that it is not every time she visits the drug shop that she is given medicines. At times the dispenser only assesses condition of her child and directs her to go to the hospital. She always heeds her advice. Famieta discloses that IMCI training she received during the ADDO dispenser course has significantly influenced the way she handles sick children and counsels their caregivers.

The training covers common causes of childhood illness including malaria, diarrhea, acute respiratory infections and management of danger signs of illness. Her advice to the government is to work closely with drug shop owners to increase coverage of ADDOs with trained dispensers, so that clients who depend on the drug shops for medicines and advice, such as Neema, can be guaranteed quality services.

3.4 Improved Regulation and Efficiency of the Private Sector Pharmaceuticals Supply Chain

One of the major problems noted during the 2001 SEAM assessment of the country's pharmaceutical sector, was inadequate regulation of the private sector drug outlets especially Part II shops. Development of ADDO regulations was the first major step toward putting the private pharmaceutical sector under stricter regulatory control, with greater involvement of the local government authorities (LGAs) at the council and ward levels in routine regulatory processes including accreditation, supportive supervision and inspection of ADDOs. The 2004 TFDA Delegation of Powers Act (amended 2006) clearly spells out the roles of LGAs in regulating and monitoring operations of the drug shops.

> *"I think ADDO program has had an outstanding contribution in securing the private sector pharmaceuticals supply chain, with a multiplier effect on medicines quality and availability in the traditionally underserved areas,"* **Margareth Ndomondo Sigonda.**

> *"In the past it was almost a dream to think that one day Part II Poison shops would be properly regulated and belong in a formal functional system. The regulatory system for ADDOs has been extremely useful. The improvement in the quality of medicines and services is a result of the regulatory system. I saw this in Ruvuma when I launched the program,"* **Dr. Anna Abdallah, former Health Minister.**

The ADDO regulations put much emphasis on adherence to the authorized list of medicines, compliance with premise standards and medicine storage conditions, and buying of medicines from legitimate sources only. This is partly enforced through a system of documentation entrenched in operations of the drug shops using a special drug register provided by regulatory authorities (previously TFDA, now Pharmacy Council) and routine inspections visits by wards and council level inspection teams. Although there are still inadequacies in the functioning of the decentralized regulatory system due to inadequate budget allocation by some councils for routine regulatory activities, regulation of the drug shops has generally improved and positively impacted the private sector pharmaceuticals supply chain.

The expansion of ADDO drugs list to include selected prescription medicines and a growing network of the drug shops across the country[4], have particularly made ADDOs more attractive for business with registered wholesalers. This has resulted in establishment of a large network of regional and district-based wholesalers across the country and increased availability of products whose quality can be guaranteed. For example, Ruvuma Region which did not have a single wholesale pharmacy at inception of the program witnessed entry of the 6th wholesaler in August 2012. Five of the wholesalers are located in Songea Urban while one is based in Mbinga District. This is in addition to the one ADDO Restricted Wholesaler (ARW) established in Mbinga.

To determine adequacy of the ADDO supply chain, the EADSI Evaluation (November 2011) asked ADDO owners in Ruvuma and Mtwara regions where they buy their medicines. Over 90% of ADDOs in Ruvuma and Mtwara bought their medicines from wholesale pharmacies and 18% in Ruvuma used an ADDO restricted wholesaler. About 42% of ADDOs in Ruvuma and Mtwara were within a 2-hour drive of a wholesale pharmacy. The increased efficiency in the supply chain has a direct relation to medicines availability and quality.

Furthermore, the ADDO regulatory system has influenced development of a wider regulatory framework which goes beyond regulation and monitoring of ADDO operations. Strengthening of TFDA zonal offices, establishment of other regulatory structures such as Regional Food and Drugs Committees (RFDCs), Council Food and Drugs Committees (CFDCs) and Ward Health Committees (WHCs) as per the Delegation of Powers Act and amendment to ADDO regulations (2006), have ensured that all drug outlets including pharmacies are better regulated. Following the transfer of ADDO program management to the Pharmacy Council from TFDA, the Council has adopted the same regulatory framework, which involves working closely with local government authorities to regulate and monitor operations of drug outlets.

> *"Although we have not yet developed a legal instrument to formally delegate some of the Pharmacy Council's regulatory functions to local government authorities, we have adopted the regulatory framework established by TFDA to ensure continuity of regulatory activities. We are also considering working closely with TFDA zonal offices and RFDCs to ensure that councils get the necessary technical support to execute the delegated regulatory functions,"* **Elizabeth Shekalaghe, Pharmacy Council Registrar.**

[4]A geo-mapping of ADDOs conducted by TFDA through Tanscott Associates (November 2013) in selected regions (Pwani, Mtwara, Lindi, Mara and Morogoro) noted that each of the 701 villages covered had at least an ADDO, which brings into perspective another important medicines access factor.

Moving Wholesalers Closer to ADDOs

"Before Pyramid Pharmacy established an ADDO restricted wholesale shop in Mbinga and Seven Pharmacy also opened a branch in the district, we used to travel all the way to Dar es Salaam to get our supplies, a process that would take five to six days if you moved fast".

Godfrey Sende, an ADDO owner in Mbinga District looks back to the period before entry of the ADDO program and recalls how difficult and costly it was to procure quality-assured medicines. He opened his first Part II drug shop in 2000 after giving up his job in the government as a clinical officer. In 2004, his shop became the first in the district to be accredited as ADDO. He says the first three years of operating the business (as DLDB) were both good and bad. Good because only three DLDBs were operating in Mbinga town center hence competition was minimal, and bad because there was no single wholesaler in the entire Ruvuma Region, so they had to procure supplies from the distant Dar es Salaam market. To get to Dar es Salaam, one had to spend a night in Songea town. The day of return was much more demanding since he had to check into a guest house with his consignment and put the goods on Mbinga-bound bus the next day. The whole procurement process would take him 5-6 days if he moved fast. However, the situation changed drastically with entry of the ADDO program. Many new players joined the business and the number of ADDOs in the district increased rapidly. The Dar es Salaam-based Pyramid Pharmacy saw the opportunity and responded by establishing an ADDO restricted wholesaler (ARW) in the district. It also opened the first wholesale pharmacy in Songea town. Sende notes that as the number of ADDOs in the district continued to increase, stock-outs in the ARW started becoming common; a situation he partly attributes to high demand for supplies. The Songea-based Seven Pharmacy sensed the opportunity and opened the first wholesale cum retail pharmacy in Mbinga in early 2014. Sende's ADDO is within 30 minutes-walk to both wholesalers. He is thankful to ADDO program for the improvements in the supply chain which have significantly reduced cost of doing business, even though he has to contend with much stiffer competition.

3.5 Delivering Public Health Interventions Through ADDO

Since the scale-up of the ADDO program implementation to the initial regions, there has been a growing recognition of ADDO as an ideal platform to offer a wide range of public health interventions at the community level and strengthen referral linkages with public health facilities. Apart from the interventions integrated in the program during the regional expansion such as ACTs and ITN distribution, reproductive and child health services and linkage with NHIF; more recent developments include malaria Rapid Diagnostic Testing (mRDT), public education on antimicrobial resistance and early TB case detection and referral. Moreover, ADDOs also provide an ideal platform for disseminating health information to the community on various public health needs through posters, leaflets, booklets, information brochures, etc.

> *"ADDO is an innovative program that has contributed significantly to the improvement of curative health services by increasing access to essential medicines and improving dispensing skills. It has also demonstrated a great potential to contribute to preventive services by providing a platform for delivering other public health interventions,"* **Dr. Hussein Mwinyi, former Health Minister.**

The growing interest in ADDOs as platform for delivering public health interventions is not without compelling reasons. A study conducted in Morogoro, Tanga, Singida and Mbeya regions by a team of researchers from MUHAS School of Public Health and Social Sciences[5] revealed that over a third of the 1,179 households surveyed (38.0%) walk for less than 15 minutes to the nearest ADDO. Over a half of the respondents (53.1%) reported that ADDOs closest to their household usually has the medicines they need, that ADDOs are the most convenient place to seek care (59.3%) and that ADDO providers do sometimes refer customers to public health facilities (55.1%). These findings clearly demonstrate that ADDOs have become an integral part of the healthcare delivery system in the community.

3.5.1 Malaria Control

Although no study has been conducted to determine the direct impact of malaria control interventions in ADDOs, successful malaria control depends greatly on effective vector control, correct diagnosis of the disease and prompt treatment using an efficacious antimalarial. Distribution of insecticide treated bed nets and re-treatment kits through ADDOs is one of the channels used to increase access to ITNs for protection of the population against malaria transmitting mosquitoes. Moreover, faced with an estimated 10 million uncomplicated malaria cases diagnosed each year and rapidly progressing resistance to the then standard treatment of uncomplicated malaria, SP, the Government of Tanzania through the Ministry of Health and Social Welfare, changed malaria treatment policy in 2006 to recommend ACT as the first-line treatment for uncomplicated malaria. In 2008, TFDA

[5]Semali I., Simba D., Kessy A., Kakoko D. (July 2014). Medicines Access, Use, Knowledge and Perceptions in Districts Served by ADDOs in Tanzania.

reviewed dispensing regulations to allow ADDOs to sell ACTs. This has enabled millions of Tanzanians who depend on ADDOs as their first contact with healthcare services outside the home and a source of medicines, to access efficacious malaria treatment with the potential to delay development of resistance.

The introduction of ACTs in ADDOs also provided a launching pad for the Affordable Medicines Facility-malaria (AMFm) in private drug outlets in the country. The AMFm is an innovative subsidy scheme aimed at expanding access to affordable ACTs. ADDOs constitute a major part of the AMFm delivery mechanism. Supported by the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM), the AMFm's objective is to increase ACTs availability, affordability and use by all population groups vulnerable to malaria, and facilitate "crowding-out" of oral artemisinin monotherapies, chloroquine and SP by enabling quality-assured ACTs to gain market share. AMFm evaluation results (2012) demonstrated significant gains especially in the private sector where availability of quality assured ACTs increased by 56 percentage points (from 10%, baseline to 66%, endline) and market share reached 32% (endline) up from 2% (baseline). On the other hand, the median price of ACTs in the private for-profit sector decreased from USD5.28 to USD.094, thereby making the antimalarial medicines more affordable to the population.

Following the increased access to ACTs in both public and private sectors and declining malaria prevalence, testing for malaria before treating the disease has become a major priority for the National Malaria Control Program (NMCP). The program's target is to provide universal access to appropriate, quality and timely malaria diagnosis to at least 80% of people with signs and symptoms of malaria by 2020. The 2011–2012 Tanzania HIV/AIDS and Malaria Indicator Survey (THMIS) showed that 10% of under-five children in Tanzania Mainland had tested positive for malaria, down from 18% in the 2008-2009 THMIS. However, prevalence of fever remains high. A recent study of etiologies of fever among 1,005 Tanzanian children *(N Engl j Med 2014;370:809-17)* attributed 51% of the 1,232 diagnoses analyzed to acute respiratory infections, followed by systemic infections (11%), other viral infections (10%) and malaria (only 9%). It is estimated that 40% of Tanzanians seek treatment for fever in the private sector and most cases of fever are treated with an antimalarial.

Informed by these realities, the NMCP with support from Clinton Health Access Initiative (CHAI), decided to pilot low-cost malaria Rapid Diagnostic Tests (mRDT) in ADDOs in Kilosa and Kilombero districts of Morogoro Region. A baseline survey conducted in the region prior to introduction of the intervention revealed that 71% of patients surveyed relied on ADDOs as the first place they sought treatment. However, only 9% of those who purchased an ACT at ADDO had previously received a positive malaria test result. The NMCP is determined that testing for malaria in ADDOs could be a way to increase access to testing and improve rational use of malaria medicines.

Consequently, in May 2013, the program trained 310 ADDO dispensers in Kilosa and Kilombero to perform mRDTs. The trainings were led by both national and district level mRDT facilitators, and used a training manual approved by the NMCP and HLPC. Only those who passed three examinations were certified to perform mRDTs. Nearly all dispensers who attended the training (95%) passed examinations. Quarterly monitoring visits were conducted to observe how the trained dispensers were performing mRDTs. Their ability to follow Standard Operating Procedures (SOPs) was also monitored during the visits. There was minimal ADDO-specific marketing in the intervention except for provision of a special signage to identify ADDOs conducting mRDTs. However, a national mRDT awareness campaign was conducted in parallel with the pilot. A subsidy was applied in one of the pilot districts (Kilombero) to evaluate whether a subsidy was a necessary or effective way of increasing malaria testing.

Results from evaluation of the pilot conducted in early 2014 showed that in both Kilosa and Kilombero, nearly half of all fever patients (49% and 47%, respectively), and the vast majority of the eligible population[6] (62% in Kilombero and 70% in Kilosa) got tested for malaria in ADDOs. The reasons given by the eligible population for not testing for malaria in ADDO included, "I know I have malaria", cost, and "I don't think it is malaria". In Mvomero which was used as a control district by the evaluation, only 2% of all fever patients and 4% of the eligible population tested for malaria in ADDO. In overall, the proportion of patients who got tested for malaria (either in ADDO or elsewhere) before getting treatment recorded a much higher increase in the pilot area than the control districts (from 23%, baseline to 61%, endline in Kilombero; from 19%, baseline to 64%, endline in Kilosa; and from 3%, baseline to 17%, endline in Mvomero). The evaluation further showed that the vast majority of patients testing in ADDOs adhered to their test results by using ACT (for those testing positive). Antibiotic use did not increase with introduction of the testing in ADDOs, an indication that negative mRDT results did not lead to excessive dispensing of antibiotics by ADDOs. It was also

[6]Eligible population is defined as the patient being present and not previously tested.

[7]In Kilombero, the retail selling price of mRDT was fixed at 500 TSH, while in Kilosa the median retail price was 1,100 TSH, which was still lower than the national average Adult ACT price (~1,500 TSH).

learnt that the subsidy applied in Kilombero did not lead to a significant larger fraction of fever patients tested for malaria in ADDO (49% in Kilombero and 47% Kilosa)[7].

