National Tuberculosis and Leprosy Programme
Tuberculosis and Leprosy Unit
Ministry of Health and Social Welfare

Engaging Private Retail Drug Outlets in Early TB Case Finding in Tanzania: Final Report

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ACRONYMS

ADDO	accredited drug dispensing outlet
DLDB	*duka la dawa baridi*
DOT	directly observed therapy
DTLC	District TB and Leprosy Coordinator
FIP	International Pharmaceutical Federation
HCW	healthcare worker
IEC	information, education, and communication
ISTC	International Standards for Tuberculosis Care
MSH	Management Sciences for Health
MOHSW	Ministry of Health and Social Welfare
NTLP	National Tuberculosis and Leprosy Programme
OPD	outpatient department
PATH	Program for Appropriate Technology for Health
PPM	public-private mix
RTLC	regional TB and leprosy coordinator
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
SSV	supportive supervision visit
TB	tuberculosis
TFDA	Tanzania Food and Drug Authority
TOT	training of trainers
USAID	US Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

The engagement of all care providers in tuberculosis (TB) case finding is an essential element of the 2009–2016 Strategic Plan of the Tanzania National Tuberculosis and Leprosy Programme (NTLP). This is in line with the World Health Organization (WHO) and Stop TB Partnership recommendation for public-private mix (PPM) to support DOTS implementation, and supports the NTLP's goal of decreasing TB-related morbidity and mortality in the country.

With funding from the US Agency for International Development (USAID) through the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, the NTLP piloted an intervention designed to increase early TB case detection through the engagement of the retail pharmaceutical sector in identifying and referring persons with presumptive TB for assessment. The pilot was conducted between August 2011 and December 2013 in pharmacies in Dar es Salaam, an urban setting, and accredited drug dispensing outlets (ADDOs) in Morogoro, a rural setting. This report describes the key activities that were conducted, as well as the challenges and accomplishments of the pilot project. To foster local ownership and lay the foundation for scale up, engagement of stakeholders was a high priority, with significant effort made to bring together key stakeholders to champion this intervention. Under the leadership of the NTLP, a pharmacy-PPM steering committee was established, which met regularly during the implementation period. The steering committee provided technical coordination and leadership in the design and execution of activities. It was composed of key stakeholders in TB case management in Tanzania, including the NTLP, Tanzania Food and Drug Authority (TFDA), Pharmacy Council, Pharmaceutical Society of Tanzania, Program for Appropriate Technology for Health (PATH), and representatives of retail pharmacies from the participating communities.

A baseline survey was conducted in August 2011 at 122 private pharmacies in Dar es Salaam and 173 ADDOs in Morogoro to assess dispensers' knowledge and practices related to TB case management. The key findings from this assessment included: (1) retail drug outlet dispensers had limited knowledge of TB symptoms, treatment, and transmission; (2) formal referral mechanisms from drug outlets to TB diagnostic facilities were nonexistent; and (3) no TB information, education, and communication (IEC) materials were available in the retail drug outlets. These findings were used to inform the development of appropriate interventions.

Based on these assessment results, with technical support from SIAPS, the NTLP agreed to enhance pharmacy and ADDO dispensers' capacity for TB management. To this end, the following priority interventions were identified and carried out: (1) training of trainers for 32 trainers drawn from NTLP and district TB and leprosy coordinators (DTLC); (2) training for 737 pharmacy and ADDO dispensers; (3) sensitization and orientation of 462 healthcare workers (HCWs) from 98 diagnostic and treatment centers on their role in receiving and evaluating referrals from pharmacy and ADDO dispensers; (4) development of tools, including TB training materials, referral forms, cough registers, TB treatment and diagnostic centers directory, and IEC materials; and (5) conduct of three supportive supervision visits (SSVs) to the retail drug outlets and TB diagnostic centers in Morogoro, and two SSVs to participating sites in Dar es Salaam, to monitor activity progress, collect data on referred clients, and carry out continuous quality improvement.

The following results were achieved by the end of the 16-month implementation period: on average, 72% of the retail drug outlets received supervisory visits; and 587 clients with TB-like symptoms were referred to TB diagnostic and treatment centers for further evaluation, of which 38% (n= 223) were tracked and found at health facilities, and 36% (81/223) clients were confirmed as having TB.

Major challenges included the limited attendance to the trainings organized for dispensers, particularly in Dar es Salaam, where a number of the dispensers reported not having permission from their pharmacy owners to attend the training; high turnover of dispensers at both the ADDOs and pharmacies; hesitancy of some clients to accept the referral forms and the fact that only 38% (223/587) of referred clients could be tracked at the TB diagnostic and treatment centers.

Despite these obstacles, this pilot intervention clearly demonstrates that the private pharmaceutical retail sector has the potential to contribute to early TB case detection. The NTLP should work with the Pharmacy Council to plan the scale-up and capitalize on the investment already made in the ADDO program with regard to training in supportive supervision, recordkeeping, reporting systems using mobile technology, and oversight of the regulatory environment provided by the Pharmacy Council. Priority should be given to regions/districts with high TB prevalence, based on the recent prevalence survey in Tanzania.

BACKGROUND

TB Burden

The 2013 World Health Organization (WHO) Global Tuberculosis Report[1] found that Tanzania had 61,126 notified new cases of tuberculosis (TB), and a 79% case detection rate for all forms of TB. In 2013, the Government of Tanzania published the results of its first national TB prevalence survey, which documented the prevalence of bacteriologically-confirmed TB as 295 per 100,000 for adults.[2] The survey also found that TB prevalence was higher in mainland Tanzania, as compared to Zanzibar, and higher in rural areas as compared to urban areas. Higher prevalence was also associated with being a man, being older, and having lower socioeconomic status. The survey concluded that the prevalence of bacteriologically-confirmed TB in the adult population was higher than expected.[2]

Engaging Private Sector Providers in TB Control in Tanzania

In Tanzania, as in many other low-income countries, TB case finding relies heavily on passive detection, in which symptomatic patients present to health facilities for diagnosis. Passive case finding is limited by the fact that it depends on patients: (1) being aware of their symptoms and motivated to seek care; (2) having access to health facilities; and (3) being evaluated by health professionals who recognize TB symptoms and have access to reliable laboratory facilities to confirm the diagnosis. Delays at any stage in this chain of activities, whether by patients or by the healthcare system, postpone accurate diagnosis and result in poor disease prognosis. Moreover, because individuals with active TB continue to be contagious until a few weeks after starting effective treatment, delays in diagnosis increase the likelihood that TB is spread to others.

