

# **Managing Pharmaceuticals for TB/HIV Collaboration:**

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## ***Lessons Learned from a Five-Country Study in East Africa***

Management Sciences for Health  
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*July 2007*

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## **About RPM Plus**

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## ACRONYMS

ART	antiretroviral therapy
ARV	antiretroviral
AIDS	acquired immunodeficiency syndrome
CDC	U.S. Centers for Disease Control and Prevention
CMS	Central Medical Stores
CPT	co-trimoxazole preventive therapy
CTC	care and treatment center (for HIV/AIDS)
DACA	Drug Administration and Control Authority [Ethiopia]
DCT	diagnostic counseling and testing [HIV]
DOT	directly observed treatment
DOTS	(internationally recommended strategy for tuberculosis control)
FBO	faith-based organization
FMoH	Federal Ministry of Health [Ethiopia]
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
IPT	isoniazid preventive therapy
KEMSA	Kenya Medical Supplies Agency
MoH	Ministry of Health
MSD	Medical Stores Department
NACP	national AIDS control program
NASCOP	National HIV/AIDS and Sexually Transmitted Infections Control Program [Kenya]
NGO	nongovernmental organization
NTP	national TB program
NLTP	National Leprosy and Tuberculosis Control Programme [Kenya and Uganda]
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PSLD	Pharmaceutical Supply and Logistics Department [Ethiopia]
RMS	regional medical store
RPM Plus	Rational Pharmaceutical Management Plus
STIs	sexually transmitted infections
SWAp	sector-wide approach
TB	tuberculosis

UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children’s Fund
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing (HIV)
WHO	World Health Organization

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## BACKGROUND

The five countries in this study—Ethiopia, Kenya, Uganda, Tanzania, and Malawi—have some of the highest tuberculosis (TB) and HIV co-infection burdens in the world. In Ethiopia, for example, the government estimates that 50 percent of TB patients in Addis Ababa are HIV-positive, while in rural areas, the estimate is 20–30 percent.<sup>1</sup> In Uganda, an estimated 30 percent of all deaths of people living with HIV/AIDS has been attributed to TB.<sup>2</sup> Although these countries have had TB control programs in place for many years and have made good progress in achieving TB case detection and treatment goals, the HIV/AIDS pandemic has presented a massive challenge to government efforts to control TB.

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<sup>1</sup> Federal Ministry of Health (FMOH), HIV/AIDS Prevention and Control Office (HAPCO), and Drug Administration and Control Authority (DACA). 2003. *Guideline in the Use of Antiretrovirals in Ethiopia*. Addis Ababa: FMOH/HAPCO/DACA.

<sup>2</sup> Ministry of Health, Uganda. 2006. *National Policy Guidelines for TB/HIV Collaborative Activities in Uganda*.



## PLANNING FOR TB/HIV COLLABORATION

*It is imperative that HIV and TB treatment and control programs across the developing world forge closer working links to develop a robust joint approach to replace the traditional separate courses initially adopted by many developing countries.* —Peter Mugenyi, Director, Joint Clinical Research Centre, Kampala, Uganda<sup>3</sup>

Due to the interdependency of these two epidemics, the international community has encouraged collaboration between national TB and HIV/AIDS programs as the best means to promote prevention, increase case finding, expand access to treatment, and reduce mortality rates among co-infected populations. The World Health Organization (WHO) has published guidance on coordinating the activities of national HIV/AIDS and TB programs (Table 1).

**Table 1. WHO Publications on Collaboration**

Publication	Website
Interim Policy on Collaborative TB/HIV Activities (2004)	<a href="http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.330_eng.pdf">http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.330_eng.pdf</a>
TB/HIV: A Clinical Manual (2004)	<a href="http://whqlibdoc.who.int/publications/2004/9241546344.pdf">http://whqlibdoc.who.int/publications/2004/9241546344.pdf</a>
A Guide to Monitoring and Evaluation for Collaborative TB/HIV Activities (2004)	<a href="http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.342.pdf">http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.342.pdf</a>
Guidelines for HIV Surveillance Among Tuberculosis Patients, 2nd Edition (2004)	<a href="http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.339.pdf">http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.339.pdf</a>
Report of a "Lessons Learnt" Workshop on the Six ProTEST Pilot Projects in Malawi, South Africa, and Zambia (2004)	<a href="http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.336.pdf">http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.336.pdf</a>

According to WHO's *Interim Policy on Collaborative TB/HIV Activities* (2004), the main objectives for collaborative TB/HIV activities are to—

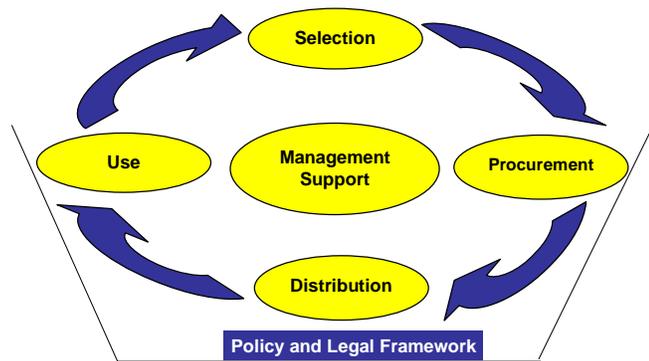
- Establish the mechanisms for collaboration
  - Set up a coordinating body for TB/HIV activities effective at all levels
  - Conduct surveillance of HIV prevalence among TB patients
  - Carry out joint TB/HIV planning
  - Conduct monitoring and evaluation

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<sup>3</sup> Mugenyi, P. 2007. Collaboration to kill: HIV/AIDS and TB. SciDev.net. <http://www.scidev.net/Opinions/index.cfm?fuseaction=readOpinions&itemid=635&language=1> (accessed Aug. 3, 2007).

- Decrease the TB burden in people living with HIV/AIDS
  - Establish intensified TB case-finding
  - Introduce isoniazid preventive therapy (IPT)
  - Ensure TB infection control in health care and congregate settings
- Decrease the burden of HIV in TB patients
  - Provide HIV testing and counseling
  - Introduce HIV prevention methods
  - Introduce co-trimoxazole preventive therapy (CPT)
  - Ensure HIV/AIDS care and support
  - Introduce antiretroviral therapy (ART)

This study focused on pharmaceutical management related to TB/HIV collaboration activities. Pharmaceutical management encompasses medicine selection, procurement, distribution, and use in a system that ensures the availability of high-quality and cost-effective products.<sup>4</sup> The elements of pharmaceutical management are supported by management systems that include financing, information management, staffing, and monitoring and evaluation. The cycle is based on a policy and legal framework that establishes the mechanism for each pharmaceutical management function. The term pharmaceuticals and commodities, which the document uses interchangeably, represents medicines, vaccines, supplies (such as laboratory reagents, syringes, gloves, etc.), and medical equipment.



Effective management of pharmaceuticals is important for TB and HIV/AIDS programs to achieve their program objectives and improve health outcomes. Pharmaceuticals for TB/HIV co-infection may funnel through a country's different supply systems, such as TB, HIV/AIDS, essential medicines, reproductive health, or laboratory supplies. Therefore, interventions to support TB/HIV collaboration need to involve the staff members who work in these different supply systems.

As public health recommendations evolve, so does the package of services that countries provide. And with the introduction of TB/HIV collaborative activities, pharmaceutical management may need to be adapted for new conditions and challenges, for example—

- Determining which program should manage TB/HIV commodities, such as isoniazid or co-trimoxazole for prevention (for example, the national TB program, the national HIV/AIDS program, or national essential medicines program)

<sup>4</sup> Management Sciences for Health. 1997. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals*. 2nd Edition. Bloomfield, CT: Kumarian Press.

- Reorganizing the management of related pharmaceuticals as both TB and HIV/AIDS programs adopt common program goals, such as early detection of HIV and TB and preventive treatment for co-infected patients
- Realigning the management information system so both TB and HIV/AIDS programs can use it to facilitate an uninterrupted supply of medicines and a high level of adherence to treatment
- Reviewing and reorganizing existing pharmaceutical management systems before introducing program collaboration to promote efficient services—for example, exploring where it makes sense to integrate, link, or partially merge services for pharmaceutical management functions



## STUDY PURPOSE

Management Sciences for Health's Rational Pharmaceutical Management (RPM) Plus Program designed a study to investigate commodity management in support of TB/HIV collaborative activities as described by WHO's *Interim Policy for Collaborative TB/HIV Activities*. This assessment focused on two issues—establishing the mechanisms for collaboration, which includes policy, planning, implementation, coordination and information management for monitoring and evaluation of TB/HIV collaboration activities, and managing pharmaceuticals needed for interventions, such as HIV testing and counseling for TB patients, IPT, CPT, and treatment adherence. Although the study focused on pharmaceutical management, it also included a review of the overall policies and practices related to all areas of TB/HIV treatment.