3.5.2 Child Health Interventions

Regarding child health, institutionalization of IMCI training in the ADDO dispenser course has made it possible to equip every trained dispenser with basic life-saving skills for children. The dispensers are not only taught about appropriate case management of common causes of childhood illness (malaria, ARI and diarrhea) but also trained to recognize danger signs of illness and refer critically sick children to the next level of care as appropriate. A multi-country evaluation of the IMCI strategy conducted prior to its national rollout to all public health facilities in Tanzania, associated implementation of the strategy with 13% lower child mortality in pilot districts after two years. Thus, extending implementation of the strategy to the private sector especially ADDOs where a significant proportion of the population seeks care, can only help to widen the gains.

A study commissioned by MSH's SDSI project to Tanzania Consumer Advocacy Society (September 2013) used the "mystery shopper" approach to assess management of ARI in ADDOs in four regions (Morogoro, Tanga, Singida and Mbeya), and indicated benefits of the IMCI training in ADDO. The study deployed three scenarios: (i) a child aged 1 year, with cough, difficulty breathing and fast breathing with harsh noise (defined as a case of pneumonia); (ii) a child aged one year, with cough, runny nose, and other cold symptoms (defined as a case of mild ARI); and (iii) a child aged one year, with a runny nose for which parent requests Septrin (defined as a case of mild ARI). Findings from the assessment showed that 85% of dispensers responded appropriately to pneumonia (referral, antibiotics, or request to see). Many more dispensers (61%) asked key questions about pneumonia cases compared to mild ARI (22%), and 20% provided advice on monitoring of danger signs.

3.5.3 Family Planning

Family planning is widely recognized as a cost-effective way to saving lives of women and children and empowering families to determine the optimal time and spacing of births. The ability to plan the number and spacing of births increases the likelihood of positive health outcomes for women, men and their children. By reducing rates of unintended pregnancies, family planning also reduces the need for unsafe abortions. Other benefits include preventing HIV/AIDS and other sexually transmitted infections through dual protection using the male and female condom, reducing pregnancy related health risks, and slowing down population growth. Promoting family planning through the ADDO platform allows these benefits to accrue to the communities served by the drug shops.

The specific family planning methods available in ADDOs are Combined Oral Contraceptives (the Pills), Lactation amenorrhea method (LAM) as well as male and female condoms. All these are short acting methods. However, ADDO dispensers are trained in both short and long acting methods including their use and where to find the services. Integration of family planning training in the ADDO dispenser course has made sure that every dispenser being allowed to practice in the drug shop is knowledgeable about the methods and can counsel clients and provide referral as appropriate for desired methods not authorized in ADDOs. This underscores the importance of linking ADDOs with health facilities and community health worker (CHW) services especially those providing family planning information and selected methods at the household level. The triangulation of ADDO, CHW and health facility services can also be greatly beneficial to other maternal and child health services.

3.5.4 Linking ADDO with Community Health Worker and Health Facility Services

Community health workers are key source persons in health promotion at the household and community levels. They have an important role in public health education, monitoring growth and development of children, counselling caregivers on appropriate childcare, providing reproductive health information and services, and identifying sick people in the homes who need support and referral care. Currently, CHWs and ADDOs are both independently linked to health facilities but lack a formal relationship to one

another. CHWs are trained to refer sick patients to health facilities for care and health facilities supervise CHW work. ADDOs are also trained to refer severely sick patients to health facilities as well as patients who require medicines not available in ADDOs. A formal linkage between ADDOs and CHWs, however, does not exist.

Linking ADDOs, CHWs and health facilities can be highly beneficial to the communities they serve. Linkage between CHW and ADDO can increase chances for a child with pneumonia identified by CHW to receive a timely first dose of antibiotic from ADDO before arriving at the health facility for advanced care; and a child with diarrhea to receive timely doses of zinc and ORS from ADDO when the health facility is far, closed or out of medicines. Health facilities would also benefit from documented and coordinated referrals from CHWs and ADDOs, while ADDOs could profit from increased sales due to more customer traffic and periodic patient referrals from CHWs and recognition of dispensers' role in providing public health services. On the other hand, CHWs would benefit from greater recognition in the community for their role in connecting patients with prompt quality care and medicines.

As the Ministry of Health and Social Welfare considers introducing a national CHW program to improve maternal, neonatal, and child health, exploring ways to optimize CHW contributions is a priority. Management Sciences for Health through the SDSI project has responded by supporting Kibaha District Council to establish linkage between ADDO dispensers, CHWs and health facility providers, to help improve delivery of health care services in the community. The process involved discussion forums with key stakeholders, sensitization of CHMT members, joint training of the service providers (ADDO dispensers, CHWs and health facility personnel), provision of essential working tools and supervision visits to monitor the function of the linkage.

A total of 142 service providers were trained (40 ADDO dispensers, 85 CHWs and 17 facility providers) and 17 CHMT members sensitized and involved in various discussion sessions. Topics covered during the training included: situation of maternal, newborn and child health in the district; status of ADDO program implementation in the district; danger signs during pregnancy; danger signs after delivery; dangers signs among newborns; family planning methods commonly used in Tanzania; roles and responsibilities of ADDO dispensers, CHWs and health facility personnel in referral care; and networking among the three categories of service providers to improve service delivery.

Results from supervision visits showed that the majority of the services providers were knowledgeable about family planning methods and danger signs of illness among newborns, pregnant women and postnatal mothers, and were referring patients to the next level of care. However it was observed that the level of knowledge among the service providers did not differ significantly although health facility providers appeared slightly more knowledgeable than ADDO dispensers and CHWs (Table 3).

Table 3: Knowledge of at least five dangers signs of illness and family planning methods

Area	**CHWs**	**ADDOs**	**HWs**
Newborn	69%	62%	73%
Pregnancy	85%	76%	91%
After delivery	70%	71%	73%
Family Planning	100%	95%	100%
Average Score	**81%**	**76%**	**84%**

In terms of service delivery, it was noted that ADDOs were leading in providing family planning services whereas CHWs were mostly consulted on care for mothers and newborns. Out of 486 patients attended by ADDOs and CHWs during the monitoring period, 56 were referred to the health facility for care. However, only 31 out of the 56 referred patients (55%) attended primary health facilities; the lowest rate being reported among newborns (only 11% reached the facilities). Given significant availability of private clinics in the district and proximity to a regional hospital, it was suspected that most neonates were taken to the regional hospital or private facilities for referral care. This further underscores the need for a stronger linkage between ADDOs, CHWs and health facility providers in monitoring referrals. The supervisors did not visit private facilities nor the regional hospital to follow up referrals.

3.5.5 Addressing Antimicrobial Resistance

A study conducted by the MSH's SDSI project (August 2013) to understand stakeholders' perception of antimicrobial resistance (AMR) and document AMR control activities at the national and council levels, revealed that AMR is widely perceived as a major problem in Tanzania. Health officials at the national council levels mainly attributed the problem to inappropriate antimicrobial user behavior such as self-medication, inadequate compliance with treatment and advice and buying of incomplete medicine doses, among others; and weaknesses in the healthcare system such as lack of diagnosis/laboratory services in primary health facilities, inadequate adherence to standard treatment guidelines and dispensing regulations, availability of counterfeit medicines in the market, poor storage of medicines, weak enforcement of regulations, and lack of public education programs on rational use of medicines.

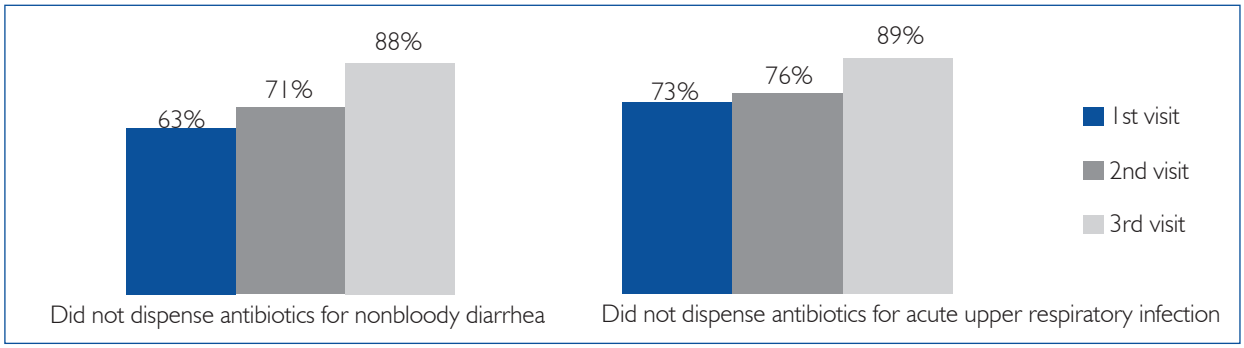
As a major source of essential medicines and health services in the community, ADDO dispensers play a potentially important role in promoting rational use of antimicrobials, which helps control antimicrobial resistance. As part of an initiative to support advocacy and containment of AMR in the community, in collaboration with TFDA piloted selected interventions in Kilosa district between June 2009 and October 2010 to help improve ADDO dispensers' antimicrobial dispensing and counseling practices. The intervention included training of the dispensers through sensitization seminars, provision of job-aids and educational materials to increase awareness about AMR in the community, and follow-up visits to provide on-site support to ADDO dispensers and monitor their performance in AMR control.

Among the job-aids distributed to the dispensers were antimicrobial dispensing guide, counter-top cards with information for customers on one side and information for ADDO dispensers on the other, and rubber stamps to label medicine packages and help dispensers to counsel customers regarding the appropriate use of antimicrobials at home. In addition, an AMR poster featured information in Swahili language to increase awareness of AMR and rational medicine use among the public. Three follow-up visits were conducted in 10 months after the intervention launch, during which dispensers were reminded to follow the recommended dispensing practices. An endline evaluation was conducted in October 2010 to determine the intervention's results, highlight challenges encountered during the implementation and provide recommendations to guide future intervention upscaling. The results of the evaluation have been published in the BioMed Central Journal of Pharmaceutical Policy and Practice and featured by the US National Center for Biotechnology, National Library of Medicine *(http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4177420)*.

The evaluation showed that although availability of tracer antimicrobials increased by 26% during the intervention period, the proportion of ADDOs that had unauthorized items for sale decreased from 53% to 13%. In overall, it was observed that the percentage of ADDO dispensers following good dispensing practices increased from an average of 67% in the first monitoring visit to an average of 91% during the last visit. The proportion of those who did not dispense antibiotics for non-bloody diarrhea increased from 63% in the first visit to 88% in the third visit. A similar trend was observed in management of acute upper respiratory infection (Figure 11).

After the intervention, more ADDO dispensers could name more factors contributing to AMR and negative consequences of inappropriate antimicrobial use, and over three-quarters (76%) of community members interviewed had heard of AMR (almost 50% of them from ADDO dispensers). The findings indicate that sensitization of ADDO dispensers on AMR and provision of essential working tools can significantly improve antimicrobial dispensing and possibly contribute to AMR containment. Moreover, ADDOs can be a useful source of information to the community on AMR.

Figure 11. Percentage of ADDO dispensers who, appropriately, did not dispense antibiotics for common conditions



3.5.6 Early TB Case Detection through Referral

According to the World Health Organization report, there were an estimated 8.6 million new cases of TB in 2012 and 1.3 million people died from TB. Over 95% of TB deaths occur in low and middle-income countries. Poor communities and vulnerable groups are most affected though TB is a risk to all. About 3 million people falling ill with TB are 'missed' by health systems. The first Tanzania prevalence survey reported that prevalence of bacteriological confirmed TB was 295 per 100,000 for adult populations. The detection of new smear-positive patients was estimated to be between 42% and 54%.

Like many other high-TB burden countries, TB case finding in Tanzania relies on passive detection among symptomatic patients who present to health facilities for diagnosis. Passive case finding is only successful when patients are aware of their symptoms and motivated to seek care; have access to health facilities; can afford the cost of seeking treatment and are evaluated by health professionals who are cognizant of TB symptoms; have access to a reliable laboratory; and collect the necessary samples for examination. Failure at any stage of this chain of activities, whether attributed to the patient or the health care system, causes delays in diagnosis. These delays may result in poor disease prognosis at the individual level and increased transmission at the community level, given that most transmissions occur between the onset of cough and when treatment is started. Additionally, diagnosis delays of up to 12 or more weeks have been recorded in Tanzania.[8]

Key actions needed to detect people with TB include intensified collaboration with public and pri¬vate health facilities that are treating patients but may not be reporting.[9] Consequently, the National TB Leprosy Program (NTLP) with support from the MSH's Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program piloted the engagement of pharmacies and ADDOs on early identification of clients with TB-suggestive symptoms and facilitation of referrals to TB diagnosis centers and appropriate treatment at DOTS centers. The intervention engaged 737 dispensers from 594 pharmacies and ADDOs and 466 health care workers from 98 diagnostic and treatment centers in the Dar es Salaam and Morogoro regions.

The major activities included a baseline survey to assess retail pharmaceutical sector provider knowledge and practices of TB and willingness to participate in the planned intensified TB case identification; training of pharmacy and ADDO dispensers on TB case detection and referral; sensitization of healthcare workers (including receptionists, outpatient department clinicians, laboratory staff, DOT nurses, and health facility in-charges) from the earmarked diagnostic and treatment centers; provision of essential working tools (such as referral forms, registers and educational materials) to pharmacy and ADDO dispensers; and quarterly supportive supervision to mentor dispensers and collect data for monitoring and evaluation purposes.

Over the 12 months of implementation (February 2013 – January 2014), 587 clients with TB symptoms seen at ADDOs were referred to TB diagnostic and treatment centers, where 13.7% were confirmed smear positive for TB. Overall, ADDO had a higher referral rate of clients with TB-like symptoms than pharmacies. On the average, three clients were referred per ADDO per quarter. About 38% of all referral clients with TB symptoms were tracked and found in health facilities records. The NTLP pilot demonstrated that the private retail pharmaceutical sector in Tanzania has the potential to contribute to increased early TB case detection through referral.

[8]Hinderaker et al. Treatment Delay among Tuberculosis Patients in Tanzania: Data from the FIDELIS Initiative. BMC Public Health 2011, 11:306. http://www.biomedcentral.com/1471-2458/11/306

[9]WHO. Global tuberculosis report 2013. http://www.who.int/tb/publications/global_report/gtbr13_annex_2_country_profiles.pdf

Speaking for the Missed 3 Million

"My plea to the government is to ensure that all service providers in primary healthcare facilities are trained in early TB case detection to minimize misdiagnosis, and medicines for TB treatment made available in all the facilities so that any patient wishing to transfer from one treatment center to another can easily access care."