Delays in treatment among individuals with TB are not uncommon in Tanzania. Between 2004 and 2008, the Tanzania National Tuberculosis and Leprosy Programme (NTLP), in collaboration with the STOP TB Fund for Innovative DOTS Expansion through the Local Initiatives to Stop TB Project (known as FIDELIS), assessed the determinants and duration of treatment delays among new smear-positive pulmonary TB patients. The studies revealed a treatment delay of 12 or more weeks in half of the new smear-positive pulmonary patients, with similar delays reported between men and women, and between rural and urban patients.[3] An important contributor to treatment delay may be care-seeking from informal healthcare providers who have limited training. Although TB diagnosis and treatment are available for free through the Tanzania NTLP, the 2010 Tanzania Demographic Health Survey revealed that the private sector provides a substantial proportion of healthcare services (up to 34% depending on the health area), with

[1] WHO. *Global Tuberculosis Report 2013*. Geneva, Switzerland: WHO; 2013. http://www.who.int/tb/publications/global_report/en/.
[2] Ministry of Health and Social Welfare. 2013. *First National Tuberculosis Prevalence Survey in the United Republic of Tanzania - Final Report*.
[3] Hinderaker SG 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.

patients being more likely to access the private sector for problems that can be treated with medical commodities, such as fever or cough.[4]

In an effort to decrease time to diagnosis, and ultimately to reduce TB morbidity and mortality in Tanzania, the NTLP developed a plan to engage all TB care providers in both the public and private sectors by 2015.[5] This objective, described in the 2009–2016 NTLP Strategic Plan, is in line with the STOP TB strategy calling for public-public and public–private mix (PPM) approaches and promoting the use of the International Standards for Tuberculosis Care (ISTC).[6]

Role of the Private Retail Pharmaceutical Sector

The need for enhanced case finding and the NTLP's commitment to collaboration with the private sector provide motivation for exploring innovative approaches to involving all healthcare providers in improved TB case detection. Retail pharmacy shops are important stakeholders in this work. For example, a study in Uganda found that almost 40% of patients with TB cited medicine shops or pharmacies as their first point of contact with the health system, as compared to 14% who initially presented to government health units.[7] However, the role of Tanzania's retail pharmaceutical sector in TB care and treatment had not been widely explored. An intervention to engage the retail pharmaceutical sector therefore offered an opportunity to provide the NTLP with insights on the potential of pharmacy shops to identify clients with TB-like symptoms and refer them to TB diagnostic centers.

There are two types of private retail pharmaceutical sector providers in Tanzania: Part I drug shops, or pharmacies, and Part II medicine stores, also known as *duka la dawa baridi* (DLDB). DLDBs have historically been a common source of medicines in the private sector because very few registered pharmacies exist outside of major urban centers. DLDBs provide an essential service to rural and peri-urban populations who have limited access to registered pharmacies, and act as a safety net when public facilities experience medicine stock-outs.[8]

Despite the important role of the DLDBs as a point for community access to health commodities, a 2001 assessment revealed many challenges with them, including: untrained staff; inadequate storage for medicines; questionable medicine quality; and inadequate regulatory enforcement and supervision. To address these performance gaps, in 2002, the Tanzania Ministry of Health and Social Welfare (MOHSW) and the Tanzania Food and Drug Authority (TFDA) worked with the

[4] White, James, Barbara O'Hanlon, Grace Chee, Emmanuel Malangalila, Adeline Kimambo, Jorge Coarasa, Sean Callahan, Ilana Ron Levey, and Kim McKeon. January 2013. Tanzania Private Sector Assessment. Bethesda, MD: Strengthening Health Outcomes through the Private Sector Project, Abt Associates In.

[5] MOHSW. *National TB & Leprosy Program (NTLP) Strategic Plan 2009/2010–2015/2016, Final Draft*. Dar es Salaam, Tanzania: NTLP; 2010. http://ntlp.go.tz/index.php?option=com_phocadownload&view=category&id=3:plans&Itemid=139

[6] Tuberculosis Coalition for Technical Assistance. *International Standards for Tuberculosis Care* (ISTC), second edition. The Hague: Tuberculosis Coalition for Technical Assistance; 2009. http://www.istcweb.org/documents/ISTC_Report_2ndEd_Nov2009.pdf.

[7] Kiwuwa MS et al. Patient and health service delay in pulmonary tuberculosis patients attending a referral hospital: a cross-sectional study. *BMC Public Health*. 2005; 5:122. doi:10.1186/1471-2458-5-122.

[8] Management Sciences for Health, Strategies for Enhancing Access to Medicines Program: Access to Essential Medicines Tanzania 2001 Arlington, http://projects.msh.org/seam/reports/access_to_medicines_tanzania.pdf.

Strategies for Enhancing Access to Medicines Program, implemented by Management Sciences for Health (MSH), with funding from the Bill & Melinda Gates Foundation, to pilot an innovative program to accredit DLDBs. These private sector medicine sellers were transformed into government-accredited drug dispensing outlets (ADDOs), known as *Duka la Dawa Muhimu*, in Kiswahili.

The goal of the ADDO program was to improve access to affordable, quality medicines and pharmaceutical services in rural and peri-urban areas that had limited access to registered pharmacies. The accreditation process for ADDOs focused on training and behavior change for individuals who use, own, regulate, and work in the medicine shops. Following the end of the pilot project in 2003, the Government of Tanzania and multiple development partners[9] continued to fund Tanzania's ADDO program for over 10 years, achieving nationwide scale up by June 2013. To date, 60% of all existing retail drug outlets (5,467 of 9,226) in all 21 regions of Tanzania have been accredited and 13,625 dispensers and 3,262 local inspectors have been trained. The ADDO program has improved the availability of essential medicines and the quality of pharmaceutical services provided by drug outlets while creating a platform for expanding community-based health service delivery.[10]

[9] Bill & Melinda Gates Foundation, USAID, Danish International Development Agency, Rockefeller Foundation, Clinton Health Access Initiative, the Global Fund to Fight AIDS, Tuberculosis and Malaria.

[10] Management Sciences for Health. *East Africa Drug Seller Initiative (EADSI) Evaluation Report*. Arlington, VA: Management Sciences for Health; 2011. http://www.drugsellerinitiatives.org/publication/altview/east-africa-drug-seller-initiative-eadsi-evaluation-report/PDF.

INTERVENTION DESIGN AND IMPLEMENTATION APPROACH

Engaging all care providers in enhanced TB case finding aligns well with the United States Government strategy of actively engaging the private sector to improve TB care and treatment.[11] The approach also supports the 2011 joint statement by the WHO Stop TB Department and International Pharmaceutical Federation[12] supporting the role of pharmacists in TB care and control.

The US Agency for International Development (USAID) funded the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) project to support active engagement of private sector providers in delivering quality services for the diagnosis and treatment of TB. SIAPS worked with the NTLP to design an intervention focused on the early identification of clients with TB-like symptoms through the retail pharmaceutical sector, and referral of these clients to TB diagnostic centers for appropriate treatment.