This study characterized how five East African countries—Ethiopia, Kenya, Malawi, Tanzania, and Uganda—are carrying out TB/HIV collaborative activities and how they are considering pharmaceutical management in policies, working documents, and in practice. The study asked the following questions—

- To what extent has pharmaceutical management been considered in the national TB/HIV policy?
- What strategy has been proposed or implemented to manage (i.e., select, quantify, procure, distribute, store, dispense, and finance) (1) commodities used by both programs, and (2) commodities required for new interventions, such as co-trimoxazole and isoniazid? What are the conditions that influenced this decision?
- To what extent have TB and HIV/AIDS programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?
- Has program collaboration in TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?
- What advantages, opportunities, limitations, and drawbacks of pharmaceutical management were experienced or anticipated as the collaboration progressed?



## STUDY METHODOLOGY

RPM Plus conducted the study in two phases: the first phase reviewed activities and experiences on TB/HIV collaboration at the national and regional levels including—

- TB/HIV national policies, areas of collaboration, and roll-out plans
- Policies and plans on pharmaceutical management that support TB/HIV collaboration
- Pharmaceutical management systems within the TB and HIV/AIDS programs and coordination of TB/HIV services; for example, linking systems through referrals and designating one program to report data
- Procedures used by the programs to select, quantify, procure, distribute, store, dispense, and finance pharmaceuticals and commodities
- Treatment adherence activities

RPM Plus based the phase one assessment on reviews of documents and policies and interviews with program stakeholders using a semi-structured interview guide. Interviewees for the first phase included representatives from the national TB control programs, the national HIV/AIDS control programs, and the pharmaceutical supply departments of the ministries of health. The interviewers, who were local consultants, gathered information on TB/HIV collaborative activities and rollout plans, and sought to provide qualitative answers to the study questions outlined above. Pharmaceuticals used by the TB and HIV/AIDS programs served as tracer items to assess how the programs were collaborating on pharmaceutical management and how the collaboration varied within each country and from country to country; for example, how the programs are using isoniazid in non-active TB patients. Examples of tracer items included isoniazid and co-trimoxazole for prophylaxis, TB and antiretroviral (ARV) medicines, and commodities required for diagnosing HIV and TB according to national guidelines. The first phase of the study was conducted in all five countries.

The second phase assessed how specific health facilities were actually implementing collaborative activities in pharmaceutical management. Data collectors reviewed reports and records of services provided in the health facilities and used structured questionnaires to interview health providers, pharmacy staff, and program staff at a variety of facilities. The assessment included the following services related to pharmaceutical management for TB/HIV collaboration—

- HIV testing in TB patients
- CPT for TB/HIV co-infected patients
- CPT after TB treatment is completed in HIV-positive patients
- CPT for HIV-positive patients without TB infection
- TB screening in HIV-positive patients
- IPT for HIV-positive patients without active TB

- Management (selection, quantification, procurement, distribution, storage, dispensing, and financing) of co-trimoxazole, isoniazid, pyridoxine, and HIV test kits and X-ray films, which are used to diagnose and treat TB/HIV co-infected patients

In addition, data collectors documented recordkeeping behaviors, supervisory practices, and training activities in the facilities as they related to pharmaceutical management services. The study refers only to adult patients and does not consider pediatric treatment. The second phase of the study was most comprehensive in Ethiopia and Malawi, where a larger number of facilities were visited, while limited facility visits occurred in Uganda and Tanzania and none in Kenya. The assessments were carried out from January to October 2006.

## STUDY RESULTS AND LESSONS LEARNED

*“We are missing many opportunities to provide better care. These are people who are in front of us, who are already part of the care system. There’s a whole manner of barriers that people have to get through to actually reach the health service, the least we can do is offer them integrated prevention, care, and treatment when they get there—and in doing so, we avoid unnecessary deaths.”* —Dr. Alasdair Reid, HIV/TB advisor, the Joint United Nations Programme on HIV/AIDS (UNAIDS)<sup>5</sup>

### National-Level Coordination Supporting TB/HIV Collaboration

The five countries all formed national committees that planned the strategy and implementation for TB/HIV collaborative activities. In some countries, the national committees also managed collaboration at the national level; however, the committees’ degree of involvement and activity level varied. Some countries established subcommittees or working groups to manage certain elements of collaboration more effectively at the national level. Ethiopia’s advisory committee developed guidelines and standard operating procedures to standardize TB/HIV prevention, care, treatment, and support activities. Uganda and Kenya plan to establish either coordinating committees or coordinators at each level of the health care system.

In most countries, the initial planning committee for TB/HIV collaboration did not include central medical store personnel to address pharmaceutical management issues, nor was pharmaceutical management for TB/HIV commodities documented in the national policy or implementation guidelines, except in Ethiopia. Committees probably did not consider pharmaceutical management during the collaboration planning phase.

All countries except Malawi have a national coordinator who facilitates the collaboration activities between the TB and HIV/AIDS programs. In the four countries, the TB/HIV coordinator is a TB program staff member or a WHO employee in the TB program. Key informants reported that stakeholders were satisfied with the role of a national coordinator as long as he or she did not have competing responsibilities. Ethiopia also established staff to serve as TB/HIV focal persons at each level of the health system to coordinate operational activities, including monitoring the availability of TB/HIV commodities at health facilities.

Ethiopia, Kenya, and Uganda have policies and guidelines in place that specifically address TB/HIV collaboration activities. The TB/HIV policy guidelines in Ethiopia include a section on TB/HIV logistics management, which defines procurement responsibilities for TB/HIV commodities, storage at the central level, buffer stocks and order frequency at all levels, and distribution through the respective programs. The guidelines list the information, forms, and registers that implementing facilities should be using.

The Tanzanian National TB and Leprosy Program revised its treatment manual in 2006 to incorporate a section on TB/HIV collaborative activities, but did not include a section on commodity management. In addition, Tanzania’s guidelines on the clinical management of

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<sup>5</sup> Smart, T. 2007. *It’s time to integrate TB/HIV care on a national scale*. HIV & AIDS Treatment in Practice, #88 (part I). <http://www.aidsmap.com/cms1230928.asp> (accessed Oct. 1, 2007).

HIV/AIDS, revised in 2005, provide information on CPT, IPT, and TB treatment in co-infected patients, but only address the clinical management of ARVs and not other pharmaceuticals. The TB program in Malawi was given the responsibility for collaborative activities, however, the TB development plan (2002–2006) did not address commodity management. Malawi later developed a CPT policy in 2005 that does incorporate co-trimoxazole supply management issues, particularly financing, procurement, and distribution.

Generally, TB and HIV/AIDS programs in each country are adding information related to collaboration as they revise their treatment guidelines, but with the exception of Ethiopia, no country clearly describes the pharmaceutical management issues in any of its guidance documents.

#### **Lessons Learned and Recommendations**

- A national committee is the appropriate body to develop a policy for TB/HIV collaboration and national implementation plans. Including central medical store staff in national-level working groups or subcommittees ensures that pharmaceutical management is considered at the planning phase and throughout scale-up of interventions to promote constant availability of commodities.
- Incorporating new stakeholders from other programs into existing national committees may be an effective and efficient strategy to address TB/HIV collaboration issues in pharmaceutical management. In Kenya, the National AIDS and Sexually Transmitted Infection Control Program (NASCO) chairs an ART Task Force that includes many national stakeholders involved with scaling up ART. The task force's mandate is to bring together experts from private, public, and faith-based health organizations, as well as people living with HIV/AIDS, to harmonize and oversee the implementation of ART throughout the country. Various task force subcommittees address specific issues that are then brought back to the main task force for final decision-making or ratification. Such an existing committee or task force could be expanded to include the TB stakeholders needed to support TB/HIV collaboration, instead of having separate, parallel committees.
- A TB/HIV coordinator is needed to oversee the coordination and management of TB/HIV activities, including pharmaceutical management.
- Establishing organizational structures within different levels of the health system to foster TB/HIV collaboration is important. Decentralizing TB/HIV committee and coordination functions down to the health facility level helps standardize activities and provides a mechanism for communicating information through regular monitoring.
- Revising national program guidelines to incorporate new interventions for TB/HIV collaboration, including managing pharmaceuticals and commodities promotes the standardization of services and commodity management—particularly at implementation level.

## Implementation of TB/HIV Collaborative Activities

*“Let’s not forget that it is action at the district, at the local level that will make the ultimate difference for people. A national plan is as good as every district plan and as every district can deliver.”*—Dr. Peter Piot, Executive Director, UNAIDS<sup>6</sup>

At the time of the assessments, the five countries were at different stages of implementing collaborative activities at the facility level. Ethiopia’s official program for TB/HIV collaborative activities, including pharmaceutical management, was the most evolved. Ethiopia had laid out the issues around pharmaceutical management of TB/HIV commodities from the planning stage of policy development.

None of the countries appeared to base its selection of which program will provide and manage the TB/HIV commodities on an analysis of its situation. No country had evaluated the ability of its pharmaceutical management system to withstand large volumes of new commodities, particularly during scale-up, or planned to upgrade existing systems to handle TB/HIV commodities.