Scolastica Chatanda

On 24th March 2014, Scolastica Chatanda, the Deputy Headmistress of Matombo Secondary School in Morogoro Region, moved the nation with a personal testimony on how for close to six months, she struggled with symptoms of TB without being detected by healthcare systems. She was speaking on TBC Taifa, a national radio station, during commemoration of the World TB Day.

When she started coughing and was also experiencing fever and fatigue, she went to a nearby drug shop and got herself a cough syrup and an antimalarial, thinking that the fever was due to malaria. When the conditions persisted, she decided to go a health facility to seek care. During the visit, she was told that she had malaria and put on treatment. When her condition got worse, she went to another facility in the same region. This time she was treated for both typhoid and malaria. Over a period of about six months, she attended three different health facilities, treated for typhoid twice and severally for malaria.

It was not until she visited the drug shop of Mr. James Mng'ong'o, an ADDO owner and dispenser in Matombo village, that she got an idea that she could be suffering from a condition she least expected. During her first visit to the ADDO, she told James that she had a serious fever and fatigue and requested for an antimalarial. James dispensed to her ACT which is a proven efficacious malaria treatment. After two weeks, she came back complaining of the same conditions including persistent cough and a lot of sweating at night. At this point, James insisted on getting her full sickness history and advised her to seek care at a TB diagnosis and treatment center at Morogoro Regional Hospital. He gave her a referral note and telephoned the TB center in-charge to arrange for an appointment.

Unfortunately the appointment coincided with the school's closing date, so she opted to go test for TB in Dar es Salaam where she had planned to spend the end-of-term holidays with her family. By the time she arrived in Dar es Salaam, her condition had deteriorated so much that her family took her straight to Mwananyamala District Hospital where it was confirmed that she had TB. She was put on treatment immediately. The holidays were soon over and she had to return to Matombo to resume work.

Upon return, James linked her up with a TB treatment center at a nearby health center to continue with treatment. However, availability of medicines at the facility was a problem. Her next option was Morogoro Regional Hospital which is quite distant from Matombo. She opted to continue getting her medicines from Mwananyamala in Dar es Salaam until she completed the treatment and recovered fully.

She can't be more thankful to James, noting that if it were not for his intervention, she would have died of TB. James was among the ADDO dispensers trained by NTLP with support from MSH (USAID-funded SIAPS), on early TB case detection and referral.

Scolastica's plea to the government is to provide the same training to all service providers in primary healthcare facilities to minimize misdiagnosis of TB cases. She also wants the government to ensure availability of TB medicines in all the facilities so that any patient wishing to transfer to any treatment center can be guaranteed care. Her message would not have come at a better time when the country was commemorating the World TB Day with the slogan, "Reaching the Missed Three Million".

3.6 Economic and Social Benefits

Socio-economic benefits of the ADDO program cannot be overemphasized. In addition to improving pharmaceutical services and creating a platform for delivery of a wide range of public health interventions to the community, ADDOs are a dependable source of economic livelihood to both the drug shop owner and dispenser. The program area is dotted with stories of ADDO providers whose economic and social wellbeing has been significantly transformed by the business.

> *"I have been able to build a four-bedroom permanent house with profits from the ADDO business and bought a car which is serving both the business and my family. My children go to a private school where I think they are getting quality education. Moreover, my working capital has increased five-fold in barely five years and made it possible for me to establish a second ADDO. The only obstacle holding me back from opening a pharmacy is lack of a pharmacist,"* **Athumani Mhongole, ADDO owner in Mbarali District.**

Various studies have demonstrated profitability and sustainability of the ADDO enterprise. In 2004, a team of MEDA staff with experience in working with urban and rural businesses monitored operations of 33 out 36 private drug outlets which had applied for accreditation in Mbinga District. However, only 23 of the 33 shops participated in both the baseline and final surveys. In the final monitoring, it was observed that all the 23 business were operating profitability, with the majority making profits every month. About 43% of the businesses reported an increase in profits following accreditation to operate as ADDOs[10].

A detailed financial analysis of the ADDO enterprise conducted by HERA in 2005 revealed a significantly high rate of return on investment (RoI) and return on equity (RoE) in the business. The analysis was based on ADDO financial information collected by MEDA in Ruvuma region on a monthly basis. The review sampled 53 ADDOs (20 in Songea Urban, 10 in Songea Rural and 23 in Mbinga) for 1 year activities (June 2004 to May 2005). The selection was based on the consistency and completeness of the available data. Using average monthly income statements for 53 ADDO, the reviewers analyzed potential rate of return on investment and return on equity after four years for each of the three groups of ADDOs (by district).

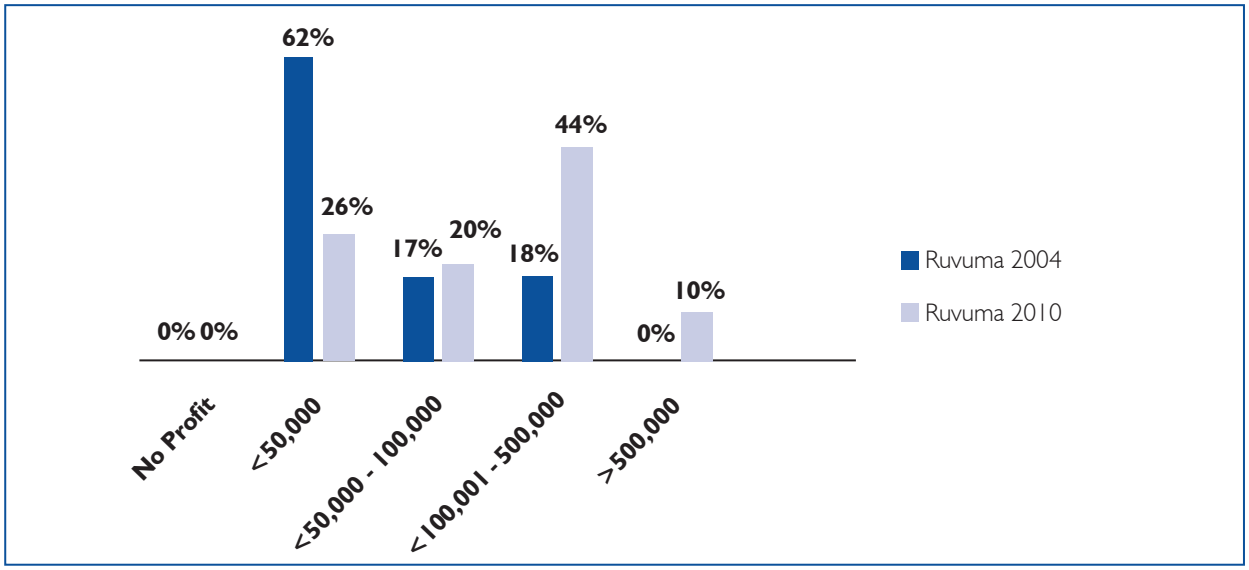
The results showed that average RoI ranged from 180% to 209%, and RoE from 281% to 356% in the study area, after four years. The calculations were based on the assumption that the total investment (fixed assets and initial stock) was financed through owner's own resources (Tsh.500,000 equity or venture capital) and through loan, and the annual average net profit will be the net cash flow for the 4 years. For RoE, repayment of loan was deducted from the cash flow of the Year 1. Based on the calculations and estimated 6,000 DLDBs in the country at the time of the study, the expected annual sales (countrywide) would reach USD 39 million (of which drug sales represent nearly USD 17 million) and the total cost of drugs sold would reach USD 8.4 million (market for wholesalers). It was also estimated that the taxes paid to Tanzania Revenue Authority (TRA) by the drug shops would reach USD 450,000.

Considering the observation in the MEDA evaluation that 43% of the private drug outlets monitored in Mbinga reported increased profits after up-grading to ADDO status, accreditation of more drug outlets would go a long way to expand the economic gains highlighted in the HERA analysis of ADDO commercial potential. By March 2014, 5,575 ADDOs had been established in different parts of Tanzania Mainland. The profitability of the ADDO enterprise is largely associated with review of regulations to allow the drug shops to sell a limited number of prescription medicines. The list of medicines authorized in ADDOs has been expanding over the years. Other factors include improved physical status of the premises making them an attractive stop for medicines in the community, improved dispensing quality by trained ADDO dispensers making them trusted service providers often consulted by community members, and increased efficiency in the private pharmaceutical supply chain which has generally reduced the cost of doing business.

These factors partly explain the remarkable increase in profitability of ADDOs in Ruvuma Region, six years after successful piloting of the program. Results of the 2010 EADSI survey revealed that all the shops surveyed in the region reported making some profit. About 84% of the surveyed ADDO had been operating for at least two years, at the time of the study. Compared to 2004, where the majority of ADDOs (62%) made a profit of less than Tsh.50,000 per month, in the 2010 survey, only 26% reported making less than Tsh.50,000 every month. About 44% reported making a net monthly profit of Tsh.100,000 – 500,000, up from 18% in 2004 (Figure 12).

[10]If data were missing for more than three months or if data appeared inconsistent (data out of range or uncertainty between zero and missing values), the ADDOs concerned were removed from the sample.

Figure 12: Average monthly net profit reported by ADDOs



In terms of gender empowerment, it is instructive to note that although most ADDO owners are men, the program provides secure job opportunities for rural women as outlet owners and as licensed drug dispensers. As of October 2007, women comprised 24 percent of ADDO owners in Morogoro region and 38 percent in Ruvuma region (MSH, 2008). It is estimated that over 90% of trained ADDO dispensers are women. By March 2014, the program had trained 18,980 dispensers, many of whom had been absorbed in public health facilities. This confirms the observation by the HERA evaluation that the ADDO dispenser training courses mainly improve educational status of women, with a positive impact on the future opportunities to participate in the formal labor market. The evaluation further noted that services provided by ADDO dispensers are valued positively by most customers, which could in the long term improve the status of women in the community.

Unlocking Potential of the ADDO Enterprise

Steven Ngonyani (in checked short-sleeved shirt) with Seven Pharmacy staff.

Steven Ngonyani was among the first group of DLDB owners in Songea Urban to join the ADDO program. He established his first drug shop in 1999. The outlet was accredited in 2003 to operate as an ADDO. This marked the beginning of a momentous journey that would see him establish a chain of three other ADDOs and a wholesale pharmacy (Seven Pharmacy) in Songea Urban and a branch of the pharmacy in the neighboring Mbinga District. He attributes the rapid growth and success of his businesses to the ADDO program.

Apart from the review of regulations to allow ADDOs to sell selected prescription medicines, other incentives provided by the program included dispenser training, business management training to ADDO owners, provision of small loans, linking of ADDOs with local financial institutions for credit and social marketing of ADDO services. The financial incentives and marketing services were mainly provided in the pilot phase. Steven benefited from the whole range of incentives.

He notes that the basic ADDO business management training and the financial incentives had the biggest impact on his business. *"The ADDO owners' training made me realize the importance of the business I am in, and I made a personal commitment to adhere to the established regulations so that I can run the business freely without having to look over my shoulders. In the process, I learnt that it is possible to stick to the list of authorized products and still run the business profitably"*, he says. He also learnt the importance of proper record keeping in monitoring business growth.

Moreover, he confesses that before the ADDO interventions, he never had any confidence to work with credit to grow a business. He therefore missed an opportunity to benefit from the small loans offered by Summa Foundation through MEDA to ADDO owners in Ruvuma, during the piloting of the program. After the Summa Foundation support ceased, MEDA, with support from MSH, went back to Ruvuma to link ADDOs with local financial institutions for credit. This time, he gathered courage to take a loan of Tsh. 1 million from National Microfinance Bank (NMB) to boost his business. He also received credit management training from MEDA and NMB. As a result, he managed to work well with the loan and repaid it way ahead of the agreed schedule.

From that experience, he gained confidence and took another loan of Tsh. 4 million from CRDB Bank, part of which he used to set up his second ADDO shop. Between 2005 and 2006, he successfully serviced two other loans from CRBD Bank totaling Tsh. 20 million. When he was establishing Seven Pharmacy in Songea, the bank gave him another loan of Tsh. 30 million which he again repaid in time. The Seven Pharmacy branch in Mbinga also received a boost of Tsh. 40 million credit from the same bank, enabling Steven to extend both retail and wholesale services to the previously underserved Mbinga District. Looking back to where he started, all he says is, "ADDO has totally changed my life!"

3.7 Contribution of ADDO to the Millennium Development Goals

In 2000, all the United Nations member states at the time (including Tanzania) and at least 23 international organizations, made a commitment to help achieve the following eight Millennium Development Goals (MDGs) by 2015: eradicate extreme poverty and hunger; achieve universal primary education; promote gender equality and empower women; reduce child mortality; improve maternal health; combat HIV/AIDS, malaria, and other diseases; ensure environmental sustainability; and develop a global partnership for development. ADDO is one of the innovative programs with the potential to contribute to most of the MDGs (Table 4).