The intervention engaged 737 dispensers from 793 retail drug outlets and 462 HCWs from 98 TB diagnostic and treatment centers. Implementation of the intervention relied on collaboration with key stakeholders to establish a steering committee under the auspices of the NTLP to coordinate and provide technical oversight of planned activities. The steering committee included representatives from the NTLP headquarters, SIAPS, PATH, the TFDA, the Pharmacy Council, the Pharmaceutical Society of Tanzania, and staff from pharmacies in the participating communities. The steering committee defined the intervention package and agreed on the implementation approach (box 1).

[11] Lantos-Hyde United States Government Tuberculosis Strategy. March 24, 2010. Key Interventions 1(c) and 2(e). http://pdf.usaid.gov/pdf_docs/PDACP707.pdf.
[12] https://www.fip.org/.

Box 1. Implementation Approach

- Conduct baseline survey of retail drug outlets/pharmacies and ADDOs in the selected districts of Morogoro and Dar es Salaam.

- Implement the following activities:

  - Work within the existing NTLP PPM coordinating mechanism by involving DTLCs
  - Enhance retail drug outlet providers' capacity for TB symptom recognition through training and repeated supervision visits
  - Fully engage healthcare workers from TB diagnostic and treatment centers through sensitization workshops
  - Develop a formal referral linkage between private retail drug outlets and TB diagnostic and treatment centers
  - Develop reporting tools, standard operating procedures (SOPs), and information, education, and communication (IEC) materials for retail drug outlets
  - Conduct monitoring and evaluation activities to assess implementation and determine the contribution of private drug outlets to TB case detection
  - Disseminate results, recommendations, and options for scale up

Selection of the Intervention Locations

Dar es Salaam and Morogoro were selected as the locations for the pilot intervention. Dar es Salaam has nearly 60% of all registered retail pharmacies in the country,[13] contributes 22% of all notified TB cases nationwide, and represents an urban population. The Morogoro region ranks seventh in national TB case notification, has had ADDOs operating for several years, and represents peri-urban and rural populations. All 243 registered retail pharmacies in Dar-es-salaam and 550 ADDOs in Morogoro were selected for the intervention.

Figure 1 below presents the timeline for implementation of activities in the ADDOs in Morogoro and pharmacies in Dar es Salaam.

[13] MOHSW, Tanzania. *Assessment of the pharmaceutical human resources in Tanzania and the Strategic Framework*. Dar es Salaam, Tanzania: MOHSW; 2010. http://apps.who.int/medicinedocs/documents/s17397e/s17397e.pdf.

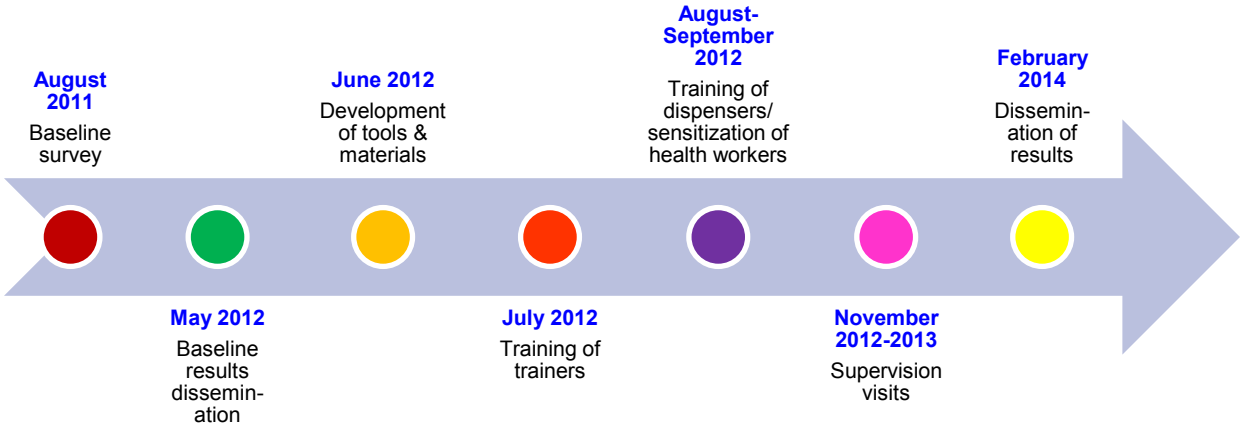

Figure 1. Activity implementation timeline

Baseline Survey and Consensus on Next Steps

A baseline survey was conducted in August 2011 in Morogoro and Dar es Salaam to assess the readiness and willingness of retail pharmaceutical sector providers to participate in the proposed TB case finding intervention. The findings from the survey enabled the MOHSW/NTLP and partners to appropriately tailor the proposed interventions to address identified gaps.

On May 23, 2012, a workshop to disseminate survey results was held with 46 participants, including representatives from the MOHSW/NTLP, PATH, TFDA, WHO, the Pharmacy Council, ADDOs, regional and district TB coordinators, and district and regional pharmacists from Morogoro and Dar es Salaam. A summary of the survey findings is presented in box 2. Complete findings of the survey have been described elsewhere.[14]

[14] Rutta E et al. Understanding Private Retail Drug Outlet Dispenser Knowledge and Practices in TB Care in Tanzania. *Int J Tuberc Lung Dis* 2014 Sep;18(9):1108-13.

Box 2: Understanding Private Retail Pharmaceutical Sector Knowledge and Practices in TB Case Management in Tanzania: A Baseline Survey

Background: A baseline survey of TB knowledge and practices of dispensers in private retail drug outlets was undertaken as a first step in an intervention to engage the dispensers in enhanced TB case finding.

Objectives: The objectives of the survey were to assess: (1) the level of TB knowledge among dispensers in Tanzania's retail pharmaceutical sector; (2) practices related to the identification of patients with symptoms suggestive of TB; (3) the availability of TB educational materials and training; and (4) the availability of first- and second-line TB medicines in retail drug outlets.

Methods: A cross-sectional descriptive study involving the administration of a structured questionnaire to medicine dispensers in 122 pharmacies and 173 ADDOs was conducted in August 2011 in Morogoro and Dar es Salaam. The two regions were selected because Dar es Salaam has the largest number of retail pharmacies in the country, contributes 22 percent of all notified TB cases nationwide, and represents an urban population. The Morogoro region ranks seventh in national TB case notification, has had ADDOs in operation for years, and represents peri-urban and rural populations.

Findings: The assessment revealed that private retail drug outlets are convenient, with most open at least 12 hours a day, seven days a week. Although 95% of dispensers identified persistent cough as a TB symptom, only 1% had received TB-related training in the previous three years. 14.8% of pharmacies and 1.3% of ADDOs stocked first-line anti-TB medicines, which are prohibited from being sold at retail outlets. The majority of respondents reported seeing clients with TB-like symptoms and, of those, 95% reported frequently referring clients to nearby health facilities.

Conclusion: Private retail drug outlets can potentially contribute to TB case detection and treatment, but a coordinated effort is needed to train dispensers and implement appropriate referral procedures.