In all countries, the TB program is in charge of collaborative activities. All countries started their collaborative activities on a pilot level before scaling up to additional districts. However, not all TB/HIV interventions are being implemented in all pilot districts. Also, outside the pilot districts, some facilities are implementing some collaborative components, but not systematically, which can cause problems during scale-up when facilities have to change their policies and practices to come into line with the standard. Appointing focal persons at all levels of the system including at the facility can help address scale-up issues.

In most countries, the initial pilot sites were comprehensive care centers that provided TB treatment, ART, and TB/HIV services. However, as scale-up began, existing infrastructure and limited resources prevented country programs from widely adopting this comprehensive care model over the model where TB and HIV/AIDS services are linked through referrals. Key informants interviewed in Ethiopia, Kenya, Tanzania, and Uganda preferred the comprehensive care model, which they felt was the most convenient for patients and providers and resulted in fewer patients lost during referrals and more reliable data collection and reporting.

Kenya and Uganda developed training documents designed to build technical knowledge and skills essential for implementing TB/HIV collaborative activities in health care delivery. These training documents did not include a section on pharmaceutical management of TB/HIV commodities. In Ethiopia, several facility pharmacists interviewed indicated that the pharmacy department had not been trained or involved in any TB/HIV collaborative initiatives, and that little information had been shared about the program planning, so they were unclear how the pharmacy could contribute to the initiative. As a result, joint integrated planning between the

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<sup>6</sup> Ibid.

pharmacy and the clinics was often weak or nonexistent. In Malawi, pharmacy staff were not trained in TB/HIV activities, but received a briefing on CPT; they said their training needs included CPT for TB/HIV patients, record keeping, and monitoring patient treatment adherence.

No matter what the level of implementation, in all countries, HIV testing was the main entry point for TB/HIV collaborative activities, and opt-out, provider-initiated testing in TB patients (meaning the provider recommends HIV testing from which the patient can opt out) was the most widely implemented activity at facilities offering TB/HIV services. Even at some facilities that were not piloting TB/HIV collaborative activities or introducing ART, most TB patients were offered or referred for HIV testing. Informants in all countries reported that opt-out, provider-initiated HIV testing was acceptable to patients in most areas of the country. However, factors such as stock-outs of HIV test kits in Ethiopia, Kenya, and Uganda, and limited access to counseling and testing centers by patients in Tanzania affected how providers offered or referred TB patients for HIV testing.

Factors that adversely affected TB/HIV activity scale-up in all countries included the limited number of skilled personnel, high turnover of trained staff, and inadequate funds for training. These factors also affect pharmaceutical management, for example, by decreasing the quality of recordkeeping and reporting, which are needed to accurately estimate the amount of medicines and to ensure consistent availability of commodities. In addition, although both TB and HIV/AIDS programs need to collaborate for successful planning and implementation of TB/HIV activities, donor-driven funding (vertical program funding streams) and uncertainties about losing program management autonomy have limited effective collaboration between programs in the study countries.

### **Lessons Learned and Recommendations**

- Provider-initiated HIV testing in TB patients can be rolled out faster than CPT and IPT, because it is a fairly simple intervention that is usually already a routine offering in the facility. Establishing mechanisms that ensure the constant availability of HIV test kits at the health facility for TB patients and easy access for TB patients to testing centers will increase the effectiveness of the intervention.
- Conducting a pharmaceutical system analysis prior to selecting which program will provide and manage new intervention commodities is an example of an evidence-based approach for effective decision making. Information from such an analysis could inform if and where it makes sense to restructure pharmaceutical management systems to improve the efficiency and effectiveness of TB/HIV services.
- Identifying long-term sources for TB/HIV commodities in the planning phase of program implementation and developing a strategy for scaling up pharmaceutical management activities could help assure that commodities are continuously available as the program expands.
- Involving the people responsible for managing commodities at all levels of the health system in the actual planning and management of TB/HIV collaborative activities would help ensure that pharmaceutical issues are addressed in planning, budgeting, and implementation in line with scale-up activities. Such involvement would also increase staff commitment to ensuring the availability of necessary commodities through good record keeping, reliable quantification estimates, and advocating for funding, which could decrease both treatment interruptions and health worker/patient treatment adherence problems.
- Although TB and HIV/AIDS programs are willing to collaborate in all areas including pharmaceutical management, each worries that integration of responsibilities might result in the loss of vital program activities or donor assistance to the other program. Careful planning, consultation, and creating clear terms of reference and guidelines are possible approaches to clarifying roles and facilitating effective collaboration between programs.
- Identifying sufficient financial and human resources during the planning phase to build capacity for TB/HIV activities and commodity management is key to successful implementation.
- Program planners need to establish standardized training documents that include a section on pharmaceutical management.

### **Managing TB/HIV Pharmaceuticals**

Study findings showed that TB and HIV/AIDS program collaboration resulted in no restructuring of the pharmaceutical management system to increase effectiveness and efficiency of new services. In general, TB and HIV/AIDS programs each quantifies its own commodities needs based on a variety of methods: consumption, morbidity, or modified consumption that includes a scale-up factor. However, lack of or inconsistent information sharing between both programs for quantifying collaboration commodities has resulted in periodic stock-outs. Ethiopia, Kenya, and Malawi have taken steps to improve information sharing between programs to improve the accuracy of quantification estimates and to minimize stock-outs in the pharmaceutical system.

Procurement practices vary between programs and countries depending on donor source and existing procurement mechanisms for individual programs.

Financial resource constraints and different funding streams affect which program provides TB/HIV collaboration commodities and how order quantities for certain TB/HIV commodities are calculated. For example, Ethiopia's TB/HIV policy and implementation guidelines state that co-trimoxazole tablets for TB/HIV co-infected patient prophylaxis will be funded, procured, and managed through the TB program. The TB program procured co-trimoxazole once, then the HIV/AIDS program took over because it secured longer-term funding to buy the medicine. Because Tanzania and Uganda do not have any dedicated funding stream to procure co-trimoxazole for CPT, they rely on the essential medicines program's supply for acute treatment needs, which usually results in stock-outs and patients having to purchase medicine out-of-pocket.

In Malawi, the TB and HIV/AIDS programs jointly plan where pharmaceuticals and supplies overlap. Although each program prepares individual procurement lists of program commodities, they collaborate on the quantification of items used by both programs. In Ethiopia, the Ministry of Health's Pharmaceutical Supply and Logistics Department handles the logistics for collaborative commodities. The TB program has placed a staff member who is responsible for commodity management in the Ministry of Health's drug management unit to promote more effective collaboration at the national level. The responsibility for quantifying products varies depending on the item and is defined by Ethiopia's TB/HIV collaboration guidelines, although functions have changed slightly over time.

Both TB and HIV/AIDS programs distribute commodities through the country's central medical stores to public-sector facilities, while some programs use parastatal or other organizations to distribute to private- and mission-sector facilities. All distribution mechanisms use a vertical approach (separate, parallel supply systems for each program) to manage and distribute pharmaceuticals and commodities to health facilities. In Ethiopia, Kenya, and Tanzania, each program has its own pharmacist who oversees program commodities at the central medical store.

It was beyond the scope of this study to investigate in depth how well distribution systems for collaboration commodities worked to ensure timely, consistent product availability at all levels.

### **Lessons Learned and Recommendations**

- Establishing a functional mechanism for TB and HIV/AIDS programs to collaborate in quantification and procurement of TB/HIV pharmaceuticals is essential to assure that common items and quantities for both programs are covered. Such information sharing will help alleviate stock-out problems experienced due to poor quantification.
- Strict donor funding requirements for vertical programs may challenge collaboration between programs and drive decisions about how to implement TB/HIV activities; however, decisions not based on a situational analysis may result in poor TB/HIV commodity management.
- Well-defined pharmaceutical management systems are usually in place for ARVs and TB medicines, but co-trimoxazole often falls between the cracks because it is used by both programs for CPT and as an essential medicine for acute infections.
- Because national government pharmaceutical distribution agencies, such as central medical stores, have TB and HIV/AIDS program pharmacists on site to manage the vertical programs, an increase in communication and coordination among these pharmacists could be a cost-effective approach to improving distribution of TB/HIV commodities.

### **Managing Information for Monitoring and Evaluation**

An accurate and reliable information system provides the basis for planning and budgeting in pharmaceutical management system, particularly in the area of quantification for procurement for commodities used in collaborative activities.

The study showed that the TB programs in all countries had incorporated TB/HIV data into their existing information systems, while a few HIV/AIDS programs have revised their information systems to include TB/HIV collaboration. The result is two separate program information systems in each country for TB/HIV collaboration—data collection, reporting, analysis, and feedback. To capture TB/HIV data from individual program sites, programs established linkages through referrals, and in all countries, the TB programs revised and implemented recording and reporting tools that included TB/HIV components. However, only the HIV/AIDS programs in Ethiopia and Malawi had revised existing data collection tools to include TB/HIV collaboration (Table 2). Key informants reported that revisions had not been incorporated because HIV/AIDS programs were too focused on rapidly scaling up activities and program reporting tools were still new.