Table 4: Potential Contribution of ADDO to MGDs

MDG 1: Eradicating poverty and hunger
• As a source of income to both the drug shop owner and dispenser, ADDO contributes directly to Target 1(a) on reducing the proportion of people living on less than USD 1.25 (Tsh.2,000) a day. Evidence from Ruvuma has shown that nearly half of ADDOs (44%) make a monthly net profit of Tsh.100,000 - 500,000. On the other hand, most dispensers earn a net monthly salary of Tsh.80,000 - 150,000. This translates to a daily disposable income of Tsh.3,300 – 16,700 for the shop owner and Tsh.2,700 – 5,000 for the dispenser. • ADDO has also demonstrated potential to contribute to Target 1(b) on achieving decent employment for women, men and young people. Although the majority of ADDO owners are men, over 90% of trained dispensers are women. Introduction of the 1-year pharmaceutical dispensing course whose entry is open to "O" level graduates, will also ensure that more young people are absorbed in ADDOs as dispensers. • By extension, ADDO also contributes to Target 1(c) on reducing the proportion of people who suffer from hunger. With a daily disposable income way above USD 1.25, ADDO owners and dispensers, especially those in rural areas where most ADDOs exist, are highly likely to afford a minimum level of dietary energy consumption for their households.
MDG 2: Achieving universal primary education
• Experience has shown that most ADDO owners use earnings from the business to educate their children. The remarks by Athumani Mhongole, the ADDO owner in Mbarali District, whose experience is shared in Section 3.6 above, is an indication that educational development of children is one of the key priorities of the ADDO providers.
MDG 3: Promoting gender equality and empowerment of women
• With over 90% of ADDO dispensers being women, the program contributes directly to the indicator on share of women in wage employment in the non-agriculture sector. The HERA Evaluation (2006) also noted that the services rendered by ADDO dispensers are valued positively by consumers and could in the long term improve status of women in the community.
MDG 4: Reducing child mortality
• Integration of the IMCI strategy in the ADDO dispenser course has ensured that the leading causes of childhood morbidity and mortality (malaria, diarrhea and acute respiratory infections) are appropriately managed using commonly available treatments in the drug shops and critically ill children referred to nearby health facilities. Evidence from IMCI multi-country evaluation associated implementation of the strategy with 13% lower child mortality in the pilot districts after two years. Integration of the IMCI strategy in the ADDO platform has enhanced the potential of the program to contribute to reduction of child mortality.
MDG 5: Improving maternal health
• ADDO also has the potential to contribute to Target 5(b) on universal access to reproductive health by addressing the indicators on contraceptive prevalence rate and unmet need for family planning. Among the family planning methods accessible in ADDOs are: combined oral contraceptives (the pills), lactation amenorrhea method (LAM), and male and female condoms.

MDG 6: Combating HIV/AIDS, malaria and other diseases
• As a source of condoms for dual protection, ADDO can also contribute to Target 6(a) on halting and reversing the spread of HIV/AIDs. Moreover, ADDOs have proved to be a useful channel for disseminating health information including resources on HIV/AIDS (in form of posters, fliers, brochures, booklets, etc).
• ADDO also has the potential to contribute to Target 6(c) on halting and reversing the incidence of malaria, through distribution of ITNs for protecting the population from malaria transmitting mosquitoes, and ACTs for treating the malaria disease. As a channel for disseminating health information, ADDOs are a potential source of messages on early care seeking, testing and correct treatment of malaria. Furthermore, the successful piloting of mRDTs in ADDOs in Morogoro Region has clearly demonstrated the potential of the outlets to increase access to malaria testing and improve rational use of medicines.
• Regarding the indicators on TB prevalence, deaths, as well as case detection and treatment [Target 6(c)], results of the interventions implemented in Dar es Salaam and Morogoro regions by NTLP and MSH to pilot early TB case detection through ADDOs, clearly demonstrated the potential of ADDOs to contribute to increased early TB case detection through referral.
MDG 8: Developing global partnership for development
• ADDO program is a public-private partnership success story already replicated in other least developed countries (Uganda and Liberia). The program was developed through strong collaboration and partnership between the government, private sector and global development partners. Among the global partners which have significantly supported its implementation are the Bill and Melinda Gates Foundation, The Global Fund, USAID and DANIDA. Thus, the program has created a unique opportunity for these development partners to contribute to MDG Target 8(b) on addressing special needs of least developed countries.
• ADDO has also demonstrated the potential to contribute to Target 8(e) on providing access to affordable, essential drugs on a sustainable basis in collaboration with pharmaceutical companies. Various evaluations have documented the program's contribution in improving the private sector pharmaceuticals supply chain, with a multiplier effect on medicines quality, affordability and availability in the traditionally underserved rural and peri-urban areas.

"After successfully completing the ADDO dispenser training course, my employer increased my salary and issued me with a formal employment contract, something which I didn't have before. Back at home, I feel my husband respects me more because of the reputable nature of my job and the financial contributions I make in our household budget," **Riziki Abdallah, ADDO Dispenser in Songea Urban.**

3.8 Transferability of ADDO in Other Countries

The benefits of the ADDO program stretch way beyond Tanzanian boarders. Since 2008, MSH has been collaborating with Uganda's National Drug Authority (NDA) to implement the Accredited Drug Shop (ADS) program based of the Tanzanian ADDO model. In November 2009, the Government of Uganda officially launched implementation of the program on a pilot basis in Kibaale District of Western Uganda. Introduction of the program was preceded by a detailed situation analysis of the country's pharmaceutical sector and a baseline assessment in Kibaale and Mpigi District in Central Uganda. At the end of the pilot project, an evaluation was conducted in September 2009 using Mpigi as the control area.

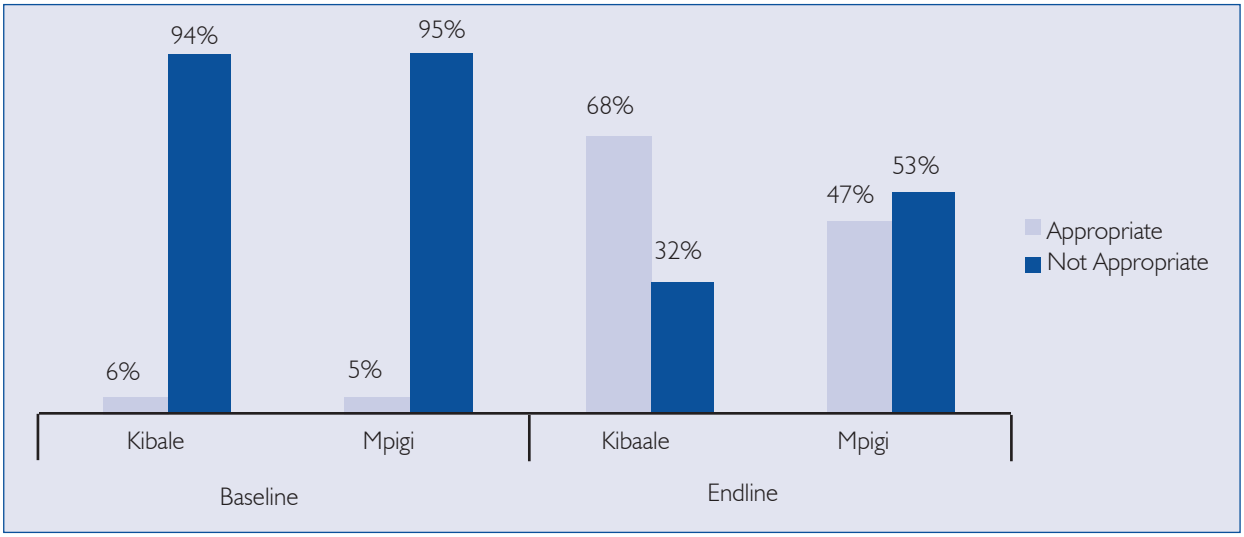
The results of the evaluation showed that the ADS project had increased availability of essential medicines and improved the quality of pharmaceutical services. For example, the availability of antibiotics in Kibaale increase from 57% (baseline) to 84% (endline), while in Mpigi, a marginal reduction of 1% was observed in medicine availability (from 65% to 64%) in the same period.

With regard to antimalarials, a remarkable increase in availability of ALU was observed in both districts – a sign of compliance with the new malaria treatment policy. However, Kibaale District demonstrated a higher degree of compliance with the new malaria treatment policy, with availability of ALU increasing from 5% (baseline) to 87% (endline), while that of chloroquine dropping from 80% to 2%, Quinine injection from 59% to 2%, and SP tablets 525mg from 88% to 7%. On the other hand, a considerable amount of chroloquine was found in Mpigi (32% at endline) while availability of quinine injection increased marginally from 41% to 44% and SP tables 525mg from 81% to 85% in the same period.

An outstanding increase in availability of antidiarrheal products (zinc and ORS) was also observed in Kibaale as opposed to the situation in Mpigi where a marginal increase was noted for both products. In Kibaale, availability of zinc increased by 56% and ORS by 49% between 2008 and 2010. In Mpigi, availability of zinc increased by only 11% and ORS by 10% in the same period.

Regarding quality of services, the evaluation showed a major improvement in malaria case management in Kibaale (Figure 13), with the proportion of malaria cases appropriately managed increasing by 62% while cases inappropriately managed also reducing by the same proportion (62%). On the other hand, the proportion of malaria cases appropriately managed in Mpigi increased by 42% while cases inappropriately managed reduced by 42% in the same period. Proportion of drug shops dispensing injectible antibiotics in Kibaale also dropped from 70% at baseline to 0% at endline survey.

Figure 13: Malaria Case Management by Drug Shops in Kibaale and Mpigi Districts (2008 – 2010)



Source: EADSI, 2011

Following the results of the Kibaale pilot, the Government of Uganda decided to extended implementation of the program to a second district in 2011, further raising hopes for increased medicines access and improved quality of services, in a wider scale. MSH continued to provide technical support to the program through the SDSI project (2011-2014) with funds from the Gates Foundation. The SDSI grant also enabled adaptation and replication of the ADDO model in Liberia, demonstrating its relevance in a post-conflict environment.

In August 2011, a team of two senior pharmacists from Liberia Medicines and Health Products Regulatory Authority (LMHRA) arrived in Tanzania for a four-week study tour to learn about the ADDO program and TFDA inspection and registration systems. The team would later play a key role in the adaptation of the ADDO standards to suite the Liberian context, and the subsequent development of the Accredited Medicine Store (AMS) program based on the ADDO model. Soon after, the LMHRA in collaboration with the Pharmacy Board of Liberia (PBL) and other key stakeholders, developed an implementation plan, setting the stage for implementation of the program in Montserrado, one of the counties with high concentration of unregulated drug retailers.

In February 2013, Liberia officially launched the program after completing all the initial key steps including mapping and preliminary inspections; training of dispensers, inspectors and shop owners; and establishment of a joint LMHRA/PBL inspection system. By June 2014, the program had mapped 635 medical stores and accredited 200 of them, while 150 shops were in the application process. The program had also trained 628 dispensers, 160 AMS owners and 17 LMHRA/PBL inspectors.

Results from an evaluation conducted in March 2014 showed increased access to quality medicines, improved service quality and increased compliance with regulations and standards. For example, the proportion of expired, damaged or counterfeit products found in accredited medicine stores in Montserrado dropped from 28% at baseline (February 2012) to 8% at endline in March 2014; the proportion of AMS with medicines not on the AMS extended list dropped from 90% (baseline) to 3% (endline); and the proportion of AMS keeping product purchase receipts/invoices for verification of medicine sources, also increased from 33% (baseline) to 81% (endline). These findings further reaffirmed the replicability and benefits of the ADDO program.

> *"Tanzanians ought to be proud of what they have been able to achieve with the ADDO program through local efforts. There is a growing interest in the program among other developing countries with medicine access challenges, as well as other health stakeholders on the global platform who want to learn more about the initiative. Going forward, I think it would be helpful to unpack the ADDO story and widely share the evidence through various channels including professional journals, to enable all the interested parties to understand and learn from the Tanzanian experience,"* **Edmund Rutta, Senior Technical Adviser, MSH-USA.**

Senior LMHRA officials on a study tour in Tanzania to learn about the ADDO program and TFDA regulatory systems.

4 Success Factors

The success of the ADDO program can be attributed to several factors including stakeholder consultation and involvement in the development of the program; collaboration and partnerships at various levels; reliable donor support; supportive policy. Legal and regulatory framework; strong political will and government ownership; institutionalized implementation; existence of sound administrative structures and political stability; experimental implementation through learning by doing; pragmatic program leadership; and individual sacrifice and teamwork.

4.1 Stakeholder Consultation and Involvement

The ADDO program was conceived in a dynamic system comprising both public and private sector stakeholders whose interests were always not well understood or mutually consistent. The stakeholders include drug shop owners and dispensers, pharmaceutical wholesalers, regulatory authorities, professionals in the pharmacy sector, government employees at regional and council levels, local government leaders, political leaders and community members (consumers). Understanding their varied interests was critical to the design, planning and management of the program. During the piloting, SEAM program conducted a formative research to understand the stakeholders' interests and attitudes, and came up with strategies for their involvement in the implementation process. This paved way for a highly participatory approach which became an integral part of the program. About 20 workshops involving different stakeholders were conducted during the piloting phase alone.

The major achievements realized through this approach include development of ADDO regulations and the subsequent reviews, development of incentive mechanisms for long term engagement of ADDO providers in the program, and review of implementation models to respond to the changing needs of the program. As implementation progressed through different phases, stakeholder consultation and involvement also evolved into a **core value**, enabling the program to gain broad-based support and ownership among stakeholders in both public and private sectors. Stakeholder-consultation has been institutionalized through a system of periodic national conferences to review progress, address challenges and reach consensus on major decisions regarding the program's future. The table below highlights the various stakeholder conferences conducted since successful piloting of the program.

Participants of the 5th National ADDO Stakeholders Conference.

Table 5: National ADDO Stakeholder Conferences

Conference & Date	Venue	Focus
1st Conference (22nd – 24th February 2005)	Kunduchi Wet & Wild Hotel (Dar es Salaam)	Dissemination of the pilot project results and discussions to come to a common understanding of the achievements, challenges, lessons and implications, and also develop ideas and options to take the achievements forward. Conveners: TFDA and MSH with financial support from the Bill and Melinda Gates Foundation through SEAM program.
2nd Conference (3rd - 5th July 2008)	St. Gaspers Conference Centre (Dodoma)	Focused on scalability and sustainability of the ADDO program following successful regional expansion through a centralized approach. The conference set the stage for decentralized implementation by addressing issues of policy, funding, human resource, institutional framework, and roles and responsibilities of different stakeholders in the national rollout of the program. Conveners: TFDA and MSH with financial support from the Bill and Melinda Gates Foundation through the EADSI project.
3rd Conference (8th - 10th September 2009)	Morogoro Hotel (Morogoro)	Reviewed early outcomes of the decentralized implementation of the program and progress made on the Dodoma Conference recommendations. It also addressed challenges experienced in the decentralized rollout and came up with recommendations toward successful completion of the process. Conveners: TFDA and MSH with financial support from the Bill and Melinda Gates Foundation through the EADSI project.
4th Conference (17th - 19th September 2012)	Tanga Beach Resort (Tanga)	Focused on the program's overall progress with emphasis on implementation quality and sustainability beyond national rollout. Thus, it reviewed findings from various assessments on different aspects of ADDO implementation (training, regulatory systems, supply chain, use of mobile technology, role of ADDO provider associations, community based initiatives and consumer advocacy); discussed recommendations and options; and agreed on feasible interventions to ensure maintenance and sustainability of the program. Conference also served to build a rapport between various stakeholders and the Pharmacy Council following transfer of the overall program management from TFDA to the Council. Conveners: Pharmacy Council and MSH with financial support from the Bill and Melinda Gates Foundation through the SDSI project.
5th Conference (5th – 6th August 2014	The Arusha Hotel (Arusha)	Focused on the ADDO implementation progress following completion of the national rollout, and reviewed results of different interventions recommended by the Tanga Conference for the program maintenance and sustainability (use of mobile technology, institutionalization of ADDO trainings and establishment of ADDO provider associations). Stakeholders also discussed findings from different operational research activities to evaluate medicines access and use in communities served by ADDOs. Most importantly, stakeholders identified various areas for future investment in expanding and sustaining the gains realized from implementation of the program. Conveners: Pharmacy Council and MSH with financial support from the Bill and Melinda Gates Foundation through the SDSI project.