At the dissemination workshop, participants reached consensus on the role of retail drug outlet dispensers in TB diagnosis and treatment. Their responsibilities include:

- Identifying clients with TB-like symptoms by taking a thorough history of every client requesting a cough mixture or presenting with cough symptoms
- Educating clients with TB-like symptoms on recognizing TB, the importance of the referral to TB diagnostic centers, and risks associated with referral noncompliance
- Providing written referrals using formal referral forms developed
- Keeping records of all clients in the cough registers, retaining copies of referral forms, and filing counter-referral forms.

Training of Trainers

Adaptation of Training Materials

Training materials to improve TB knowledge and skills of pharmacy and ADDO dispensers were adapted from an MOHSW package for training community-based health workers and former TB patients in DOTS and other TB control services. A two-day workshop to develop the training materials was held on May 24 and 25, 2012. A broad range of stakeholders from the national and district levels of the NTLP, the Pharmacy Council, the Pharmaceutical Society of Tanzania, SIAPS, ADDO trainers, PATH, pharmacy representatives, the Morogoro regional TB and leprosy coordinator (RTLC), select DTLCs, and district and regional pharmacists participated in the workshop, providing valuable input for the finalization of the training materials. The adapted training materials included a trainer's guide, participant's manual, and a PowerPoint presentation (figure 2).

Figure 2. TB training materials

Training of Trainers Workshop

A training of trainers (TOT) workshop was conducted June 20–22, 2012, in the Kibaha Coast region. A total of 32 participants attended from 6 districts of Morogoro and 3 districts of Dar es Salaam. Participants included DTLCs, district pharmacists, community pharmacists, and clinicians. The objectives of the TOT workshop were to:

- Equip participants with basic knowledge of TB and provide an overview of the proposed referral system for linking private drug outlets with TB diagnostic and treatment centers

- Strengthen participants' capacity to train dispensers from private drug outlets in TB case identification

The facilitation team included the following: three staff from the NTLP (the PPM coordinator, NTLP training coordinator, and NTLP pharmacist), three SIAPS staff, and one RTLC. The workshop provided an opportunity for participants to make suggestions for the proposed referral process to help ensure successful implementation. For the workshop organizers, it allowed for

the pre-testing of the training materials before training the dispensers. At the end of the workshop, all observations and comments were compiled for further discussion with the project's steering committee. The TOT training agenda is attached in annex A. Recommendations from the workshop are presented in box 3.

Box 3: TOT Workshop Recommendations

Integrating TB into other health services is a top priority for the MOHSW. Participants provided a number of recommendations on how referral linkages between retail drug outlets and health facilities should work:

- For referral systems to be successful, participants recommended that an adequate number of staff from each TB diagnostic and treatment facility should be sensitized. The list of proposed health workers to be sensitized included the receptionist, health facility in charge, one outpatient department (OPD) clinician, one laboratory staffer, and a TB focal person or a directly observed therapy (DOT) nurse.
- To oversee implementation of this intervention at the facility level, there was general consensus that each DTLC should facilitate the appointment of a facility focal person in each TB diagnostic and treatment center.
- Clients referred to health facilities should be asked to return the lower portion of the referral form to the retail drug outlets. The referral form consisted of two parts: (1) the upper section captured client details, reasons for referral, information about the referring dispenser and retail drug outlet, and details about the facility to which the client is being referred; (2) the lower part of the referral form consisted of a detachable slip known as a counter-referral form. This part of the form captured details on the facility from which the referred client received services, including the facility name, date client is received, and name and signature of the healthcare provider who evaluated the client.
- The potential use of mobile technology, such as texting the dispenser once the client is received, should be explored. However, participants noted that this activity has cost implications for healthcare providers.
- In order to motivate dispensers, there should be a mechanism to ensure that dispensers who refer a certain number of clients are rewarded. For example, "Appreciation Certificates" could be given to dispensers who meet certain criteria. An additional area for consideration is continuing education through workshops, distance newsletters, or other materials from the NTLP.

Development of Formal Referral Linkages between Retail Drug Outlets and Health Facilities

Adaptation and Printing of Tools

Following the TOT, the steering committee finalized the tools for the intervention, including an adapted cough register designed for use by health facilities in intensified TB case finding. All referred clients would pass through the triage nurse and have their information recorded in the

cough register before being directed to the OPD clinician. In facilities where there is no OPD clinician, receptionists would be trained on how to complete the cough register. The information collected in the cough register included:

- Date
- Client name
- Sex
- Age
- Place of residence (village/street and phone number)
- Reasons for referral
- Name of the referring retail drug outlet
- Outcome of referral
    - No TB
    - Pulmonary TB positive
    - Extrapulmonary TB
    - Tested for HIV

An additional tool developed for the intervention was the referral form, designed to facilitate the linkage between the retail drug outlets and the TB diagnostic and treatment centers; 1,100 copies of referral books were printed and distributed to the participating retail outlets. The referral form consisted of two parts: (1) the upper section captured client details, reasons for referral, information about the referring dispenser and retail drug outlet, and details about the facility to which the client is being referred; (2) the lower part of the referral form consisted of a detachable slip known as a counter-referral form. This part of the form captured details on the facility from which the referred client received services, including the facility name, date client is received, and name and signature of the healthcare provider who evaluated the client (figure 3).

As part of the referral process, dispensers were trained to complete two carbon copies of the referral form for each client identified with TB-like symptoms. A copy of the referral form remained at the referring retail drug outlet, and the original form was given to the client to submit to the clinician at the health facility to which s/he was referred. The clinician was then required to sign the counter-referral form and return it to the client to give back to the drug outlet, thus serving as a feedback mechanism.

To facilitate referral to TB diagnostic and treatment centers, all pharmacies and ADDOs were given a referral directory that provided the name of the nearest center to refer their clients (figure 4). In addition, the steering committee developed, printed, and distributed 1,100 posters displaying an inventory of TB diagnostic and treatment centers operating in Dar es Salaam and Morogoro.

Figure 3. Sample referral form for medicine dispensers

Figure 4. Sample referral directory for retail drug outlets

Dispensers Training Workshop

Following the TOT and development of the referral materials, a three-day training was conducted in the Morogoro region, August 13–18, 2012, and in Dar es Salaam, September 12–19, 2012. A total of 737 dispensers participated in the training, including 595 dispensers from 6 districts of Morogoro (table 1) and 142 dispensers from 3 districts of Dar es Salaam. The official invitation to the training was sent through district pharmacists, DTLCs, and leaders of ADDO associations in Morogoro. At the district level, further dissemination of information about the training was done through local radio stations operating in the respective districts, with support from district teams. Topics covered during training included basic facts about TB, the proposed referral process, and communication skills.