**Table 2. TB/HIV Recording and Reporting Tools**

<b>Country</b>	<b>Programs Using New or Revised Tools for TB/HIV</b>
Ethiopia	TB and HIV/AIDS programs
Kenya	TB program
Malawi	TB and HIV/AIDS programs
Tanzania	TB program (HIV/AIDS program has revised, but not implemented tools)
Uganda	TB program

Because all TB programs had revised recording and reporting forms to include TB/HIV collaboration activities, existing TB information systems are in place to report collaboration information in all countries. However, key informants reported that incomplete, delayed, or no reporting of TB/HIV collaboration information has limited the use of collected data for effective decision making, including for pharmaceutical management. In Tanzania, because not all collaboration sites had received training, recording and reporting was still not routine. In Ethiopia, health providers complained of the heavy work load in filling out the different forms. Providers suggested that reducing the number of forms, changing the formats for data recording and reporting, or hiring a clerk to handle the reporting would ease the burden. In Uganda, key informants reported that at the time of the study about 70 percent of 28 TB/HIV implementing districts were reporting some TB/HIV data to the national TB program.

Some countries have introduced indicator-based methods to monitor and evaluate TB/HIV collaboration. Ethiopia, Kenya, and Uganda monitor program performance for TB/HIV collaboration through the use of standardized indicators that they track through revised TB information systems. No country has any indicator that monitors the availability of TB/HIV collaboration commodities, although a few of Ethiopia's and Kenya's indicators could provide relevant information for quantification of TB/HIV commodities.

#### **Lessons Learned and Recommendations**

- A joint information system can support both program monitoring and pharmaceutical management of commodities required for TB/HIV collaboration. Where linkages are in place between programs, data collection and reporting forms need to be adapted to capture the information required to monitor collaborative activities.
- Incorporating TB/HIV activities and commodities into existing recording and reporting tools could improve data collection and reporting; funds need to be earmarked for this purpose.
- Using multiple or redundant reporting forms is inefficient and creates confusion about which one to use, leading to inconsistencies in recording and reporting, and fostering underreporting.
- For tracking program progress, including indicators that monitor TB/HIV commodities will help effectively oversee TB/HIV implementation.

## Supervising TB/HIV Collaborative Activities

“One of the problems in TB/HIV is that both sides of the equation are viewed as someone else’s problem.”—Dr. Kevin de Cock, Director, WHO Department of HIV/AIDS<sup>7</sup>

Although several countries’ collaborative guidelines make recommendations regarding supervision of TB/HIV collaborative activities, no countries were consistently conducting these visits, especially as TB/HIV activities were scaled-up to more facilities. In the past, the TB and HIV/AIDS programs in Malawi collaborated on the supervision of TB and HIV/AIDS activities at peripheral facilities, but when ART scaled up and program administration became more cumbersome, the programs separated their supervisory activities. The difference in frequency and duration of supervisory visits between programs and the facilities also limited effective collaboration.

Ethiopia integrated TB/HIV collaboration activities into its existing mechanism for TB program supervisory visits, and they incorporated TB/HIV commodities into TB supervisory checklists. Key informants reported that supervisors are required to assess the availability of TB/HIV commodities during their visits, however, health facility staff said that program supervisors had not checked on the availability of CPT and IPT supplies as recommended. Some respondents thought that stock monitoring was the sole responsibility of the pharmacy unit at each level, while one hospital pharmacy reported not even being aware of TB/HIV collaborative activities. Staff interviewed at the zonal health department were not involved in or aware of any program training on TB/HIV plans, activities, or supervisory visits. Review meetings conducted twice per year at the national, regional, and zonal levels, and quarterly at the *woreda* (district) level, provide a forum for information sharing and problem solving for TB/HIV collaboration activities. However, only two review meetings were held in 2006 because program managers reported that the main emphasis is still on expanding services.

### Lessons Learned and Recommendations

- Integrating supportive supervision for TB/HIV activities into already existing mechanisms is a sustainable strategy for monitoring TB/HIV activities.
- Regular meetings that include TB and HIV/AIDS program supervisory team members as well as members of related programs responsible for ensuring availability of TB/HIV commodities are needed to monitor how well collaborative activities and commodities are being implemented and to address challenges.

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<sup>7</sup> Smart, T. 2007. *It’s time to integrate TB/HIV care on a national scale*. HIV & AIDS Treatment in Practice, #88 (part II). <http://www.aidsmap.com/cms1230928.asp> (accessed Oct. 1, 2007).

## HIV Testing in TB Patients

All study countries have a national policy to offer provider-initiated HIV counseling and testing to TB patients. The actual testing is done either at the TB clinic, voluntary counseling and testing (VCT) center, or laboratory depending on how the health facility organizes its TB/HIV services. The Kenya TB program recommends that if a TB clinic does not have the capacity to test for HIV in patients, patients should be referred to laboratories for testing. The least preferred option in Kenya is referral to VCT centers because more patients are lost due to long waiting times. Four countries (Ethiopia, Kenya, Tanzania, and Uganda) reported that the loss of TB patients during referrals for HIV testing from the TB program was a problem, mostly due to inadequate patient follow-up and HIV test kit stock-outs.

Acceptance of HIV testing among patients varied by country and within countries; for example, in 11 facilities assessed in Ethiopia, acceptance (meaning not opting out of HIV testing when it is offered) ranged widely. Health care providers reported that some patients are reluctant to be tested because they believe that TB itself is a deadly disease, and they do not want to add to their burden by being tested for HIV.



In all countries, the HIV/AIDS program is responsible for funding and managing HIV test kits and reagents, including those used to test TB patients. Quantification for HIV test kit requirements has usually been based on the number of HIV test kits needed for VCT clinics without considering TB patient data. Kenya was the only country where the TB program had started providing information to the HIV/AIDS program to quantify test kits. All countries had noted some stock-outs, which were attributed to

the failure of health workers to request test kits on time or because quantification had been based on VCT needs only without considering TB patient consumption. During a national shortage in Tanzania, large hospitals purchased kits out of their own budgets using a cost-sharing program and were able to keep the tests free for patients. In Ethiopia, one health facility reported that during stock-outs patients are either offered non-rapid testing or asked to come back, which contributed to loss of patients to testing. However, cooperating partners and local nongovernmental organizations often provided the services or the commodities needed to fill the gaps at many health facilities.

### **Lessons Learned and Recommendations**

- Even when HIV test kits are available at regional or national warehouses, health facilities have stock-outs because they fail to requisition new stock on time or consider TB patient consumption. Staff responsible for quantifying HIV test kits and testing supplies at the facility level should work with health care providers to quantify future needs and use data from both TB and HIV/AIDS programs to achieve a more accurate estimate. At the national level, a quantification working group with representatives from all relevant programs should forecast medium- to long-term needs, secure resources, and develop procurement and distribution plans.
- Quantifying needs for HIV test kits is complex, especially when scaling up TB/HIV activities. Accurate quantification relies on effective communication, technical assistance, capacity building on proper storage practices, inventory management, and tools for quantification and reporting.
- TB patients' acceptance of provider-initiated HIV testing depends on the setup of counseling and testing services. For example in Kenya, acceptance was highest when counseling and testing was done directly by the TB clinic nurse and was lower when patients were referred to the VCT clinic, where they had to wait in line. The number of patients who accept testing affects the inventory of HIV testing commodities and could result in stock outs or overstocks if not adequately planned.

### **Pharmaceutical Management in Isoniazid Preventive Therapy**

Ethiopia is the only country with a policy for providing IPT in HIV-positive patients without active TB; however, even the pilot sites for collaborative activities were not consistently offering the treatment. Stakeholders in every country expressed concerns about providing IPT because of the difficulty in ruling out active TB and the fear of antimicrobial resistance if active cases are not treated properly.

The Kenya TB program recommends using IPT with caution, and only in restricted populations and settings. In Uganda, institutions that want to offer IPT must meet stringent eligibility criteria, including having a TB treatment default rate of no greater than five percent, which is difficult to meet (Table 3). Malawi was gathering further information on the intervention before making a policy decision.

**Table 3. Eligibility Criteria for Institutions or Organizations to Provide IPT in Uganda**

<b>A. Human resources</b> <ul style="list-style-type: none"><li>• Medical officer</li><li>• Laboratory assistant</li><li>• Trained counselor</li><li>• Pharmacy technician</li><li>• Adherence supporters</li></ul>
<b>B. Infrastructure</b> <ul style="list-style-type: none"><li>• Functional laboratory</li><li>• X-ray or access to X-ray services</li><li>• Counseling room/space</li><li>• Consultation room</li></ul>
<b>C. Equipment and logistics</b> <ul style="list-style-type: none"><li>• Facilities for TB microscopy</li><li>• Facilities for tuberculin skin testing</li><li>• Cold chain system</li><li>• Facilities for HIV testing</li><li>• Sustainable supply of anti-TB drugs including isoniazid</li><li>• Sustainable supply of HIV test kits</li></ul>
<b>D. Other key performance issues</b> <ul style="list-style-type: none"><li>• TB default rate of NOT greater than five percent</li></ul>

Source: MOH Uganda. TB/HIV Draft Policy, 2005.