4.2 Collaboration and Partnerships

Collaboration and partnerships are key pillars of the ADDO program. It all started as collaboration between MSH and the then Pharmacy Board in conducting the 2001 comprehensive assessment of the pharmaceutical sector, which would later give to the ADDO concept. In 2002, MSH signed a Memorandum of Understanding (MoU) with the Ministry of Health to pilot ADDO implementation in Ruvuma Region in close collaboration with TFDA. The MoU formalized the relationship between MSH and the government by clearly stating roles and responsibilities of each partner.

As the process moved down to the ground in Ruvuma region, engagement of other key stakeholders including regional authorities, local government authorities at the council and community levels and private drug shop owner, became inevitable. Each of the stakeholders played an important role in the designing, planning and implementation of the program. Other service providers such as MEDA, NMB and later CRDB Bank and Mbinga Community Bank also came on board, particularly to support the business component. National pharmaceutical wholesalers were also approached to support efforts to improve the ADDO supply chain system, and the Dar es Salaam based Pyramid Pharmacy accepted to join the initiative, further expanding private sector's participation in the pilot.

As implementation of the project was expanded to other regions, the scope of partnership correspondingly expanded, with coming on board of more regional authorities, local government authorities, drug shop owners and dispensers, and development partners. Other national health programs such as malaria, IMCI, family planning and NHIF also joined the efforts to strengthen the ADDO platform as a vehicle for delivering various health interventions to communities served by the drug shops. When the program's implementation model was changed from centralized expansion to decentralized rollout, the number of stakeholders participating in the program multiplied rapidly in both public and private sectors. Their involvement also increased in terms of financial inputs, with some districts/councils allocating funds for ADDO implementation activities, and ADDO providers meeting part of their training costs.

At the national level, MSH continued to provide technical support to the regulatory agencies (TFDA and later to Pharmacy Council) through its country technical team with sufficient backing from the international team of experts based at MSH's headquarters in Arlington, Virginia, USA. The support spanned all the three implementation phases of the program (pilot, regional expansion and national rollout) through three successive grants (SEAM, EADSI and SDSI), all funded by the Bill and Melinda Gates Foundation. The technical support mainly focused on strengthening internal capacity of the regulatory agencies to effectively coordinate ADDO implementation; promoting innovation through experimental implementation; generating evidence through research and documentation to inform policy and planning; and raising ADDO profile nationally and internationally through various stakeholder meetings, international conferences and publications.

At the Ministerial level, the MSH-MoHSW partnership inspired establishment of the National Medicines Steering Committee to provide guidance and oversight to major program activities. Membership in the committee expanded from 7 members in 2003 to 18 by 2013, to reflect the growth in number of stakeholders supporting program. The members are largely drawn from relevant MoHSW departments including directorates and vertical programs such as Malaria; Prime Minister's Office, Regional Administration and Local Government (PMO-RALG); regulatory agencies (TFDA and PC), WHO as a technical adviser on health issues, Medical Stores Department (MSD), NHIF, development partners such as MSH and CHAI, professional associations such as PST, and private sector representatives. The committee is chaired by the Chief Medical Officer, with TFDA Director General as the secretary (before transfer of the program management to PC).

Commenting on the long history of collaboration and partnership with MSH among other stakeholders, Mr. Hiiti Sillo, the TFDA Director General describes MSH as a dependable partner who remained sensitive to the need of the program and priorities of the regulators. In 2013 during TFDA's 10th anniversary celebrations, the agency gave MSH a special "partnership award" in recognition of its contribution to the efforts to improve medicines access in Tanzania through the ADDO program. The MSH Executive Vice President and Chief Operating Officer, Mr. Paul Auxila, received the award on behalf of the organization, during a visit to Tanzania a few weeks later.

> *"Our partnership has worked very well. I feel that trust has been built up and that there is a genuine desire to move the ADDO initiative forward in order to benefit more Tanzanians. A lot has been learned to help other countries adapt and implement the Tanzanian model more efficiently. Funding initial development and scale up is probably the greatest challenge in new programs, but Tanzanians have shown that it can be done,"* **Keith Johnson, Director, Private Sector Programs, MSH-USA**

Jafary Liana, a senior MSH technical adviser explains that the organization's approach to partnership and empowerment is guided by the over 3,500 year old Tao (Way) of Leadership, which emphasizes working shoulder to shoulder with local colleagues and partners toward their empowerment and success. However, he notes that the approach requires patience, tolerance and at times compromise, to ensure that partners' priorities are well harmonized and support shared objectives. He thanks the Bill and Melinda Gates Foundation for the flexibility and reliable funding, which enabled the MSH approach to work in the Tanzanian context.

THE TAO OF LEADERSHIP

Go to the people
Live with them
Love them
Learn from them
Start with what they have
Build on what they know.

But of the best leaders
When their task is accomplished
The work is done
The people will say
We have done it ourselves.

-Lao Tzu

"When I look at ADDO, I not only see a successful national program that is changing the lives of ordinary Tanzanians, but a powerful Tanzanian brand developed by Tanzanians through working together with global partners," **Jafary Liana, MSH Senior Technical Adviser.**

4.3 Donor Support

The success of the ADDO program would not have been possible without financial support from different development partners. The Bill and Melinda Gates Foundation, the trailblazer in this front, began by supporting the 2001 comprehensive assessment of the country's pharmaceutical sector, which resulted in conceptualization of the ADDO program. The Gates Foundation solely funded the piloting process in Ruvuma region and continued to support implementation of the program through different phases, with emphasis on innovative interventions with potential to hasten realization of the program's goal.

With the pilot results showing significant gains in terms of medicines access and other social and economic benefits, and the government's determination to expand implementation becoming apparent; other donors came on board to support the expansion efforts. They included USAID, DANIDA, The Global Fund, CHAI and the Rockefeller Foundation. Table 6 below highlights major processes supported by different donors at various stages of implementation of the program.

Table 6: Donor support for ADDO implementation

Donor	Intervention/Activity Supported	Funding Mechanism	Period
Bill and Melinda Gates Foundation	Assessment, project conceptualization, design and planning.	SEAM Program	2001 - 2003
	Pilot project development and implementation in Ruvuma region.	SEAM Program	2003 - 2005
	Evaluation of the pilot project.	SEAM Program	2003 - 2005
	Review of the ADDO implementation model from centralized to decentralized implementation and evaluation of the efforts.	EADSI Project	2007 - 2011
	Operational research activities on different ADDO components and implementation of interventions to ensure the maintenance and sustainability of the program.	SDSI Project	2011 - 2014
USAID	ADDO rollout in Morogoro Region with resources from the President's Emergency Plan for AIDS Relief (PEPFAR).	MSH's RPM Plus Program	2006 - 2008
	Implementation of child survival interventions through ADDOs in Morogoro Region.	BASICS and MSH's RPM Plus program	2007 - 2009
	Subsidized ACT distribution through ADDOs in Morogoro and Ruvuma regions using funds from the President's Malaria Initiative (PMI).	MSH's SPS Program	2007
	Interventions to engage ADDOs in Morogoro Region in early detection of people with TB.	MSH's SIAPS Program	2010 - 2012

Donor	Intervention/Activity Supported	Funding Mechanism	Period
DANIDA	Independent evaluation of the ADDO project through HERA	HSPS	2006
	Support to TFDA to develop and print training materials used for ADDO scale-up, conduct training of trainers and district inspectors, and carry out national sensitization seminars to LGAs.	Health Sector Program Support (HSPS)	2007 - 2008
	Initial ADDO rollout activities in Lindi, Pwani and Mbeya regions.	HSPS	Sept. - Dec. 2008
The Global Fund	ADDO roll-out/implementation in high impact malaria regions, to increase access to antimalarials (Kigoma, Lindi, Pwani, Singida, Mbeya, Tanga, Rukwa and Morogoro).	GFATM Round 7 through AMFm	2008 - 2009
CHAI	Initial ADDO rollout activities in Dodoma and Shinyanga regions.	TSMP	2009
Rockefeller Foundation	Interventions to promote ADDO sustainability through establishment of ADDO provider associations.	MSH's SPS Program	2009

4.4 Supportive Policy, Legal and Regulatory Framework

Implementation of the ADDO program is supported by an elaborate policy, legal and regulatory framework. The policies include: the National Health Policy, National Drugs Policy, National Public-Private-Partnership Policy and the National Policy of Centralization by Devolution championed through the Local Government Reforms Program. These policies are inspired by the major national development goals and commitments articulated in the National Vision 2025, Millennium Development Goals (MDGs), and the National Strategy for Growth and Reduction of Poverty (commonly known by its Swahili language acronym, MKUKUTA).

The Vision 2025 aims to awake, coordinate and direct national efforts and resources towards core sectors that will enable the country to realize its development goals and withstand the intense competition in the global economy. It envisions high quality livelihood, good governance and rule of law, and a strong and competitive economy. These priorities are captured in MKUKUTA as the key clusters of poverty reduction outcomes, identified as: (i) growth and reduction of income poverty, (ii) improvement of quality of life and social well-being, and (iii) good governance. The ADDO program fits within both the quality livelihood and economic development goals.

In 2000, Tanzania joined other developing countries in signing the Millennium Development Goals, which are internationally agreed targets for reducing poverty, hunger, diseases, illiteracy, environmental degradation and discrimination against women by 2015. While ADDO addresses most of the MDGs, the program is well covered under the MDG Target 8(E) which emphasizes the role of the private pharmaceutical sector in increasing access to affordable quality essential medicines on a sustainable basis. The target resonates well with the goal of the ADDO program, which is increased access to quality essential medicines by underserved populations mostly found in rural and peri-urban areas. Over 70% of Tanzanians live in rural areas.

The inception of ADDO implementation coincided with reviews of various national policies to align them with the MDGs, Vision 2025 and reforms in the key sectors such as health and local government, which peaked in early-to-mid 2000. In 2003, the process of reviewing the National Health Policy (1990) was initiated and culminated in the updated Health Policy (2007). The review of the policy put emphasis on the need for increased community involvement in health development and improved access and equity in health and health services.

Issues of community involvement, access and equity, are central to the design, approach and goal of the ADDO program. The "rural focus" in ADDO implementation is driven by the need to bridge the gap that exists between rural and urban areas in terms of availability of pharmaceutical services, and ensure more equitable access to essential medicines towards improved health and wellbeing of all Tanzanians, which is the vision of the National Health Policy. The ADDO program's focus is also supported by the National Drugs Policy, whose overall objective is to make available to all Tanzanians, at all times, the essential pharmaceutical products which are of quality, proven effectiveness and acceptable safety, at a price that the individual and the community can afford, when the products are needed to prevent, cure or reduce illness and suffering. In 2009, ADDO was included in National Drugs Policy Implementation Master-plan (2009 -2025).

The Secret behind the Gates Foundation Generosity to ADDO

***"From the start, the Gates Foundation told us that they did not fund the same idea twice nor scale-up of proven concepts. What was possible, however, was leveraging additional funding to strengthen and move the ADDO program forward",* Keith Johnson, Director, Private Sector Programs, MSH-USA**

Ten years after successful implementation of the ADDO program in Tanzania, Keith Johnson, the MSH Director of Private Sector Programs who played a key role in the development of the program, reveals how his organization worked with the Bill and Melinda Gates Foundation to provide support for the ADDO program. The first grant was the Strategies for Enhancing Access to Medicines (SEAM) program, awarded in late 2000. It was a 5-year grant for improving access to essential medicines through public-private sector partnerships.

Countries or specific projects were not identified in the SEAM proposal; rather, 6 countries were selected as candidates for access-to-medicines assessments that outlined access gaps, the pharmaceutical situation, and challenges and opportunities. Tanzania was one of the 6 countries. In November 2001, the findings for each of the 6 countries were presented at the first SEAM conference held in Washington, DC, during which Tanzania put forth the ADDO concept as the focus for the proposed SEAM work in the country. The recommendation was accepted, resulting in the piloting of the ADDO program in Ruvuma region.

Although the SEAM-funded ADDO pilot demonstrated proof of the concept, it did not provide guidance for effective scale-up or replication in other countries. Thus, the second grant, the East African Drug Sellers Initiative (EADSI) program (2007-2011), focused on revising the ADDO implementation model to make it more efficient and cost-effective. The resulting decentralized implementation model allowed Tanzania to scale up more quickly and at a lower cost. The grant also supported replication of the ADDO concept in Uganda.

With Tanzania's scale-up success, the next frontier was sustainability and maintenance of the program. The third grant, the Sustainable Drug Seller Initiatives (SDSI) program (2011 – 2014), largely focused on increasing the private sector's participation in the efforts to improve implementation quality and enhance sustainability. Among the key components addressed in Tanzania included: institutionalizing ADDO trainings in both public and private institutions; integrating the use of modern information and communication technology (ICT) in program management; expanding the role of ADDO provider associations in implementation of the program; and strengthening linkages between ADDOs, community health workers and health facility services. SDSI also allowed further scale-up and strengthening of Uganda's program and enabled adaptation and replication of the model in Liberia, demonstrating use of the model in a post-conflict environment.

All this was made possible through the convergence of a number of positive factors including:

- A donor that had the vision and trust that a multi-year initiative was possible and necessary for success;
- A host country that saw the value of the ADDO concept in improving access to quality medicines and pharmaceutical services, particularly in underserved populations;
- The commitment and energy of host country leaders and stakeholders in taking ownership of the program;
- A private sector that seized the opportunity to operate profitable businesses and contribute to public good;
- Strong technical support from Tanzanian organizations and businesses, which helped to build the capacity needed to expand and maintain the ADDO program and provide South-to-South technical support for new programs, and from MSH.