Table 1. Morogoro: Number of Dispensers Trained and Tools Distributed

No.	District	Number of dispensers trained per district	Number of retail drug outlets	Total number of referral books distributed	Total number of posters of TB diagnostic centers distributed
1	Morogoro Urban	45	43	43	43
2	Morogoro Rural	55	50	50	50
3	Kilombero	190	73	73	73
4	Mvomero	92	87	87	87
5	Kilosa	137	125	125	125
6	Ulanga	76	68	68	68
	Total	595	446	446	446

Sensitization of Health Workers from TB Diagnostic and Treatment Centers

To inform health workers at the TB diagnostic and treatment centers about the pilot intervention, half-day sensitization meetings were held in all six districts of the Morogoro region from August 13 to 18, and in Dar es Salaam from August 29 to 31, 2012. A total of 462 providers from 98 diagnostic and treatment centers were sensitized on the formalized referral system in Morogoro and Dar es Salaam (table 2). Each TB diagnostic center was represented by a receptionist, OPD clinician, laboratory staff, and DOT nurse. The sensitization meeting was facilitated by representatives from the NTLP, TFDA, SIAPS, RTLC, and the Pharmacy Council.

The objectives of the sensitization meetings included the following:

- Share the new initiative on engaging private retail drug outlets in TB case finding
- Describe the referral process and roles of each stakeholder in the implementation process
- Share the tools developed to support the proposed referral process
- Describe the information captured on the referral and counter-referral forms
- Discuss the process for how referrals slips should be handled at the health facility level, including where they should be received and stored
- Present the methods for tracking referrals from private outlets using existing tools
- Introduce the cough register
- Describe the mechanism by which feedback will be given to the referring facility
- Discuss and agree on how to improve the proposed referral process, where necessary

Table 2. HCWs Sensitized in Morogoro and Dar es Salaam

No.	District	Region	Number of facilities involved	Number of HCWs sensitized
1	Morogoro Rural	Morogoro	10	49
2	Morogoro Urban			
3	Kilombero		5	26
4	Mvomero		12	56
5	Kilosa		7	37
6	Ulanga		4	18
	Subtotal		*38*	*186*
7	Kinondoni	Dar es Salaam	22	94
8	Temeke		19	94
9	Ilala		19	88
	Subtotal		*60*	*276*
	Total		98	462

Figure 5. Health workers from TB diagnostic centers, Ilala district, Dar es Salaam

Development of IEC Materials

To develop supportive IEC materials for the pilot intervention, a three-day workshop was organized, in collaboration with the NTLP. Conducted from October 23 to 25, 2012, and held in Mkuranga district, workshop participants included representatives from the MOHSW/NTLP, MOHSW/Health Education Unit, PATH, SIAPS, the host district of Mkuranga, and the districts implementing the intervention. District-level staff included pharmacists, DTLCs, and community-level pharmacists/trainers. Regional-level pharmacists also participated.

The purpose of the IEC materials was to:

- Increase knowledge among dispensers and patients on basic TB facts.
- Increase client demand for TB information and services.
- Promote changes in client attitudes, such as the perceived relationship between HIV and TB, and TB and witchcraft.
- Create community awareness about the dispensers' new role in TB control.
- Facilitate communication between dispensers and clients with TB-like symptoms.

The following IEC materials were developed:

- Posters on TB symptoms, transmission, and prevention, which were adapted from existing MOHSW advocacy, communication, and social mobilization materials

- Posters on the dispensers' new role in TB case finding
- Job aids for facilitating communication between dispensers and clients with TB-like symptoms

Supportive Supervision

Following the training of dispensers and the sensitization of staff at TB diagnostic and treatment centers, the team planned to conduct three SSVs on a quarterly basis in Morogoro and in Dar es Salaam. In the end, three SSVs were conducted in all six districts of Morogoro and two supervisory visits were conducted in Dar es Salaam. There was a delay in starting SSVs in Dar es Salaam because we needed to conduct a second dispenser's training due to low turnout at the first training; therefore, we could not achieve the three SSVs for Dar es Salaam. All participating outlets were not visited during SSVs because of geographic inaccessibility, closing on the day of the visit, and in some instances, change of the outlet's physical address.

The objectives of the SSVs were to:

- Reinforce dispensers' knowledge gained during training
- Help resolve any issues that may have affected implementation of client identification, referral, and follow up
- Collect information on the number of clients referred to TB diagnostic and treatment centers
- Track the number of TB cases, notified by private retail drug outlets, at TB diagnostic and treatment centers.

To ensure that all referrals were captured, each TB diagnostic and treatment facility created a tailored plan for data collection. Because the majority of health facilities did not have triage nurses, the cough register was frequently placed at reception, which is the entry point for all patients visiting the facility. Commonly, two people were given responsibility for completing the cough register: the receptionist, who was tasked with recording client details, reasons for referral, and the name of the retail drug outlet referring the client. The TB focal person or DOT nurse was tasked with updating the column in the cough register for laboratory outcome and action taken.

Due to the lack of a system for keeping patient files, the TB focal person was responsible for collecting referral forms from consultation rooms on a weekly basis. For clients requiring TB laboratory investigations, referral forms were stapled to the sputum request form so that laboratory and TB clinic staff could identify them. For referred clients who received treatment or investigations other than those related to TB, their referral forms were filed in the consultation room. All referral forms from pharmacies and ADDOs were clearly marked and coded to help laboratory and TB clinic staff easily identify them. Laboratory staffs indicated in the remarks

column of the laboratory register if the client came from a retail drug outlet; this helped track the client laboratory results during the SSVs.

During SSVs, the supervision team systematically reviewed records at the retail drug outlets, collected data, and tracked referred clients at the TB diagnostic and treatment centers. Here, the supervision team crosschecked records available at the reception area, in the consultation room, at the laboratory, and at the TB clinic with referrals information from the drug outlets. The team, then, collected information on the number of patients received and their outcome at the TB diagnostic and treatment center. The referral linkage and information flow are summarized in figure 6.

Private Retail Drug Outlets					
Pharmacies and ADDOs		**Health Facility/TB Diagnostic and Treatment Center**			
		Reception Area	Consultation Room	Laboratory	TB Clinic
Actions & Tools	• Screen clients presenting with cough • Structured interview (Questionnaire) • IEC materials • TB diagnostic and treatment centers referral directory • Drug outlets referral book	• Interview and register clients referred from retail drug outlets with TB symptoms • Cough register	• Review all referred cases by taking clinical history • Refer cases with TB symptoms to lab for sputum investigation	• Sputum investigation of all cases referred • TB laboratory register	• Record all confirmed cases into the TB unit register • TB unit register
Data to be Collected	• Number of clients with TB symptoms referred • Number of counter-referral forms returned to the outlet	• Number of cases referred from drug outlets	• Number of cases referred • Number of cases sent for sputum investigation	• Number of sputum tested • Number of confirmed TB cases (smear-positive)	• Number of confirmed TB cases • Number of referral forms

Figure 6. Referral linkage and information flow and action for clients with TB symptoms

RESULTS

SIAPS collaborated with the NTLP to develop data collection forms so that the knowledge, attitudes, and practices of dispensers and TB diagnostic and treatment center staff could be assessed during the SSVs. The data collection forms featured questions on the availability of referral tools, recordkeeping, dispenser knowledge of TB symptoms, and referral tracking. They also included qualitative and quantitative questions assessing dispenser experience with the referral process. Seven supervisors (all of whom were pharmacists from the NTLP, DTLC, and Pharmacy Council) were trained on the administration of the data collection forms and the methods for conducting SSVs. Data entry and analysis were performed in Excel by contracted data clerks under the supervision of SIAPS and the NTLP.