Health care providers in Ethiopia indicated that patients may be willing to take IPT when properly counseled about the benefit of preventive therapy, but providers themselves were not convinced of the overall benefit of this intervention, especially in light of the difficulty in totally excluding active TB in patients and fears of increasing resistance to TB. Stakeholders in all five countries appeared to share this opinion.

The Ethiopian guidelines for IPT recommend that pyridoxine should be given as an adjunct treatment to prevent peripheral neuropathy; however, pyridoxine was not included in the TB program's commodity procurement list, and as a result, it was not routinely stocked in any facility in the study. Because pyridoxine was also difficult to obtain from private pharmacies, some health care providers prescribed vitamin B complex as a substitute, while other facilities simply discontinued IPT to overcome the problem. In addition, at some facilities in Ethiopia, patients have to pay for X-ray services, which presents a barrier not only for the introduction of IPT, but more importantly, for the accurate detection of patients with active TB.

For those countries offering IPT, the TB programs were responsible for quantifying and procuring isoniazid; however, even in Ethiopia where IPT is national policy and some facilities were offering treatment, record keeping on the number of patients and consumption quantities was spotty. Key informants did not report any shortages of isoniazid.

Adherence monitoring for IPT is important because of the risk of developing drug resistance and adverse drug reactions, which may affect treatment compliance. Only one health facility out of the five providing IPT in Ethiopia was documenting patient-reported IPT adherence status using

registers developed at the pharmacy. At another hospital in Ethiopia, health care providers claimed to track adherence through appointment cards and registers and also through self-reporting of missed doses, but they did not record the information. Records examined showed that when IPT is administered together with ARVs patients frequently discontinued their isoniazid.

Although ensuring that isoniazid resistance due to irrational prescribing as monotherapy to active TB patients is a priority for implementing IPT, no country has a standardized validated tool or approach to monitor and promote IPT treatment adherence. Key informants reported that treatment adherence monitoring and promotion is weak, and technical assistance is needed in this area.

#### **Lessons Learned and Recommendations**

- IPT has not been widely implemented, in part because of provider reluctance related to the difficulty in excluding active TB cases.
- Countries need to improve their ability to exclude active TB cases. A reliable detection technique and the associated supplies and services must be accessible, such as radiological services and X-ray films, tuberculin skin tests, and a cold chain system.
- To improve adherence monitoring for IPT, the national program should build the capacity of health workers to track and promote treatment adherence by providing validated tools and standardized techniques to perform monitoring tasks.
- TB programs in some countries, such as Uganda, use community-based health workers to directly observe treatment and track defaulters. A similar strategy can ease the burden on health facilities by promoting treatment adherence for IPT at the community level.

### **Pharmaceutical Management in Co-trimoxazole Preventive Therapy**

Every country in the study except Malawi has a national policy that promotes co-trimoxazole preventive therapy for all HIV-positive patients with active TB or who are HIV-positive with symptomatic HIV-related diseases (usually determined by WHO-recommended clinical staging). The duration of therapy is life long in the absence of ART; however, if ART is available, CPT can be discontinued after the patient's CD4 count reaches from 200 to 500 cells/mm (depending on the country policy) for a specified period. In Malawi, at the time of the assessment, CPT was provided to co-infected patients only, but a policy was in place and plans underway to increase coverage to include eligible HIV-positive patients.

The practices on quantification and procurement of co-trimoxazole vary by country. Ethiopia's TB/HIV implementation guidelines state that co-trimoxazole will be funded and managed through the TB program; however, in practice, both the TB and HIV/AIDS programs have procured co-trimoxazole for CPT in the past, and at the time of the assessment, the co-trimoxazole supply was coming from the HIV/AIDS program. In Uganda and Tanzania,

procurement of co-trimoxazole used for CPT and to treat acute infections is done through the essential medicines program with funding from health facility and district budgets; no additional budget is available to implement CPT at health facilities. In Malawi, the central medical store initially procured co-trimoxazole for the TB program using TB program funds; currently, UNICEF carries out the procurement using Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) support. In Kenya, the TB, HIV/AIDS, and essential medicines programs provide co-trimoxazole as a component of the respective program’s kits. Each health program procures and handles its own commodities with very little collaboration. All countries have applied to or are currently receiving GFATM funding support for CPT. Table 4 shows which program provides co-trimoxazole and the stock-out situation in the five study countries.

**Table 4. Pharmaceutical Management of Co-Trimoxazole Tablets: Practices in Five Countries**

Country	Sources of co-trimoxazole in health facilities	Stock-out reported in previous 12 months*
Ethiopia	<ul style="list-style-type: none"> <li>• TB program</li> <li>• HIV/AIDS program</li> <li>• Health facility budget</li> </ul>	Yes
Kenya	<ul style="list-style-type: none"> <li>• TB program</li> <li>• HIV/AIDS program</li> <li>• Essential medicines program (All through kit systems)</li> </ul>	Yes
Malawi	<ul style="list-style-type: none"> <li>• TB program</li> <li>• HIV/AIDS program (current source)</li> </ul>	Yes
Tanzania	<ul style="list-style-type: none"> <li>• Essential medicines program using health facility and district budgets</li> </ul>	Yes
Uganda	<ul style="list-style-type: none"> <li>• Essential medicines program using health facility and district budgets</li> </ul>	Yes

\*From the time the study was conducted

Because countries use co-trimoxazole both for HIV/AIDS prevention in TB patients and as an essential medicine for short-term infections, quantification is challenging and often inadequate to meet CPT needs. In addition, in countries like Uganda and Tanzania that have no dedicated funding stream for CPT, quantification is based on available financial resources rather than on actual patient need. As a result, all countries reported stock-out problems with co-trimoxazole.

Ethiopia is an exception—quantification is done separately for prophylaxis (CPT), and co-trimoxazole for prophylaxis therapy has separate stock cards from co-trimoxazole for acute treatment. However, facility visits indicated that this approach still did not assure a continuous supply of co-trimoxazole, mainly because the demand is not accurately estimated. All countries reported that when co-trimoxazole was unavailable for CPT, health care providers asked patients to buy co-trimoxazole from an outside source, or providers used the co-trimoxazole stock intended for acute care, when available, to fill the gap for CPT. However, in Uganda, patients requiring acute treatment are usually given preference over patients that need prophylaxis. When stock-outs occurred, they were reportedly filled by the Ministry of Health, donor agencies, or international nongovernmental organizations. Shortages sometimes occur at facilities, even when

the programs provide sufficient supplies for CPT because co-trimoxazole stock for CPT and for acute care are stored together, but priority is given to dispensing for acute treatment.

In Malawi and Kenya, co-infected patients receive CPT with their other TB medicines as part of the directly observed treatment (DOT) approach. (DOT is when a caregiver watches the patient swallow his or her TB medicines—mostly done during the intensive treatment phase). After TB treatment, patients are supposed to transfer to the HIV/AIDS program to continue CPT.

However, TB programs generally lose track of patients' access to CPT after they complete their TB treatment. The assessment also showed that record keeping for patients on CPT varied; TB clinics generally tracked their patients on CPT, but the pharmacies and HIV/AIDS clinics rarely recorded the total number of patients receiving CPT, nor did they record or report patients that had treatment interruptions or stopped CPT due to adverse reactions. One hospital in Ethiopia reported that 30 of the 67 TB/HIV co-infected patients had discontinued CPT since the start of the program, supposedly because of gastrointestinal upset (however, confirmative records were not kept).

#### **Lessons Learned and Recommendations**

- Dedicated funding of co-trimoxazole for CPT by the ministry of health helps assure consistent availability. Using a decentralized district budget alone to purchase co-trimoxazole is insufficient to assure continuous CPT for HIV-positive and TB/HIV co-infected patients. Involving all key stakeholders in forecasting and estimating mid- to long-term resource needs and to mobilize resources is important for successfully implementing CPT intervention.
- Lack of joint, coordinated procurement planning among programs can result in stock-outs of co-trimoxazole for CPT. Defining large buffer stocks in the guidelines does not make up for poor quantification at the facilities or a lack of coordination at national level.
- Local nongovernmental organizations and donor agencies can help bridge the gap when shortages of pharmaceuticals and commodities occur at the facility level.
- A good referral and follow-up system is vital to ensuring that both HIV-positive and TB/HIV co-infected patients who are transferred to other facilities receive CPT without interruption. Pharmacies can play a role in identifying patients that drop out of treatment.
- Good collaboration between HIV/AIDS and TB programs in standardizing recording and reporting tools for CPT will help assure a uniform source of data for estimating co-trimoxazole needs, budgeting, and making important management decisions. Mobilizing funding during the planning phase is needed to revise the individual programs' recording and reporting tools, especially in HIV/AIDS programs; such standardization is a first step toward promoting effective collaboration.

Table 5 shows treatment dispensing at TB/HIV collaborating facilities of countries participating in the study.