Another major policy development which happened just in time for implementation of the ADDO program, was the development of the Second Health Sector Strategic Plan (HSSP II) at the peak of the health sector reforms of the early 2000. The HSSP II (2003-2008) focused on priorities of the health sector reform process, aimed at addressing the recognizable deficiencies in the sector and achieving specific goals and targets in health as set out in the MDGs and MKUKUTA. The strategies included: strengthening district health services; accelerating hospital reforms; enhancing role of the central ministry and central support systems for health; improving human resources for health, increasing health sector financing, promoting public private partnership (PPP), enhancing sector-wide coordination and strengthening HIV/AIDS programming.

The third Health Sector Strategic Plan (2009 - 2015) furthers implementation of the HSSP II objectives and other key health sector priorities such as: improving maternal, newborn and child health; preventing communicable and non-communicable diseases; emergency preparedness and response; social welfare protection; research, monitoring and evaluation for evidence-based decision-making; capital investment in health infrastructure; improving availability of medicines and supplies; and use of ICT in health promotion and management. The major theme in the implementation of the third Health Sector Strategic Plan (HSSP III) is "Partnership for Delivering MDGs". The HSSP II & III recognize the role of the private sector, with identification of PPP as one of the key strategies for improving delivery of health services.

The ADDO program is widely acknowledged as a PPP success story which not only complements the government's efforts to increase the population's access to essential medicines but also embraces some of the HSSP objectives. Development of the National Public Private Policy (2009) has helped to strengthen the position of PPP as a strategy for development, and created a favorable environment for implementation of PPP initiatives such as ADDO. The main objective of the policy is to promote private sector participation in the provision of resources for PPP enterprises in terms of investment capital, managerial skills and technology. The policy is a potential catalyst to the on-going reforms in the key socioeconomic sectors.

Having been conceived at the height of the health sector reforms, the ADDO program is arguably a product of the reform process and a beneficiary of the various policies, legislations and regulations inspired by the reforms and broader national development goals. The legislations included the repeal of the Pharmaceuticals and Poisons Act No.9 of 1978 which established the Pharmacy Board, and its replacement with two Acts: the Pharmacy Act No.7 of 2002 which established the Pharmacy Council, and the Tanzania Food, Drugs and Cosmetics Act No.1 of 2003 which established Tanzania Food and Drugs Authority (TFDA) as semi-autonomous government agency responsible for comprehensive regulation and control of food, drugs, medical devices, cosmetics, herbal drugs and poisons.

Although tabling of the Food, Drugs and Cosmetics Bill of 2003 in parliament coincided with designing of the ADDO program, TFDA was able to amend the bill to authorize establishment of ADDOs. This paved way for the development of ADDO Regulations (2004) and the subsequent review in 2009 to accommodate increased demands of the program and the need to align the regulations with other reforms in the health sector, which included strengthening district health services through establishment of relevant management structures (such as the Council Health Management Team, Hospital Management Team, Council Health Service Board and Health Facility Governing Committee) and institutionalization of the Comprehensive Council Health Planning (CCHP) process. Through the CCHP process, several councils have been able to budget own financial resources for implementation of different ADDO program activities.

The regulatory improvements and the wider reforms in the health sector, interface local government reforms at the council level within the national policy of Decentralization by Devolution (D-by-D). The D-by-D policy aims to strengthen the capacity of councils as the custodians of development processes at the community level, through provision of responsibility, authority and resources. In line with the policy, TFDA made a decision in 2006 to delegate some of its powers and functions to local government authorities. The decision was largely informed by the realization that given the vastness of the country, increasing number of providers joining the ADDO program and greater demand for effective regulation of the pharmaceutical sector; a more efficient regulatory system which directly reaches communities, would be necessary for closer regulation and monitoring of all private drug outlets including ADDOs.

Consequently, TFDA signed a Memorandum of Understanding with the Prime Minister's Office, Regional Administration and Local Government (PMO-RALG) to facilitate delegation of some of its powers and functions to the councils. This was effected through Government Notice (GN) Number 162 of 2006 (Tanzania, Food, Drugs and Cosmetics Delegation of Powers Order,

[11]MDG Target 8(E): "In co-operation with pharmaceutical companies, provide access to affordable essential drugs in developing countries". The only indicator for this target is "proportion of population with access to affordable essential medicines on a sustainable basis".

2006) which allowed PMO-RALG to issue a circular to all councils to execute the delegated TFDA functions. The Order was amended through GN No.165 of 2007 (Delegation of Powers Amendment Order, 2007) to accommodate changes to the ADDO program implementation approach (from the centralized to decentralized model) and give councils more responsibilities and authority in the implementation of the program.

Accordingly, Council Food and Drugs Committees (CFDC) and Ward Drug Inspection Committees were established to coordinate the delegated TFDA functions including implementation of the ADDO program. The committees have a key role in the accreditation of ADDOs and monitoring their operations through routine inspections and supportive supervision. The councils also have an important role of coordinating ADDO trainings and pre-accreditation processes.

In 2011, further statutory changes were made to streamline functions of the regulatory agencies (TFDA and Pharmacy Council) and ensure more efficient regulation of the pharmaceutical sector. The Pharmacy Act, 2002 was repealed and replaced with the Pharmacy Act, 2011 which mandates the Council to regulate the pharmacy practice at all levels, in addition to overseeing the training and registration of pharmacy professionals countrywide. Following enactment of the Act, the overall management of the ADDO program was transferred from TFDA to the Pharmacy Council, leaving TFDA with the core function of regulating the quality, efficacy and safety of pharmaceutical products.

4.5 Institutionalization of the Program

Institutionalization was one of the key strategies deployed in the implementation of the ADDO program. The aim was to increase management efficiency, minimize implementation costs, achieve broad-based stakeholder participation and ownership, leverage resources (technical, material and financial) for the implementation, and enhance the program's long term sustainability.

One of the major steps towards the institutionalization was the integration and positioning of the ADDO program within the government structures. The process began way back in 2003, with the appointment and deployment of two TFDA staff (Emmanuel Alphonce and Yona Hebron) to support the MSH/SEAM program team during the program's piloting in Ruvuma Region. Their major roles were to represent TFDA in all the key piloting activities, provide the necessary facilitation to the pilot team and report back to the institution routinely. One of the staff, Mr. Emmanuel Alphonce, was assigned the lead role in the collaboration with MSH and later confirmed as the first ADDO program coordinator, directly answerable to the TFDA Director General. In the same year, the National Medicines Access Steering Committee was established at the ministerial level under the chairmanship of the Chief Medical Officer, to provide technical support and policy guidance on all issues regarding implementation of the program.

In 2006, as the scale of the program's activities increased following the government's decision to expand the implementation to Mtwara, Rukwa and Morogoro regions; TFDA established the ADDO Unit under the Directorate of Business Support, with Emmanuel Alphonce, the ADDO coordinator, as the first unit head. Five additional staff were transferred from other TFDA departments and units to the newly established ADDO Unit to help strengthen its capacity to support implementation of the program in the new regions. The additional staff were: Elizabeth Shekalaghe, Bryceson Kibassa, Heri Ngemera, Tumaini Mikindo and William Nkondokaya. The unit was fully equipped with essential working tools including computers and unlimited access to transport for official use. More staff (David Maganga, Cliffson Maro, Mshindo Musulla and Philip Amani) would later be included in the team as the momentum and coverage of the program increased, with the introduction of the decentralized implementation approach.

> *"As the national rollout of the program peaked, we had to make ADDO implementation everyone's responsibility because the human resource needs of the rapid rollout process were far beyond to the capacity of the ADDO unit,"* **Dr. S.S. Ngendabanka, the TFDA Director of Business Support.**

In view of the fast-evolving stature of the program, the increasing demand from the local government, the growing interest among development partners and the emerging implementation challenges from the initial expansion regions; a decision was made to reposition the ADDO Unit by putting it directly under of the Office of the Director General (DG). A major restructuring of the TFDA would soon follow in early 2008, during which the ADDO Unit would be elevated to department status and housed

in the Directorate of Medicines and Cosmetics, under the DG's Office. Ms. Elizabeth Shekalaghe became the first head of the department and served as the program manager until early 2012 when the management of the program was transferred to the Pharmacy Council. In the restructuring, TFDA also established zonal offices to enable it to work more closely with the regional and council authorities to strengthen regulatory oversight.

> *"The ADDO program greatly influenced and benefited from the restructuring of the TFDA aimed at increasing efficiency in service delivery and effective execution of the agency's regulatory mandate,"* **Margareth Ndomondo-Sigonda.**

Another major step towards institutionalization was the delegation of TFDA regulatory powers and functions to local government authorities (LGAs) and decentralization of the ADDO program management. The delegation of TFDA powers and functions was largely informed by the lessons learnt from Ruvuma Region during the development of the ADDO regulatory system. The Ruvuma experience had shown that a council-based regulatory system with an extended reach to the community through the ward health committee had a greater potential for improving regulatory monitoring and control, than concentrating regulatory functions and powers at the central and regional levels. Consequently, as the country was preparing to rollout the ADDO program nationally through the decentralized approach, TFDA had already taken steps to delegate to LGAs, some of its powers and functions (especially inspection, supervision and collection of regulatory fees). This was made possible by the development and execution of the the Tanzania Food, Drugs and Cosmetics Delegation of Powers Order (2006), commonly referred to as "Delegation of Powers Order".

In 2007, after gaining some experience from the initial expansion regions, it became clear that decentralizing ADDO implementation was the way to go. The Delegation of Powers Order was therefore amended to include ADDO program management responsibilities. The amendment also addressed the sharing of regulatory fee collections between the TFDA and LGAs, in line with the principle of decentralization by devolution which demands that delegation of responsibility must be matched up with the necessary powers and resources for effective execution of the assigned roles. These processes greatly facilitated institutionalization of the program at the local levels.

Another key aspect of the institutionalization was integration of the program in the comprehensive council health planning (CCHP) process to ensure utilization of local resources to implement ADDO activities, promote local ownership and enhance sustainability. The CCHP integration had been a major focus of the TFDA sensitization seminars to LGAs and remained a permanent advocacy agenda throughout the national rollout of the program. The benefits were seen since the early stages of the rollout, with some districts in Shinyanga, Tabora, Iringa, Arusha, Kagera and Kilimanjaro regions taking initiative to introduce the ADDO program using their own funds, as the country was still waiting for funds from the Global Fund to proceed with the process. Since then, councils have continued to budget for ADDO program activities in the CCHP (mostly training, inspection and supervision), although not all councils do so regularly.

With most of the decentralization groundwork accomplished and the extended regulatory system clearly outlined, the next critical step was establishment of coordination and reporting systems to ensuring these fundamental changes were institutionalized and sustained. In 2009, the TFDA carried out the firs review of the ADDO Regulations (2004), which included among other things, renaming of the regulatory bodies at regional, council and ward levels, to create the Regional Food and Drug Committees (RFDCs), Council Food and Drugs Committees (CFDCs) and Ward Health Committees (WHCs), respectively. The review also included a description of the roles and responsibilities of each of these committees, as well as coordination and reporting systems.

Although the decentralized ADDO implementation approach was highly favorable in the Tanzanian context, it created a huge demand for skilled dispensers in different parts of the country. The district-based trainings could no longer suffice the high demand for these key personnel. Accordingly, institutionalization of ADDO trainings was prioritized to help alleviate the problem. Under the leadership of the Pharmacy Council, the regular 35-day dispenser training course was institutionalized in the government zonal health training and resource centers, and a training curriculum for a one-year pharmaceutical dispensing certificate course also developed. The course has been institutionalized in both public and private training institutions as a National Technical Award (NTA) Level 4 course.

In overall, the institutionalization of the ADDO program would not have been possible without the development and use of various essential working tools. The tools include among others: the ADDO regulations of 2004 (amended in 2009); the national ADDO rollout strategy (2006); the TFDA Delegation of Powers Order of 2006 (amended in 2007); standard guidelines for establishing ADDO; ADDO dispenser and owner training manuals; and ADDO inspection guidelines. These tools have been very instrumental in regulating and standardizing the implementation quality of the program.

4.6 Sound Administrative System and Political Stability

Tanzania is made up of two formerly independent countries, Tanganyika and Zanzibar, which united in 1964 to form the United Republic of Tanzania. Since formation of Tanzania, Tanganyika is commonly referred to as Tanzania Mainland. Both Zanzibar and the Mainland have separate administrations under the Union Government. The ADDO program has only been implemented on the Mainland.

Administratively, the United Republic of Tanzania is divided into 30 regions, of which 25 are on the Mainland and 5 in Zanzibar. Each region is subdivided into districts. The districts are sub-divided into divisions and further into wards. Urban wards are sub-divided into streets (known in Swahili as mtaa *[singular]* or mitaa *[plural]*), and rural wards into villages. Because of their relatively bigger size than *mitaa*, villages are further subdivided into hamlets. On the Mainland, there are 159 districts and 2,643 wards and over 16,000 villages and *mitaa*. Functionally, these structures serve as governance units.

Tanzania has a two-tier system of government (the central government and local governments) within a unitary state. Local governments are either urban authorities (city, municipal and town councils), or rural authorities (district councils). The latter incorporate small towns (township authorities) as well as village councils (governments). The stated basic functions of the local government are: (i) maintenance of law, order and good governance; (ii) promoting economic and social welfare of the people within their areas of jurisdiction; and (iii) ensuring effective and equitable delivery of qualitative and quantitative services to the people within their areas of jurisdiction.

In 1996, Tanzania embarked on a comprehensive local government reform agenda in line with Section 28 of the Ruling Party (Chama Cha Mapinduzi) Election Manifesto of 1995, which promised to strengthen local authorities so as to transform them into engines of social and economic development, and of extending the realm of democracy. The aim was to make the local authorities more efficient, effective, transparent and accountable to the people.