Change in Knowledge

To monitor the dispensers' knowledge, during each SSV, dispensers were asked about the primary symptoms of TB. Data from the SSVs were compared over time as well as to the baseline data collected in August 2011 from the 122 private pharmacies in Dar es Salaam and 173 ADDOs in Morogoro. A comparison of the data reveals that, overall; dispenser's knowledge on the five TB symptoms used for screening clients in need of referral for further diagnosis improved and was maintained well above the baseline levels. Figures 7 and 8 present the results from the knowledge assessments, by region and by visit.

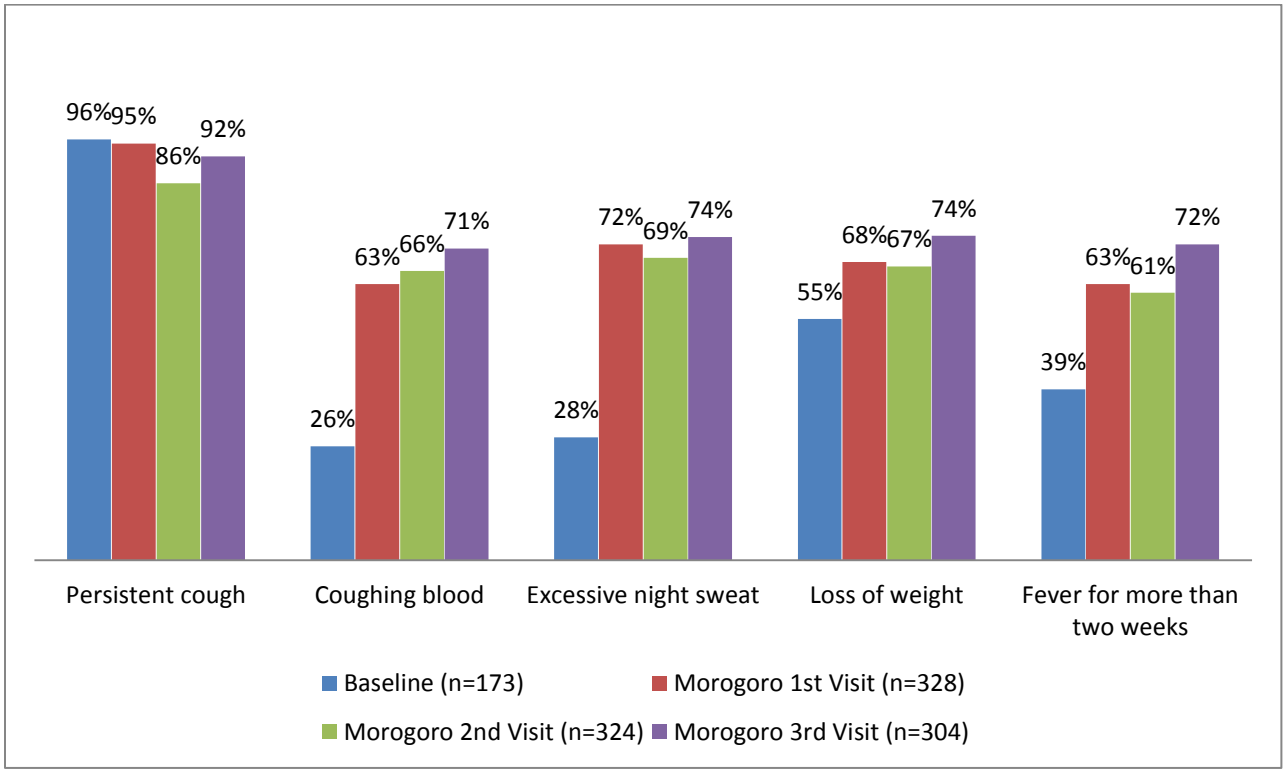

Figure 7. ADDO dispensers' TB knowledge at baseline and during SSVs, Morogoro

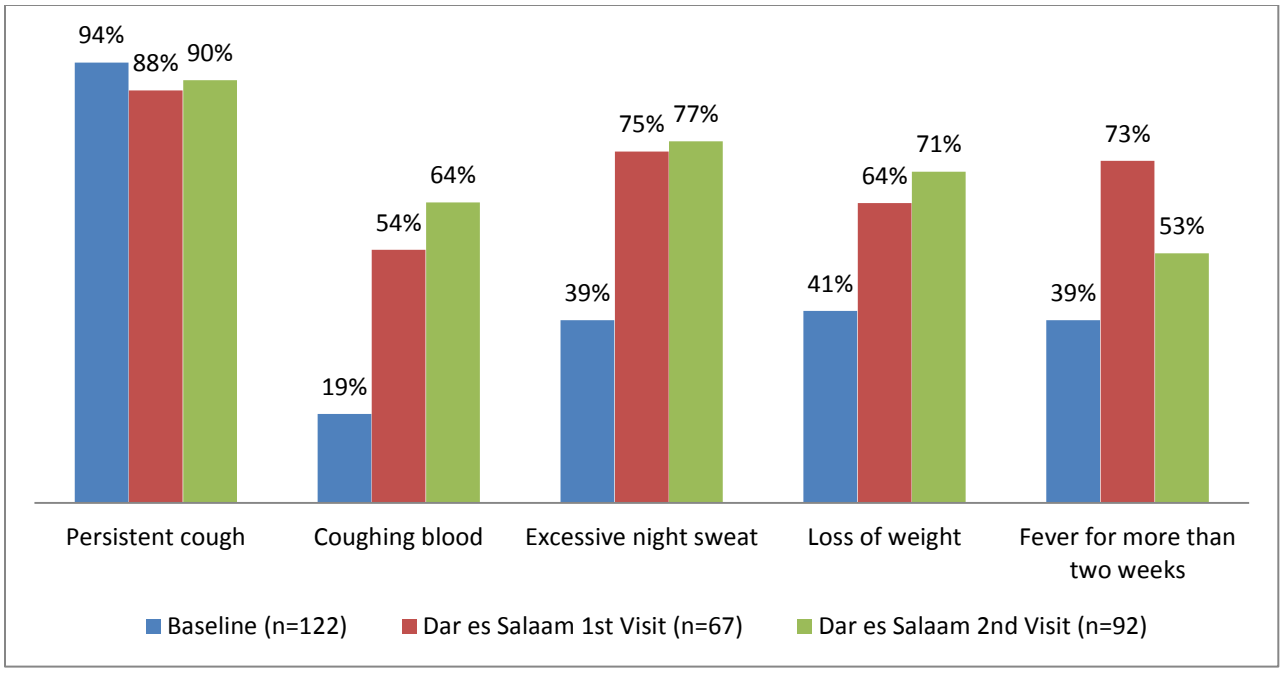

Figure 8. Pharmacy dispensers' TB knowledge at baseline and during SSVs, Dar es Salaam

Referrals and Diagnoses

As noted above, three SSVs were conducted in the six districts of Morogoro and two SSVs were conducted in Dar es Salaam. Table 3 presents the number of outlets visited during each SSV, and the corresponding percentage covered by the pilot intervention as compared to the total number of outlets whose dispensers were trained.