**Table 5. Dispensing of TB and HIV-related Medicines at TB/HIV Collaborating Facilities to Co-infected Patients**

Treatment Dispensed	TB Clinic	ART Pharmacy or Clinic	Outpatient Pharmacy	VCT	Lab	Notes
<b>Ethiopia</b>						
ARVs		x				
TB	x					
CPT	Prescribing/dispensing	Prescribing/dispensing	Dispensing			Post-TB CPT comes from the ART clinic, but no follow-up is done
IPT				x		Although IPT is the policy, few facilities implement it
HIV testing				x	x	
<b>Kenya</b>						
ARVs		x				
TB	x					
CPT	1°	Post TB	2°			
IPT		x				ART clinics are allowed to dispense, but IPT is not widely implemented
HIV testing	1°				2°	
<b>Malawi</b>						
ARVs		x				
TB	x					
CPT	x					CTP during TB; post TB is planned but not provided
IPT						IPT is not part of the policy
HIV testing	minimal			x		
<b>Tanzania</b>						
ARVs		x				
TB	x					
CPT	2° prescribing	1° prescribing	1° dispensing			
IPT						IPT is not implemented
HIV testing	1°			2°		
<b>Uganda</b>						
ARVs		x				
TB	x					
CPT		2°	1°			
IPT						IPT is not part of the policy
HIV testing	1°			2°		

x = dispensing carried out in this location; 1° = primary location choice; 2° = secondary location choice

## **Monitoring and Promoting Treatment Adherence**

All countries followed the DOTS for adherence to TB treatment, although some countries and facilities had different policies and practices related to treatment adherence in the continuation phase. Some countries used community-based approaches, while others were facility-based. Examples of community-based approaches include the use of volunteers (such as former TB patients) and home-based care givers. In Tanzania, most facilities use a combination of different approaches, depending on their location and the availability of funding and human resources.

Monitoring and promoting treatment adherence for ART is not standardized in any country, and approaches sometimes vary from facility to facility in the same region. Examples of monitoring include pill count, patient self-reporting, tracking missed appointments, and noting clinical and immunological markers (for example, CD4 count). Adherence promotion strategies include the use of home-based care givers, telephone calls, patient calendars, and recruiting family and community members for support. For CPT and IPT, program managers indicated that some health facilities that collect the patient's contact information and a relative's information before treatment begins are able to track treatment defaulters, but that adherence monitoring and measurement is not yet practiced in collaborative sites. All program managers interviewed identified adherence monitoring as one of the weakest performance areas, not only for preventive therapy introduced with the TB/HIV collaboration, but also for ART.

Treatment adherence monitoring and promotion for CPT is one area that received little attention in the study countries, and programs use different techniques to monitor CPT adherence. In Ethiopia, pharmacy staff in the facilities have become more involved in adherence monitoring, particularly for compliance with regular appointments for ART, and for CPT, when it is provided together with ART. However, pharmacies are not recording adherence data, and pharmacy staff indicated that when their work load is heavy, adherence monitoring efforts decline. In Malawi and Kenya, co-trimoxazole for CPT is dispensed with TB medicines to co-infected patients. Although national policies in these countries do not yet stipulate any adherence monitoring and promotion measures for CPT, patients sometimes benefit from the regular monitoring done for TB treatment as reported in Malawi. No country had a mechanism in place for recording or reporting adherence information, and CPT defaulters were rarely followed up to ensure continued treatment.

In Ethiopia, health care providers reported that one of the barriers to patients adhering to CPT is the gastrointestinal discomfort that occurs when co-trimoxazole is taken with TB medicines. To mitigate the effect, health care providers recommended that patients take co-trimoxazole and TB medicines at different times of the day, or take co-trimoxazole every other day instead of daily, or that co-trimoxazole be provided in a capsule formulation because the tablet formulation may be more irritating to the stomach. Although the Ethiopia Drug Administration and Control Authority (DACA) has a system in place for reporting adverse drug reactions observed during treatment, none of the health facilities had filed any reports at the time of the study.

### **Lessons Learned and Recommendations**

- Treatment adherence monitoring and promotion is a weak component in most country programs. Monitoring needs to be linked to a set of strategies for promoting adherence that are validated, efficient, and feasible. Establishing an adherence policy, standardizing procedures, and using validated tools strengthens adherence monitoring.
- Adherence monitoring and counseling suffer when increases in patient load are not met with adequate human resources and infrastructure; staff that monitors adherence needs to collect information on why patients default, including adverse drug reactions, so programs can review guidelines and develop interventions and approaches to improve adherence.
- Home or community-based treatment adherence efforts including for ART, TB treatment, and CPT, has the potential to provide relief for over-stretched health services and to promote treatment adherence.
- Incorporating CPT into the DOT approach to TB treatment services has been a successful way to promote CPT adherence and monitoring while patients are on TB treatment, but once patients finish TB treatment, a mechanism, such as community-based DOT must be put into place to assure that they continue CPT.

## CONCLUSIONS

*“As far as the specific models of care go, although delivery models may differ, outcomes should be identical: diagnosis of both diseases; successful treatment of tuberculosis to cure or completion, reduction in HIV disease progression and mortality, and a decrease in the transmission of both diseases.”—Dr. Kevin de Cock, Director of WHO Department of HIV/AIDS<sup>8</sup>*

The goal of the assessments was to answer a series of questions regarding different pharmaceutical management issues related to TB/HIV collaboration activities.

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

Current policies and implementation guidelines on TB/HIV collaboration generally provide insufficient information on pharmaceutical management. There is limited guidance on the procurement and management of commodities required for TB/HIV collaborative activities or how facilities need to manage those commodities. Sometimes, pharmaceutical management is addressed in separate program guidelines; for example, in Malawi, CPT guidelines describe how co-trimoxazole should be managed.



Some TB and HIV/AIDS programs had incorporated information for TB/HIV collaborative activities into their existing program guidelines, while other countries developed TB/HIV policy guidelines collaboratively. For example, in Tanzania, the two programs worked together to draft a policy guideline for TB/HIV collaboration and to develop a joint clinical guideline for implementing TB and TB/HIV activities at dispensaries, health centers, and district outpatient clinics.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense, and finance) (1) commodities used by both programs, and (2) commodities required for new interventions? What conditions influenced this decision?*

The TB and HIV/AIDS programs in the five countries primarily operate independently, and collaboration has so far focused on the clinical aspects of patient care. Collaboration between program staff and pharmaceutical management staff during planning and implementation of TB/HIV activities was weak. Joint implementation plans, although developed in all countries, did not adequately address procurement, distribution, and financing strategies for TB/HIV commodities. Often, the pharmaceutical management strategy was to make one program responsible for the management of a specific commodity, which would be integrated into that program's regular supply system. Study participants did not indicate that specific conditions guided decisions about which commodities would be provided by which program; decisions

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<sup>8</sup> Ibid.

were apparently based on the historic supply of particular drugs (for example, isoniazid by the TB program), or by the sources of funding available (for example, co-trimoxazole being procured with HIV/AIDS donor resources). None of the country TB and HIV/AIDS programs had any intention of merging their commodity systems.

In Ethiopia, Kenya, and Uganda, a TB/HIV coordinator facilitates the collaboration between the programs at the national level. In Ethiopia, a TB program staff member responsible for commodity management is now positioned in the pharmaceutical management unit of the Ministry of Health, rather than in the TB program office, which may promote more effective collaboration in commodity management between the programs. Plans in Kenya to establish TB/HIV coordinating committees in every province, district, and facility could hasten changes at all levels of the health care system.

*To what extent have TB and HIV/AIDS programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?*

Information management is an important area of collaboration, and in some countries the TB and HIV/AIDS programs wanted to introduce complementary recording forms for HIV testing and CPT prescribing to simplify data collection. However, TB and HIV/AIDS program collaboration on data collection at the facility level is inconsistent, and often such data are not used to quantify pharmaceutical and commodity requirements. Stakeholders often complained about the burden of data collection due to redundant forms and lack of human resources.

The TB and HIV/AIDS programs did not establish any common procedures to promote treatment adherence; the methods they used mainly depended on available resources. In some countries, the HIV/AIDS program is planning to build on the experiences of home-based care and community-based directly observed treatment for TB, although limited human resource capacity and confidentiality issues are challenges. Collaboration had not resulted in better reporting of adverse drug reactions, although a system for reporting adverse drug reactions was already established in Ethiopia.

*Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?*

TB/HIV collaboration had not led to a general restructuring of pharmaceutical management systems in any country. However, as TB/HIV collaborative programs evolve and mature, the management of related pharmaceuticals and commodities may be revised at the national level, which will eventually be rolled out to the facilities.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed?*

In the countries studied, weak human resource capacity, shortages of some pharmaceuticals in the public supply system, and lack of respective policies have limited the expansion of collaborative activities. Some advantages of collaboration included the potential to use human

resources more efficiently, such as providing CPT in the TB clinic instead of referring to a VCT center, and by using patient guardians to monitor treatment adherence to ART, TB, and preventive treatment.