Guided by the national policy of decentralization by devolution and the goals of the National Vision 2025, the local government reforms focused on five key dimensions: (i) opening up more revenue sources to the local authorities, including introduction of conditional and unconditional grants from the central government (financial dimension); (ii) decentralizing local government personnel by integrating them in the local governments from ministerial subordination, and restructuring the local government administration (administrative dimension); (iii) streamlining central government agencies and ministries previously in command positions to concentrate on policy making, support and facilitation, monitoring and quality assurance, and control, all within the law (central-local relations dimension); (iv) decentralizing public services to bring service provision and management to end users, while increasing the services' quantity and quality (service function dimension); and (v) strengthening local democratic institutions by enhancing public participation and bringing control to the people (democratic dimension).

A major feature of the system is citizen participation in decision-making and a determination to link the government and the citizenry to allow national policies to reach the people and guide development processes. At the community level, village governments in rural areas and the urban *mtaa* committees are established to mobilize citizen participation in development. Priorities for local service delivery and development projects are brought to the urban *mtaa* committee or the rural village assembly for discussion before being forwarded to the Ward Development Committee (WDC) where the first semblance of a development plan is produced. Members of the committee include the ward counsellor (an elected representative) as the chairman, ward executive officer (an employee of the local government) as the secretary, village/*mtaa* chairmen (elected representatives), village/*mtaa* executive officers (local government employees) and technical personnel in the community including health facilities in-charge, school heads, community development officers, social welfare officers and agricultural extension staff.

With approval from the village councils/*mtaa* committees, the ward development plans are presented at the "Full Council", a 5-day planning session at the district/council level, where political representatives (ward counselors) meet with technical experts (heads of all council departments e.g. planning, health and social welfare, education, agriculture, infrastructure, trade, cooperatives, community development, etc.) to discuss the community development priorities and needs of the various departments, and come up with a council plan. The Full Council (FC) is chaired by the Council Chairperson elected from among the ward councilors, with the Council Executive Director as the secretary.

The FC is preceded by another development forum at the council level, the "stakeholders forum", where development partners (the civil society, faith-based organizations, community based organizations, etc.) working in different development sectors, meet

with relevant council departments to share their priorities and resource commitments for the fiscal year in question, for consideration in departmental plans. The departmental plans such as the CCHP, are discussed together with the community priorities articulated in the ward development plans, during the Full Council, to come up with one council plan. Priority setting and resource allocation are standardized using planning guidelines provided to the councils by the central government through the local government ministry.

The council plans are reviewed by Regional Planning Officer (RPO), a key member of the Regional Administration , to ensure compliance with the established planning guidelines, and provide direction as appropriate on areas which need improvement. Once approved by the RPO, the plans are sent to local government ministry, where they are subjected to a similar review and approval process, before being forwarded to the Treasury for resource allocation based on a nationally agreed resource allocation formula. This system enabled the country to entrench a truly bottom-up development planning and ensure that priorities of communities are addressed.

As the engine of development, reforms in the local government and the resultant system of administration created a fertile ground for reforms in other key sectors to thrive. The reforms intensified between 2000 and 2005, coinciding with the conceptualization and piloting of the ADDO program. The delegation of TFDA powers and functions to council was largely made possible by the reforms, which had put more responsibility, authority and resources in the local authorities. Institutionalization of ADDO implementation at the council level through integration in the CCHP and establishment of the regulatory structures (CFDC and ward inspection committees) which reach communities, was largely guided by the local government architecture which accommodates development priorities and needs of communities through the decentralized council planning framework.

These achievements would not have been possible without political stability and peace in the country. During the 10 years of ADDO implementation, Tanzania conducted two successful general elections (in 2005 and 2010) and witnessed a peaceful transfer of power from the third to the fourth post-independence administrations under the ruling Chama cha Mapinduzi (CCM). While the third administration led by President Benjamin William Mkapa set in motion the momentous public sector reforms, the fourth administration under President Jakaya Mrisho Kikwete took over on a platform of continuing the reforms with renewed speed, vigor and resolve towards realization of quality livelihood for every Tanzanian.

4.7 Political Will and Government Commitment

Political will and government commitment to the development and implementation of the ADDO program has been evident the very beginning. The final SEAM program report documents that one of the reasons why Tanzania was selected as a SEAM target country was because the TFDA, as represented by its Director General (Ms. Margareth Ndomondo-Sigonda), was an ambitious, forward-looking institution with visionary leadership that was willing to try something innovative, such as the ADDO program. The report further notes that as the program evolved, it benefited immensely from her continued involvement, flexibility and willingness to actively find solutions to problems and ensure that the program moved forward. It is also instructive to note that as preparations for the ADDO pilot project got underway, the Tanzania Food, Drugs and Cosmetics legislation was passing through parliament, but the TFDA was able to move fast to amend the bill to authorize the establishment of ADDOs.

At the Ministry of Health Social Welfare, the role and personal commitment of the former Chief Medical Officer (CMO), Dr. Gabriel Upunda is widely acknowledged in the development and implementation of the program. Apart from the powerful pitch he made for ADDO at the first SEAM Conference in Washington DC, he was instrumental in the establishment of the National Medicines Access Steering Committee which he chaired until he retired from office. While acting as the Health Ministry Permanent Secretary, he also hastened the approval of integration of the IMCI strategy in the ADDO platform, a process which had dragged so much until his intervention. The enthusiasm of the former Health Minister, Dr. Anna Abdallah (MP) also came out strongly during the national launch of the program which she officiated in Ruvuma Region. She would later become a strong advocate for the program at the national level. The decision by the government to expand implementation of the program to Mtwara and Rukwa regions using state funds, was largely associated with the strong support for the program by the top leadership of the ministry.

The support for the program at the regional, council and community levels, has also been evident. The integration of ADDO activities in the CCHP and their implementation using councils' own resources, attest to their commitment to the program. The local level support and ownership has been instrumental to the successful implementation of the decentralized ADDO model.

[12]The major role of Regional Administration is to provide technical support to councils, monitor implementation of national policies and service delivery by the councils, and link the council authorities with the central government.

4.8 Innovation and Learning by Doing

Innovation and experimental nature of the ADDO program are some of its key strengths. The program is in itself, an innovative public-private partnership initiative grounded on a sounding of the situation of the country's pharmaceutical sector and driven by continuous efforts to finding local solutions to local problems. The 2001 assessment of the pharmaceutical sector conducted prior to the development of the ADDO concept suggested that the existence of DLDBs together with the available local government and regulatory structures would provide the basis on which to launch the ADDO program. Although the existing structures were indispensable, by themselves they would have been inadequate to establish ADDOs.

The final SEAM program report notes that the innovative and experimental nature of the ADDO program meant not only that new structures and systems had to be developed (such as accredited, supervision, strengthened linkages between local and central authorities, and micro-lending outside the traditional financial institutions), but also that the existing structures had to be used in new ways (such as TFDA delegating shop inspections to ward level). Thus, the open-minded and intrinsically experimental nature of the ADDO approach needs to be understood by anyone willing to replicate the approach elsewhere. A willingness to take risks, make mistakes, learn from them, and revise plans on the basis of lessons learned needs to be imbued into the philosophy and working practices of all partners involved.

The innovative and experimental nature of the ADDO program meant not only that new structures and systems had to be developed but also that the existing structures had to be used in new ways.

Other innovative initiatives in the ADDO program include the integration of other public health interventions health intervention on the ADDO platform, such as the child health component, subsidized ACT distribution, family planning, early TB detection and referral, malaria rapid diagnostic testing and health insurance, among other; the review of the ADDO implementation model from the centralized to decentralized approach; integration of mobile technology use in the overall program management; and the development of a system of self-regulation by ADDO providers through associations.

Emmanuel Alphonce, the first ADDO program coordinator adds a light touch to this important feature of the program by describing ADDO as a "practicals university" where learning happens through doing. He is, himself a self-proclaimed vice chancellor of the ADDO University, while the position of the chancellor is designated to Dr. Romauld Mbwasi, a key member of the pilot team and a national ADDO champion who has played a major role in the development of the program.

4.9 Individual Commitment and Teamwork

ndividual commitment and teamwork have also been strong drivers of the program's success. The remarks by Emmanuel Alphonce denote a strong belief in each other's ability to make meaningful contributions in the program – an ingredient which has been key to building strong teams through the different phases of implementation of the program. The difficult conditions in which the central level teams worked in some areas also helped to build solidary in the teams.

> *"We have been such a strong team with our colleagues at the TFDA and Pharmacy Council that at times it is hard to tell who belongs to which institution,"* **Richard Valimba, Technical Advisor, MSH-Tanzania.**

MSH's Jafary Liana (Left) together with TFDA's Tumaini Mikindo (2nd right) and Mvomero Council staff

5 Sustaining the Gains

10 Years after Launch, Joyce DLDM Shines Brighter

The story of Joyce DLDM is as old as the story of the ADDO program. It was inside this shop, on the 11th day of August 2003 that the long but rewarding ADDO journey began. As the first shop to be accredited in Tanzania, Joyce DLDM is a towering symbol of the ADDO program and a powerful statement of the strength of public-private partnership. The proprietor, Joyce and her husband, Mponela, fondly remember the day of the official launch, when national media cameras zoomed inside the shop as the then Health Minister, Dr. Anna Abdallah walked in cheerfully to flag off delivery of ADDO services. Their greatest joy, however, is that over the ten years, the enterprise has helped to increase access to quality essential medicines in the previously underserved community. Through the business, the family has also been able to take their children to good schools and build the home where they live currently in Songea town.

What strikes most about Joyce DLDM, are the changes it has gone through over the years. In terms of premise standards, the size of the shop has been expanded to create more space for stock and movement, the wooden counters and shelves which existed at the time of the launch have all been replaced with heavy glass and shiny aluminum frames. On top of the shelves, all the legal documents are nicely displayed in glittery picture frames and the shop is beautifully decorated with overflowing flowers. The shop dispenser, Devota Luoga has also maintained her dispensing coat. Several years after it was given out to her by the program, the coat still shines in all its brightness. Her joy to serve in the nice-looking shop naturally comes out in the broad smile that lights up her face as she shares her experience. She is also paid thrice as much as the first dispenser at the time of the inauguration of the shop – a sign that the business is doing well.

These developments confirm the findings of the 2011 EADSI Evaluation which revealed that all ADDOs in Ruvuma were making profits, and compared to 2004, the amount of profit had increased. The evaluation also showed that the quality of dispensing services was maintained, and for some indicators, even improved. For example, the percentage of encounters where a customer received malaria treatment according to standard treatment guidelines had increased significantly from 6% in 2003 to 24% in 2004 and 63% in 2010. The story of Joyce DLDM is a powerful statement that the gains of the ADDO program can be sustained and deepened.

Since taking over management of the ADDO program, the major priority of the Pharmacy Council is ensuring the implementation quality and sustainability of the program. With support from the MSH's SDSI project, the PC has been able to focus attention on various key initiatives aimed at enhancing sustainability of the program. The initiatives include: (i) integrating the use of the modern ICT in program management; (ii) institutionalizing of ADDO trainings; (iii) strengthening of the ADDO inspection system; (iv) expanding the role of ADDO associations; and (v) strengthening the linkage between ADDOs, community health workers and health facility services.

5.1 Integrating the Modern ICT Use in Program Management

> All pharmaceutical wholesalers (100%) and 90% of ADDO providers use mobile phones in their day-to-day business operations.

Considering the rapidly increasing number of drug drops, dispensers and shop owner enrolling in the ADDO program countrywide, more efficient program management and regulatory monitoring are needed. The use of the modern ICT is one of the strategies the PC has rolled out to help increase efficiency and improve service delivery. This effort is guided by the national e-Government strategy which aims to accelerate efficient delivery of quality and responsive services to the citizens and businesses.

To a large extent, the effort is informed by the fast growth of the modern ICT use in the country (especially mobile phone technology) and increased demand for real time access to information in an increasingly digitalised communication age. Data from Tanzania Communications Regulatory Authority (TCRA) shows that the number of mobile phone subscribers in Tanzania had increased from 2.9million in 2005 to 27.4million in 2013. The number of internet users also increased from 3.5million in 2008 to 9.3million in 2013. A situation analysis conducted in mid-2012 by the SDSI project with technical support from Inventions and Technological Ideas Development Organization (ITIDO) revealed that all pharmaceutical wholesalers (100%) and 90% of ADDO providers were using mobile phones in their day-to-day business operations.

Informed by these realities, the Pharmacy Council with support from the SDSI project embarked on development of an Integrated Mobile Information System (IMIS) to help increase efficiency in the overall ADDO program management and execution of other regulatory functions. The system has four major components: (i) web-based database (ii) mobile indicator reporting module (iii) mobile payment component, and (iv) mobile information exchange module. To operationalize the system, mobile technology applications compatible with basic phones were developed with technical assistance from ITIDO, the SDSI project contractor.

The **web-based database** will provide basic information about ADDOs and pharmacies countrywide (e.g. registration status, personnel qualifications and certifications, inspection status, premise conditions, license fee payments, etc.). It will be GIS enabled and connected to Google Earth to facilitate geospatial analysis of the drug shops data. It will also allow Pharmacy Council field officers and district staff to access and enter data through an electronic platform designed for routine regulatory processes (e.g. registration, supervision, inspection and disbursement of funds). The database is linked to the other three IMIS components (mobile payment, reporting and information exchange) and programmed to generate summary reports at regular intervals. Non-confidential data and reports are made available on the Pharmacy Council's website for public consumption.

The **indicator reporting** module will enable ADDO dispensers and pharmacy personnel to submit reports on selected indicators via short text message (e.g. product availability, dispensing practice, patient care, etc.). Through this platform, Pharmacy Council central level and field officers, and district health staff will also be able to submit summary reports from routine supervision and inspection activities. Information from all the stakeholders will be transmitted to the Pharmacy Council database in real time. The system is expected to increase access to information for planning and decision-making at both policy and implementation levels.

The **information exchange** module will allow ADDO providers and pharmacy personnel to request for specific information or clarifications from the Pharmacy Council, make comments or forward complaints on different regulatory issues. This will be done through short text messages (SMS) and emails which will be transmitted to the web-based database and assigned to the relevant Pharmacy Council Staff for appropriate action. On the other hand, the Pharmacy Council will use this platform to issue SMS alerts whenever necessary (e.g. fees update, product safety information and medicine recall alerts). The module is envisaged to create

interactions between the Pharmacy Council and pharmaceutical service providers at all levels, including ADDOs in remote hard-to-reach areas.