Table 3. Outlets Visited During Supervision

SSVs made between September 2012 and October 2013	Number of outlets visited	Percentage of outlets visited out of total outlets participating
Morogoro SSV 1	328/446	74%
Morogoro SSV 2	324/446	73%
Morogoro SSV 3	304/446	68%
Dar es Salaam SSV 1	114/142	80%
Dar es Salaam SSV 2	92/142	65%

After 16 months of activity implementation (August 2012–December 2013), the following key results were achieved:

- A total of 587 clients (482 in Morogoro and 105 in Dar es Salaam) with TB-like symptoms were referred to TB diagnostic and treatment centers by the participating

outlets. On average, three and two clients with TB-like symptoms were referred per ADDO and per pharmacies, respectively, per supervision.

- 38% (n = 223 out of 587) of the referral forms for all clients referred with TB-like symptoms were tracked and found at the health facilities. Of those, 83% (n = 186 out of 223) were sent for sputum investigation.

- Of the 186 cases sent for sputum investigation, 43% (n = 81 out of 186) were confirmed as having TB. There was variation among the districts, with Kilosa and Morogoro Urban having higher case notification rates than the other districts. Tables 4 and 5 provide a detailed summary of the results.

- A total of 81 clients referred from ADDOs and pharmacies were confirmed as having TB.

Table 4. Summary Results, Morogoro

Districts: Morogoro Urban & Rural, Mvomero, Kilombero, Kilosa and Ulanga	SV1 May 2013	SV2 Sept 2013	SV3 Nov 2013	Total
Total number of ADDOs in the districts				550
Number of ADDOs engaged in the pilot intervention				446
Number of ADDO dispensers trained by the pilot intervention				595
Number of ADDOs visited	328	324	304	956
Number of TB diagnostic and treatment centers visited	36	36	40	112
Number of ADDOs that referred at least one client with TB-like symptoms during the implementation period (A)	71	66	62	199
Number of clients with TB-like symptoms referred from the ADDOs (B)	167	226	89	482
Number of clients referred with TB-like symptoms found in health facility records (C)	82	61	27	170
Number of clients referred with TB-like symptoms sent for sputum investigation (D)	62	61	30	153
Number of clients referred with TB-like symptoms that were confirmed TB cases (E)	11	35	16	62
Number of counter-referral forms returned to ADDOs (F)	20	58	21	99
Of the ADDOs visited, the proportion that referred at least one client with TB-like symptoms, per SSV	22% (71/328)	20% (66/324)	20% (62/304)	21% (199/956)
Among the ADDOs that referred at least one client to a TB diagnostic center, the average number of cases referred per ADDO, per SSV (B/A)	2.35 (167/71)	3.42 (226/66)	1.44 (89/62)	2.42 (482/199)
Proportion of referred clients whose referral forms were found at health facilities (C/B)	49% (82/167)	27% (61/226)	30% (27/89)	35% (170/482)
Of the ADDO clients who could be tracked at the health facilities, proportion sent for sputum investigation (D/C)	76% (62/82)	100% (61/61)	111% (30/27)	90% (153/170)
Of those clients investigated with a sputum test, proportion smear-positive for TB (E/D)	18% (11/62)	57% (35/61)	53% (16/30)	41% (62/153)
Proportion of referral forms returned to ADDOs (F/B)	12% (20/167)	26% (58/226)	24% (21/89)	21% (99/482)
Of clients referred who could be tracked at the ADDOs, percentage confirmed as having TB (E/C)	13% (11/82)	57% (35/61)	59% (16/27)	36% (62/170)

Table 5. Summary Results, Dar es Salaam

Districts: Ilala, Temeke, and Kinondoni	SV1 May 2013	SV2 Nov 2013	Total
Total number of pharmacies in the districts			243
Number of pharmacies engaged in the pilot intervention			142
Number of pharmacy dispensers trained by the pilot intervention			142
Number of pharmacies visited	114	92	206
Number of TB diagnostic centers visited	35	55	90
Number of pharmacies that referred at least one client with TB-like symptoms to a TB diagnostic center during the implementation period (A)	22	36	58
Number of clients with TB-like symptoms referred from pharmacies to a TB diagnostic center (B)	39	66	105
Number of clients referred with TB-like symptoms found in health facility records (C)	18	37	55
Number of clients referred with TB-like symptoms sent for sputum investigation (D)	13	20	33
Number of clients referred that were confirmed TB cases (E)	11	8	19
Number of counter-referral forms returned to pharmacies (F)	4	3	7
Of the pharmacies visited, the proportion that referred at least one client with TB-like symptoms, per SSV	19% (22/114)	39% (36/92)	28% (58/206)
Among the pharmacies that referred at least one client to a TB diagnostic center, the average number of cases referred per pharmacy (B/A), per SSV	1.77 (39/22)	1.83 (66/36)	1.81 (105/58)
Proportion of clients referred whose referral forms were found at health facilities (C/B)	46% (18/39)	56% (37/66)	52% (55/105)
Of the pharmacy clients who could be tracked at health facilities, proportion sent for sputum investigation (D/C)	72% (13/18)	54% (20/37)	60% (33/55)
Of the clients investigated with a sputum test, proportion smear-positive for TB (E/D)	85% (11/13)	40% (8/20)	58% (19/33)
Proportion of referral forms returned to the pharmacies (F/B)	10% (4/39)	5% (3/66)	7% (7/105)
Of clients referred who could be tracked at the pharmacies, percentage confirmed as having TB (E/C)	61% (11/18)	22% (8/37)	35% (19/55)

We observed a discrepancy between the number of people who were referred to health facilities (collected from retail drug outlets records) and the number of referred individuals that could be tracked at TB diagnostic and treatment centers. Typically, there is a cough register kept at the reception area, which is the entry point of the health facility. On arrival at the health facility, referred patients are recorded in the cough register by the triage nurse before being directed to the appropriate department.

Only 38% of referred patients could be tracked in the cough register at the TB diagnostic and treatment center. On the other hand, a few patients were found in the laboratory registry and were recorded as having been sent for sputum examination; however, the record for these patients could not be found in the cough register of the health facility.