Experiences have shown that even though the five countries had the political will and TB/HIV policies in place; it is a challenge to translate policies into action. In most of the countries, pharmaceutical management issues were not adequately addressed either at the planning phase or implementation phase of TB/HIV collaborative activities. Some broad areas where countries faced challenges included—

- Financing for procurement and treatment (varied and unreliable funding sources)
- Human resources (high turnover of trained staff)
- Occasional stock-out of HIV/AIDS test kits for TB/HIV collaboration
- Scaling up (problems increase as activities are scaled up to lower levels)
- Inadequate understanding of TB/HIV policy and health workers' responsibilities
- Inadequate budget for training health workers
- Ineffective referral systems between TB and HIV/AIDS services
- Implementing IPT intervention
- Physical infrastructure (limited space for counseling)
- Inadequate monitoring and evaluation and supervision
- Collaboration concept not well understood at all levels

**Steps to Implement a National TB/HIV Collaboration Program  
in Pharmaceutical Management**

- Mobilize stakeholders and build advocacy: ministry of health, national and local TB programs, national and local HIV/AIDS control programs, donors, national medical stores, health care providers, and any staff responsible for managing medicines and supplies.
- Establish national committees and working groups to develop TB/HIV collaboration policy and implementation plans. The planning should include the development of financial, procurement, and distribution strategies for TB/HIV commodities, particularly as activities are scaled up. Establish working groups involving all key stakeholders including people responsible for pharmaceutical management particularly the quantification of TB/HIV commodities.
- Establish coordinating committees at the lower levels of the health system (regional, district, facility) to plan for and monitor local pharmaceutical management activities.
- Develop a mechanism for the TB and HIV/AIDS programs to collaborate at all system levels including pharmaceutical management (name a coordinator to liaise, develop standard operating procedures, schedule regular joint meetings).
- Include pharmaceutical staff in planning and management of TB/HIV activities, including training.
- Pilot collaborative activities before scaling-up nationwide and address any pharmaceutical management issues that prevent patients' access to TB/HIV medicines and supplies. Develop a long-term plan that identifies financial resources for TB/HIV commodities during scale-up.
- Assess existing program pharmaceutical systems to determine which program has the capacity to adequately manage TB/HIV commodities (finance, quantify, procure, distribute, store, dispense, and promote treatment adherence) to assure uninterrupted availability at health facilities. The assessment will also identify areas that need strengthening, which could allow early planning for improvement.
- Incorporate activities into existing systems (pharmaceutical management, supervision, monitoring, recordkeeping) to assure efficiency and sustainability.
- Develop a long-term strategy for strengthening the pharmaceutical management information system, including sharing data across programs and integrating information systems where possible. Also, develop or adopt simple tools to help staff collect and process data.
- Standardize training procedures and materials and include a section on pharmaceutical management of TB/HIV commodities; assure that the human and financial resources are in place to carry out the training plan.
- Develop or adopt validated tools for monitoring treatment adherence across programs. Review program responsibilities to avoid duplication and gaps, and explore innovative strategies such as community- or home-based approaches to promoting treatment adherence

In summary, study findings suggest that many opportunities exist to improve pharmaceutical management of TB/HIV commodities and services in public health programs. The following questions need additional study to determine how to best improve TB/HIV collaboration in pharmaceutical management; however, the list of opportunities that follow can serve as a starting point for ministries of health that are planning to implement or roll-out TB/HIV collaborative activities.

**Additional Study Areas for TB/HIV Collaboration in Pharmaceutical Management**

- How can planning for TB/HIV collaboration activities better incorporate pharmaceutical management?
- When developing mechanisms for collaboration, is a separate committee needed to manage TB/HIV pharmaceuticals and commodities?
- As initiatives and policies change, the list of pharmaceuticals for TB/HIV collaboration also changes. What are the implications of these changes on the supply system?
- How has scaling-up TB/HIV activities affected storage space and distribution of related commodities at medical stores and health facilities?
- What pharmaceutical management challenges have been encountered with managing co-trimoxazole for children? What strategies have been put in place to address challenges?
- How well do individual program distribution systems assure the availability of TB/HIV commodities at health facilities? What challenges exist and how are they addressed?

### **Opportunities for Improvement**

- Increasing awareness and commitment of pharmacy staff and supervisors to assure an uninterrupted supply of commodities by including staff in the planning process and training for TB/HIV collaborative activities
- Assuring adequate funding for commodities required for the collaboration
- Improving data collection in pharmaceutical management by developing a comprehensive management information system for TB/HIV commodities and providing respective training for the system
- Using human resources and recording tools more efficiently by training data clerks to keep records for collaborating units (for example, TB and HIV/AIDS clinics and pharmacy) or using real time data entry tools (electronic) where possible
- Setting up systems to allow pharmacists to contribute more efficiently (for example, providing technical oversight) may be beneficial given the fact that pharmacists are scarce and other cadres of staff will be doing the dispensing
- Improving quantification of co-trimoxazole requirements for both CPT and acute care through more systematic data collection at facility level; increasing the coordination of pharmaceutical management staff and program managers to develop appropriate assumptions for scale up
- Improving patient adherence to preventive therapy by investigating and designing simple validated techniques for adherence monitoring and involving the community in promotion
- Using the addition of TB/HIV collaboration among multiple programs and supply systems to strengthen the whole pharmaceutical management system; for example, by increasing efficiencies through sharing developing tools, management information systems, and training

## ANNEX 1.

### MANAGING PHARMACEUTICALS FOR TB/HIV COLLABORATION IN ETHIOPIA: RESULTS FROM A TWO-PHASE ASSESSMENT

#### Background

With a population of about 76 million and an incidence of TB cases estimated at 353 per 100,000 people per year, Ethiopia ranks eighth in global TB burden.<sup>9</sup> The case detection rate for smear positive cases is estimated at 36 percent, while the treatment success rate is 70 percent in 2003.<sup>10</sup> TB is the third leading cause of outpatient morbidity and the leading cause of death.<sup>11</sup> Efforts to control TB in Ethiopia started in the 1960s with the establishment of TB centers and sanatoria; however, it was not until 1976 that the Ethiopian Federal Ministry of Health (FMOH) established the National TB Control Program. Ethiopia introduced WHO's DOTS initiative in 1992 as a pilot in a few areas of the country, and by 2005, DOTS coverage had reached 100 percent of zonal areas and 90 percent of *woreda* areas.<sup>12</sup>

In 2005, the prevalence of HIV in Ethiopia was estimated to be 3.5 percent (urban—10.5 percent and rural—1.9 percent), while the total number of people living with HIV/AIDS was estimated at 1.3 million.<sup>13</sup> The number patients needing ART was estimated at 277,800.<sup>14</sup> The government established the HIV/AIDS and sexually transmitted infection (STI) prevention and control program in 1987. The HIV/AIDS pandemic presents a massive challenge to the government's efforts to control TB; reports estimate that 50 percent of TB patients in Addis Ababa are HIV-positive, while in rural areas, the estimate is 20–30 percent.<sup>15</sup>

#### ***Planning for TB/HIV Collaboration in Ethiopia***

Efforts to implement TB/HIV collaborative activities in Ethiopia started in 2001 after WHO proposed that Ethiopia's FMOH develop an implementation plan for collaborative activities between the TB and HIV/AIDS programs. The FMOH responded by establishing a national TB/HIV advisory committee with members from TB and HIV/AIDS programs and other partners working in the area of TB and HIV, including representatives from academic and research institutions and associations. The TB/HIV advisory committee is charged with coordinating and harmonizing national efforts to combat the TB and HIV/AIDS co-epidemics and providing guidance and technical support for the collaborative activities. Toward that end, the advisory

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<sup>9</sup> WHO. 2006. Global tuberculosis control: country profile Ethiopia.  
<http://www.stoptb.org/countries/GlobalReport2006/eth.pdf> (accessed Oct. 3, 2006)

<sup>10</sup> Ibid.

<sup>11</sup> FMOH (Federal Ministry of Health) 2004/5 (1997 E.C.). *Health and Health Related Indicators*. Addis Ababa, Ethiopia: FMOH.

<sup>12</sup> FMOH (Federal Ministry of Health). 2005. *Tuberculosis, Leprosy, and TB/HIV Prevention and Control Programme Manual, Third Edition*. Addis Ababa, Ethiopia: FMOH.

<sup>13</sup> FMOH (2006). Federal Ministry of Health) 2006. *Sixth Report, AIDS in Ethiopia*. Addis Ababa, Ethiopia: FMOH.

<sup>14</sup> Ibid.

<sup>15</sup> FMOH, HAPCO and DACA (Federal Ministry of Health, HIV/AIDS Prevention and Control Office, Drug Administration and Control Authority) 2003. *Guideline in the Use of Antiretrovirals in Ethiopia*, Addis Ababa, Ethiopia: MOH/HAPCO/DACA.

committee initiated advocacy, communication, and social mobilization activities to create awareness about TB/HIV. In addition, the committee developed guidelines and standard operating procedures to standardize TB/HIV prevention, care, treatment, and support activities.

As described in the committee's terms of reference, the number of committee members is limited to 15 to keep the committee manageable; however, specific experts are invited to participate as required. To facilitate the work, the advisory committee created a technical working group that meets monthly to deal with specific TB/HIV issues. A national TB/HIV coordinator was recruited to manage the implementation of activities.