The **mobile payment** component will enable ADDOs providers and pharmacy personnel to pay regulatory fees through mobile money services. During the piloting, system was linked to Vodacom M-Pesa services but this did not rule out including other mobile money service providers at a later stage. The mobile payment component is linked to the database which will automatically record payments and promptly notify the person paying and the Pharmacy Council in case of a problem. Payment confirmation, payment reminders and penalty notifications for late fee payment will be sent via SMS alerts. This platform will also allow the Pharmacy Council to disburse funds to local government authorities for implementation of different regulatory activities and expedite collection of fees.

5.2 Institutionalizing ADDO Trainings

Availability of a trained dispenser is a mandatory requirement for legal operation of an ADDO. Shortage of these key personnel therefore severely constrains delivery of ADDO services. In an effort to ensure sustainable production of skilled dispensers, the Pharmacy Council with support from the SDSI project set out to explore two major options: Option 1 would focus on institutionalizing the regular 35-day ADDO dispenser training course in the government zonal health training and information centres; and Option 2 would focus on institutionalizing the one-year Pharmaceutical Dispensing Certificate Course in accredited training institutions, both public and private.

Between 2012 and 2014, the Pharmacy Council worked together with MSH through the SDSI project to support institutionalization of the short ADDO dispenser and owner training programs. The efforts largely focused on strengthening the capacity of selected institutions to provide the ADDO dispenser and owner training courses, developing specific implementation plans for each institution including onsite and outreach training plans, conducting training of trainers (TOT) to enable each institution to offer both courses, and monitoring the quality of the trainings and documenting results and lessons for scale-up.

Seven institutions participated in the training of trainers and work-plan development processes. Among the institutions were: Kigoma Clinical Officers Training Centre, Mtwara Clinical Officers Training Centre, Morogoro Public Health Nursing School, Bugando Medical Centre, Ruaha University College, Kilimanjaro School of Pharmacy and St. Peter's College of Health Sciences in Dar es Salaam. The first four are government-owned Zonal Health Resource Center (ZHRC). Between November 2013 and July 2014, the 6 institutions trained a total of 438 ADDO dispensers. The major lesson learnt from the efforts was that institutionalization of the ADDO trainings is feasible, as the trainings are a potential source of revenue to the institutions to support sustainable delivery of the courses.

The Pharmacy Council also introduced the one year pharmaceutical dispensing certificate course as a long term measure to the chronic shortage of dispensers in retail private drug outlets. Curriculum development began in earnest in 2009 and went through a rigorous review process resulting in registration of the course by NACTE as National Technical Award Level 4 course. NACTE also authorized the Pharmacy Council to oversee quality control in delivery of the course by the accredited training institutions, set and mark final examinations, and award certificates to successful candidates.

The course consists of 12 modules delivered in blocks of two semesters (6 modules per semester), followed by one month of field study. A form four leaver (O level graduate) with at least a pass (grade D) in biology and chemistry, is eligible to join the course. Upon completion of the course, successful candidates receive NTA Level 4 Certificate in Pharmaceutical Dispensing and can work in ADDOs as dispensers. Such candidates may also proceed to NTA Level 5 (certificate in pharmacy) which is a two-year course. In this way, the one-year medical dispensing course opens up the career path for the ADDO dispensers to advance in the pharmacy profession.

In May 2014, the first lot of the newly introduced Pharmaceutical Dispensing Certificate Course sat final examinations at St. Peter's College of Health Sciences in Dar es Salaam. The college was the first in Tanzania to be accredited by the Pharmacy Council to offer the course. Fifteen candidates enrolled in the first class in April 2013, out of which twelve managed to complete the course and sat the final examinations. Other colleges accredited by June 2014 to offer the course included: Royal Pharmaceutical Training Institute, Dar es Salaam College of Health Sciences, City College of Health Sciences, Kam College of Health Sciences and Gataraye Research and Training Centre.

5.3 Strengthening the ADDO Regulatory System

The June-August 2012 situational analysis conducted by the SDSI project with technical assistance from Apotheker Consultancy Ltd, demonstrated potential of the decentralized regulatory system, but noted that the functionality of the system was generally weak. It was observed that in most councils, inspections were not taking place as regularly as stipulated in ADDO regulations; accreditation procedures were not strictly followed and the process was generally slow in most councils, leading to mushrooming of illegal ADDOs; misconduct was prevalent in some ADDOs; and inadequate communication between Council Food and Drug Committees (CFDCs) and ward inspectors was hampering regulatory oversight. At the national level, the transfer of the overall program management from TFDA to the Pharmacy Council (PC) meant an urgent need to strengthen capacity of the Council (human resource, working tools, equipment, etc.) to be able to cope with its expanded regulatory oversight role, and also address information gaps in implementation of the ADDO program.

Among the measures taken at the national level included: hiring of two staff (one technical, one support) to support ADDO program activities; development of a web-based database to enhance collection and storage of information on drug outlets and personnel; development of mobile payment system to help increase collection of regulatory fees; development of electronic data collection tools to increase efficiency in documentation, monitoring and evaluation processes; review of ADDO regulations to reflect the expanded PC functions as stipulated in the Pharmacy Act of 2011; and development of client service charter to guide PC's response to client needs.

Two regions (Pwani and Mtwara) also benefited from SDSI support through establishment of a pool of regional and district inspector trainers; training of 278 ward inspectors in 14 districts (7 per region), reaccreditation of functional ADDOs in the 14 districts; accreditation of new ADDOs in both regions; and sensitization of ADDO providers (owners and dispensers) and pharmacists in Dar es Salaam and Pwani regions on the newly established Pharmacy Council ICT system.

5.4 Strengthening and Expanding the Role of ADDO Associations

Since inception of the ADDO program, the role of ADDO provider associations has been emphasised. The associations are instrumental in providing a platform for common voices, empowering the members economically, promoting compliance with regulations, building institutional networks for collaboration and partnerships with other ADDO stakeholders, and improve relations among ADDO providers.

> *"Associations can be very helpful in enabling regulatory authorities to reach ADDO providers. They can play a very important role in improving quality of ADDO services by communicating government policies to their members and working together with regulatory authorities to control malpractices. I personally think that their establishment should be encouraged",* **Dr. Hussein Mwinyi, former Minister of Health and Social Welfare.**

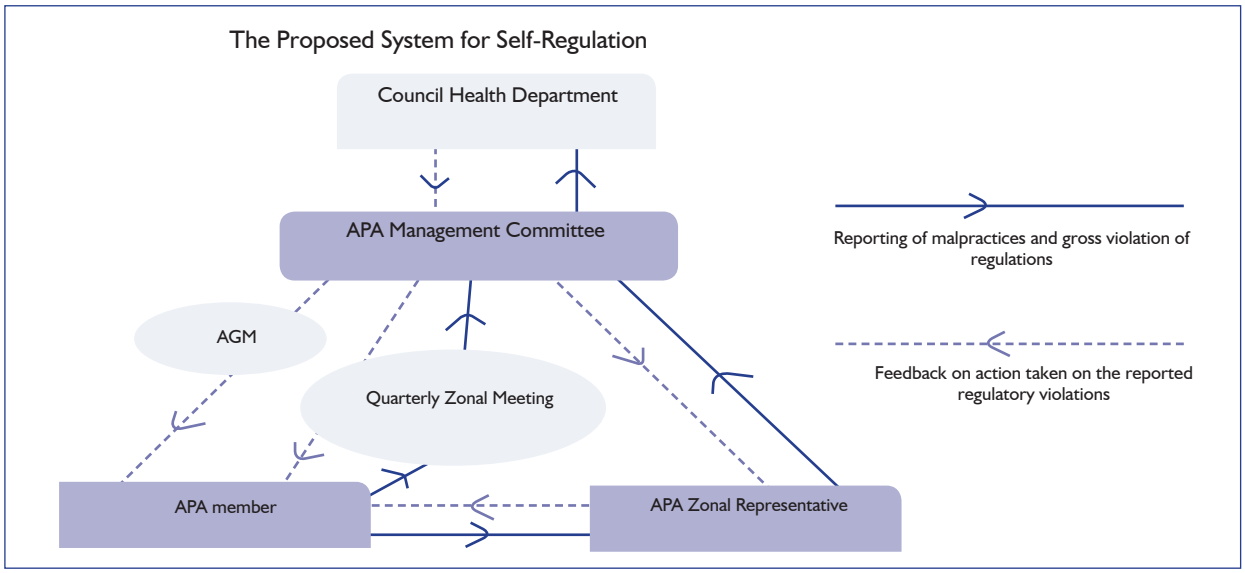
However, a situational analysis conducted in 2012 by the SDSI project with technical assistance from MediaNet Limited, revealed several gaps and challenges in the establishment and management of associations. The major ones were: weak membership and leadership, limited scope of services to members, long and delayed process of registration, lack of basic facilities for formal operation, lack of management systems, and inadequate resource mobilization.

To enable the associations to realize their potential, the SDSI support focused on three key result areas: fostering establishment, strengthening operations and enhancing sustainability of the associations. In line with these priorities, various sensitization and training activities were conducted to various associations, with concentrated efforts in four learning districts (Bagamoyo, Kilombero, Mbarali and Mbinga). Efforts were also made to map associations nationally.

As a result of the SDSI support, 88% the targeted ADDO providers in the learning districts were sensitized on the roles, benefits and responsibilities of associations, 33 officials of 18 different associations were also sensitized, 37 associations were mapped nationally and basic information on their status of establishment documented, 33 out of 40 association officials in the four learning districts were trained in planning and effective management, and each of the 4 learning associations developed a three-year activity plan.

Major outcomes of the interventions included: a 78% increase in the number of active association members in the four learning districts, a two-fold increase in contribution of funds by the active members, development of an elaborate system for self-regulation (Figure 14), successful peer supervision visits conducted by 3 associations (CHAWAMAMU in Mbarali, RUDDOA in Songea Urban and UWAMADAMUDA in Dar es Salaam), improved working relations between associations and regulatory authorities at all levels, and movement toward formation of a national association.

Figure 14



This system envisages that ADDO providers will be more proactive in reporting malpractices and violation of regulations, and that association officials and council authorities will be held to account on cases of regulatory violation reported to them.

5.5 Strengthening Linkages Between ADDO, CHWs and Health Facilities

Linking ADDOs, CHWs and health facility providers can be highly beneficial to the community. Linkage between CHWs and ADDOs can increase chances for a child with pneumonia identified by a CHW to receive timely first dose of antibiotic from ADDO before arriving at the health facility for advanced care; and a child with severe diarrhea to receive timely doses of zinc and ORS from an ADDO when the health facility is far, closed or out of medicines. Health facilities would also benefit from documented and coordinated referrals from CHWs and ADDOs, while ADDOs could profit from increased sales due to more customer traffic and periodic patient referrals by CHWs and recognition of dispensers' role in providing public health services. On the other hand, CHWs would benefit from greater recognition in the community for their role in connecting patients with prompt quality care and medicines.

Consequently in June 2014, MSH (through the SDSI project) in collaboration with the Pharmacy Council, the Reproductive and Child Health Section (RCHS) of the Ministry of Health and Social Welfare, and Kibaha District Council, explored these potentials in Kibaha District by bringing together the three groups of services providers through a joint training that focused on working together to improve maternal, newborn and child health services. After the training, supervision visits were conducted to monitor the performance of the service providers and offer technical guidance as appropriate. Lessons and best practices from the process will be replicated in other areas to help improve maternal and child health services.

6 Conlusion

The ADDO program has come of age. From the piloting in Ruvuma Region to the centralized expansion in the initial scale-up regions and the decentralized countrywide rollout, it has shown that where there is a strong collective will to bring about transformational change, nothing can stand in the path of change. It has also shown that through public-private partnership, it is possible to overcome some the system challenges which constrain the population's access to essential social services, health care included.

On the health front, the program has not only increased access to quality essential medicines but improved the quality of pharmaceutical services, made consumers more quality conscience by encouraging buying of medicines from authorized sources and created a broad platform for delivering other public health interventions to the population. It has also improved the regulation and monitoring of the private drug outlets to ensure that they provide quality medicines and services.

In terms of business development, program has streamlined the private sector pharmaceuticals supply chain, with a multiplier effect on medicines availability and quality. The pharmaceutical wholesalers which would previously confine their operations in the major urban areas, have lately found new markets in the better regulated and commercially viable ADDOs and followed them to the rural districts to tap the potential, as ADDOs gain easier access to supplies and reduce the cost of doing business. Business practices of the outlets especially recording keeping, have also improved significantly, enabling the shop owners to monitor the business performance and manage taxes better, while allowing regulatory authorities to track sources of supplies and assure product quality.

Economically and socially, thousands of employment opportunities have been created especially for the rural women mostly working in the shops as dispensers, gender relations have improved for some families, financial security of households headed by the ADDO providers has been enhanced and quality of life improved, and children also taken to school with proceeds from the ADDO enterprise.

Despite all the benefits, many of which have been extended to other countries through replication of the ADDO concept, challenges do exist. The inadequate financing of the program affects smooth implementation of key activities especially inspection and supportive supervision. The weak and varied district level enforcement of regulations, slow process of accreditation and shortage of skilled dispensers and inspectors, all compromise compliance with regulations and standards, hence delivery of quality services. The resistance to ADDO implementation by DLBD owners in major urban areas undermines the program's potential. Inadequate coordination and reporting at all levels diminishes regulatory efficiency, while weak monitoring and evaluation makes it difficult to track progress and gather evidence to inform policy, intervention planning and decision-making at implementation levels.

However, beyond the challenges there is evidence that the gains realized through implementation of the ADDO program can be sustained and even deepened by tapping the emerging opportunities to tackle the challenges and build on the strengths of the program. The use of the modern ICT, especially the mobile technology as a management tool, promises opportunities to improve coordination and reporting, increase efficiency of inspections using electronic tools, improve documentation and data processing and increase collection of regulatory fees through mobile money transfers. Regarding enforcement of regulations, evidence points to the potential of the decentralized inspection system especially at the ward level, while institutionalization of ADDO trainings promises continuous production of skilled dispensers in the market. On the other hand, establishment of linkages between ADDOs, CHWs and health facilities offers prospects for improving maternal and child health services; while establishment of ADDO provider associations is creating new opportunities to improve communication between regulatory authorities and ADDO providers, promote compliance with regulations through self-regulation and peer supervision, and address contentious issues such as the bottlenecks of urban implementation which undermine the program's potential.

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