These discrepancies could be attributable to a variety of causes, including lack of patient follow-up, loss of referral slip, patient seeking services at another TB facility or pharmacy, or the patient purposely not presenting the referral form when they visited the TB center. However, the discrepancy could also stem from inadequate recording at the TB centers.

Cost of Implementation

The project tracked the cost of implementing activities to inform future scale-up plans. It should be noted that these costs do not include expenses associated with SIAPS provision of technical assistance to NTLP. The pilot model incorporated NTLP capacity building for future program expansion; therefore we consider that the scale-up will not incur those technical support costs. Table 6 provides a summary of the costs incurred during implementation of this activity

Table 6. Cost of Activity Implementation

Activity	Actual costs ($)	Remarks
Training (TOT and dispensers) in Dar es Salaam and Morogoro (venue rental, per diem for participants, lunch and coffee,)	87,571	
Sensitization of HCWs from TB diagnostic and treatment centers (venue rental, per diem for participants, lunch, and coffee)	26,845	
Printing of training materials, SOPs, referral books, IEC materials, health facility directories	7,376	
Supportive SSVs (Morogoro)	47, 639	Includes costs of supervision team travel from headquarters in Dar
SSVs (Dar es Salaam)	7,204	
Total	176,635	

- The average costs are $115 for three-day training for dispensers and trainers (all training costs included), $60 per HCW sensitized, $50 per SSV per ADDO, $35 per SSV per pharmacy, and $15 per shop (ADDO or pharmacy) for printing all IEC/SOP materials.
- It cost $300 per case referred to health facilities for proper diagnosis and $ 2,180 per smear-positive TB case identified.

KEY CHALLENGES

- A number of the ADDO and pharmacy dispensers noted hesitancy on the part of some clients to accept the referral to a TB diagnostic center and to take the referral form. It is possible that some of these clients went on their own, without any referral note, and therefore could not be tracked during the SSVs. There were also some instances when staff at the TB diagnostic and treatment centers reported that the counter-referral form had been returned to the client, however, the form could not be found at the referring ADDO or pharmacy.

- The supervisors observed high turnover of dispensers at both the ADDOs and pharmacies. Some dispensers who were trained took referral tools with them when leaving their retail outlets. Consequently, the incoming dispenser was left without any tools. This challenge was particularly problematic if the new dispenser had not attended the training.

- There was limited attendance at a number of the trainings organized for dispensers, particularly in Dar es Salaam, where a number of the dispensers reported not having permission from their pharmacy owners to attend the training.

- Supervisors observed a lack of information sharing between participants who attended the pilot intervention training and those who did not. This occurred at both the retail drug outlets and health facilities and may have contributed to the difficulty in locating paperwork on clients referred to the health facilities.

- While the referral linkage appeared to work well, not all referral forms from the outlets were found at the health facilities, and not all referrals were recorded in the cough registers. Thus, it was quite difficult to trace client diagnostic results. Supervisors also noted a significant challenge with returning counter-referral forms to the outlets, which resulted in a lack of feedback to dispensers.

Lessons Learned

- Overall, ADDOs referred more clients with TB-like symptoms than pharmacies, leading to higher case notification rates in Morogoro than in Dar es Salaam.

- Well over 50% of dispensers had good knowledge of TB and were able to identify clients presenting with TB-like symptoms and refer them to the TB diagnostic and treatment centers. Dispensers noted that a key motivator for referring clients was the opportunity to participate in the training and enhance their capacity to identify clients presenting with TB-like symptoms.

- Many dispensers noted that additional sensitization of the community through the use of posters, radio spots, and other IEC mechanisms were needed. In future work, additional forms of media, such as radio spots, village gatherings/meetings, and TV transmissions, could be used to increase public awareness of the retail outlets' engagement in early TB case detection.

CONCLUSIONS AND RECOMMENDED NEXT STEPS

This intervention demonstrates the enormous potential of Tanzania private retail drug outlets to contribute to TB detection and control efforts. The pharmacy-centric model recommended by the WHO and the International Pharmaceutical Federation (FIP)[15] is a feasible option to engage ADDO and pharmacy dispensers in TB control. Approximately 3 million people who developed TB in 2012 were missed by national TB notification systems. The 2013 WHO global TB report[16] identified reaching these missed cases as a key priority in worldwide TB control efforts. Collaboration with private sector providers offers an important opportunity to detect some of the missing cases. Furthermore, the recent Tanzania prevalence survey found a higher TB prevalence than previously thought; specifically, the case detection rate of new smear-positive adults is markedly lower than previously reported.

The following are SIAPS's recommendations to the Tanzania NTLP:

1) Scale up the intervention in rural regions to take advantage of the ADDO platform, which is now nationwide. Priority should be given to regions/districts with high TB prevalence, based on the recent prevalence survey. The NTLP should work with the Pharmacy Council to plan this scale up and capitalize on the investment already made in the ADDO program with regard to training in supportive supervision, recordkeeping, reporting systems using mobile technology, and oversight of the regulatory environment provided by the Pharmacy Council.

2) For engaging pharmacies in urban settings, particularly in Dar es Salaam, adequate resources should be devoted to fully advocate, sensitize, and follow up with the owners and dispensers and ensure comprehensive data collection.

3) Facilitate the progressive integration of the pharmacy-centric model for early identification of TB cases and increased TB case finding into the existing NTLP operational structure, especially monitoring and SSVs.

4) Organize regular training to respond to the identified challenges, such as high turnover of trained dispensers.

5) Develop a concept proposal that describes in detail the scale-up scenarios, targets with expected number of new cases to be notified, and a budget. SIAPS will collaborate with the NTLP in the development of the scale-up proposal. The MOHSW/NTLP should use this information to mobilize resources from donors, such as the Global Fund, for implementation of the above recommendations and associated technical assistance.

[15] WHO-FIP Joint Statement on the role of pharmacists in tuberculosis care and control, Hyderabad, India, September 4, 2011. http://www.who.int/tb/features_archive/who_fip_initiative/en/index.html
[16] WHO. Global Tuberculosis Report 2013. Geneva, Switzerland: WHO; 2013. http://www.who.int/tb/publications/global_report/en/.

ANNEX A. TRAINING OF TRAINER'S AGENDA

Day 1	Day 2	Day 3
Roles of dispensers in their day-to-day activities	TB/HIV collaborative services	Provision of TB-specific health education
Overview of the National Tuberculosis and Leprosy Programme	• Importance of good communication • Components of effective communication • Types of communication • Communication skills	• Referral process • What is a referral system? • Proposed ADDO-TB diagnostic center referral process • Completing the referral form
ADDO program and its contribution to community health programs	Barriers to effective communication with clients	Documentation and performance monitoring
• Overview of TB • TB symptom recognition • Diagnosis of TB • TB transmission • Health effects of TB • TB treatment, recommended medicines, and DOTS • Multidrug-resistant TB and extensively drug-resistant TB • TB prevention	Discussion groups	Roles of dispensers in TB case identification