Nine pilot sites were launched in 2004 to implement collaborative TB/HIV activities (six hospitals and three health centers). Their success resulted in the collaboration expanding to about 300 additional health care facilities in 2006. The scale-up process was facilitated by involving new partners that included four U.S. universities working at hospitals; Family Health International working at the health center level; and IntraHealth International working in the private sector.

## **Study Methodology**

The study was conducted in two phases: the first phase assessed information on activities and experiences on establishing mechanisms for TB/HIV collaboration at the national and regional and levels and how pharmaceutical management was addressed in the process. The second assessment phase looked at how the collaboration was being implemented at the facility level. This phase examined the specifics on HIV testing and providing preventive therapies, such as how facilities are managing pharmaceuticals and commodities, monitoring and evaluation, and addressing issues of patient adherence.

### ***Phase One***

RPM Plus based the phase one assessment on document review and interviews with stakeholders at the national, zonal, and woreda level using a semi-structured interview guide. Stakeholders included representatives from the TB and Leprosy Prevention and Control Program, the Disease Prevention and Control Department, the FMoH, the HIV/AIDS and other Sexually Transmitted Infections (STIs) Program; the TB/HIV Coordination, Pharmaceuticals Supply, and Logistics Department of FMoH; the Addis Ababa City Administration Health Bureau; and the Oromia Regional Health Bureaus. The interviewers, who were local consultants, gathered information on TB/HIV collaborative activities and rollout plans and sought to provide qualitative answers to the study questions outlined above. Pharmaceuticals used by the TB and HIV/AIDS programs served as tracer items to assess how the TB and HIV/AIDS programs were collaborating on pharmaceutical management. Examples of tracer items included isoniazid and co-trimoxazole for prophylaxis, TB and antiretroviral (ARV) medicines, and commodities required for diagnosing HIV and TB according to national guidelines.

Areas addressed in the first assessment phase included—

- TB/HIV national policies, areas of collaboration, and rollout plans
- Policies and plans on pharmaceutical management in support of TB/HIV collaboration
- Pharmaceutical management structures of the TB and HIV/AIDS programs and for the coordination of TB/HIV services, including information management
- Procedures used by the programs to select, quantify, procure, distribute, store, dispense, and finance pharmaceuticals and commodities
- Treatment adherence activities

The first phase of the survey was carried out from August to September 2006.

### **Phase Two**

The second assessment phase verified and quantified findings from phase one, assessed access to commodities required for TB/HIV collaboration activities, and observed collaborative practices in health facilities.

The second phase included visits at 11 health facilities (seven hospitals and four health centers) from four regions, plus health offices at *woreda* and zonal level, where data collectors (local consultants) used structured questionnaires to interview health providers, pharmacy staff, and program staff at VCT clinics, ART clinics, and TB clinics (see Table 1). Because budget restrictions did not allow for a representative sample of health facilities, study visits aimed to include a range of facilities providing TB/HIV services, (including some of the original hospitals that offered ART), reflecting a comprehensive picture of TB/HIV collaboration, and limiting travel costs. Health facilities were categorized as being either TB/HIV pilot sites, second-phase expansion sites providing ART services, or other health facilities. In addition, three health offices were included in the survey (Gondar Zonal Health Department, Gondar Town Woreda Health Office, and Hadya Zone Health Department, (see Annex 1. Table 2). Under the MoH, the health offices oversee the administration of facilities in their areas with responsibilities that include compiling data from health facility registers, reporting data to the central level, and supervising and training. Data sources for the second phase assessment included interviews with key respondents in the health facilities and reports and records of services provided in the health facilities clinics and health departments.

**Table 1. Health Facilities Assessed in Phase Two**

Health facility	Resume TB/HIV			Level of health facility		Region
	Pilot	Expansion	Non-pilot	Hospital	Health center	
Zewditu	X			X		AA
Kazanchis	X				X	AA
ALERT		X		X		Federal
Bole			X		X	AA
Bishoftu			X	X		Oromia
Adama		X		X		Oromia
Butagera			X		X	SNNPR
Butagera			X	X		SNNPR
Hosaena	X			X		SNNPR

Health facility	Resume TB/HIV			Level of health facility		Region
	Pilot	Expansion	Non-pilot	Hospital	Health center	
Gondar	X				X	Amhara
Gondar University		X		X		Amhara
Total	4	3	4	7	4	

RPM Plus prepared five sets of questionnaires for the different interview locations: (1) TB clinic, (2) VCT and ART clinics, (3) hospital pharmacy, (4) health center, and (5) district health office.

The results of the assessment of the health facilities cover the following services related to TB/HIV collaboration: HIV testing in TB patients; CPT for TB/HIV co-infected patients; CPT after TB treatment is completed; CPT for HIV-positive patients without TB infection; TB screening in HIV-positive patients; IPT for HIV-infected patients without active TB; and the management of co-trimoxazole, isoniazid, pyridoxine, and HIV test kits and X-ray films. In addition, the assessment looked at record keeping, supervision, and training activities in the facilities.

## **Assessment Results**

### ***Establishing Mechanisms for Collaboration***

#### *Policies and Guidelines for TB/HIV Collaboration*

Relevant policies and guidelines included as part of the assessment included the *TB/HIV Implementation Guideline*, the *Ethiopia Tuberculosis and Leprosy Prevention and Control Team Manual*, and the HIV/AIDS and STIs policy and guidelines.

Ethiopia launched a TB/HIV implementation policy and guidelines for collaborative activities in July 2005. The guidelines developed by the TB/HIV advisory committee aim to standardize TB/HIV collaboration activities at the program and patient management levels. The guidelines describe how to organize and implement a comprehensive approach for prevention, care, treatment, and support of co-infected patients. The TB/HIV implementation guideline includes a section on TB/HIV logistics management, which defines procurement responsibilities for TB/HIV commodities, storage at the central level, buffer stocks, and order frequency at all levels, and distribution through the respective programs. The guideline lists formats and registers that should be available at all implementing facilities, but it does not define which unit in the facility should use them.

The 2005 revision of the *Tuberculosis, Leprosy, and TB/HIV Prevention and Control Programme Manual, Third Edition* incorporates emerging concepts about TB/HIV collaboration. The manual dedicates a separate chapter to TB/HIV collaboration that describes the objectives and strategies of the collaboration. The discussion of the diagnosis and management of TB in AIDS patients includes the important roles of IPT and CPT, and TB and ART treatment. A section is also dedicated to supply and logistics of TB program supplies, including isoniazid quantification; however, data recording formats that are useful to estimate isoniazid and co-

trimoxazole needs are not shown in any of the manual's forms, although the national implementation guidelines state that procurement and quantification of co-trimoxazole and isoniazid are the TB program's responsibility. In addition, co-trimoxazole, pyridoxine (for prevention of isoniazid side effects), and other supplies, such as tuberculin skin tests and X-ray films, are not included in the consumption recording and reporting forms. The manual contains supervision checklists for monitoring TB/HIV collaborative activities at the different levels of the health care system, which may be modified by the user. The only question on pharmaceutical management in the checklist is, "Are TB/HIV stocks collected, stocked and distributed on time? Yes or No" There is no guidance on what to look for specifically to answer the question, and such limited information appears inadequate for program decision making.

The 2005 HIV/AIDS and STIs policy and guidelines for implementing ART in Ethiopia concentrates on providing ART services, but also mentions the need for co-trimoxazole prophylaxis for all HIV-positive patients, albeit without giving adequate explanations on the indications and dosage. This information is laid out in the *TB/HIV Implementation Guideline and Standard Operating Procedures*. The ART guidelines dedicate a separate section to ARV adherence and monitoring that describes patient predictors of nonadherence and the role of the ART team in counseling and monitoring ART patients. The method of measuring and calculating adherence to ART or CPT was not clearly documented.

### *Implementation of TB/HIV Collaborative Activities*

Following WHO's 2004 interim policy recommendations, the TB/HIV collaborative services in the nine pilot sites included IPT for HIV-positive patients; CPT for HIV and TB co-infected patients; and provider-initiated HIV counseling and testing in TB patients. These services are mostly free to all patients; however, the program funding is highly dependent on external donors and sustainability is not assured.

TB/HIV services and ART services are gradually being decentralized from hospitals down to lower-level health care facilities, and patients are going from being managed by internists to general practitioners to health officers and then to nurses. TB/HIV coordinators from all regions, most zones, and some *woredas* have been trained. Replacement training to handle employee turnover has been an ongoing challenge during the expansion of services.

In Ethiopia, most health facilities have separate TB, VCT, and ART clinics. Patients most commonly flow from the VCT clinic to the ART clinic, and from the ART clinic to the TB clinic. Referral between the VCT and TB clinics is rare, as TB suspects are usually checked at the ART clinic. TB patients are given provider-initiated testing (or diagnostic counseling and testing [DCT]), with the HIV test conducted by laboratory personal at the facility laboratory or the VCT clinic.

HIV testing is the main entry point for TB/HIV collaborative activities and DCT in TB patients was the activity most widely implemented at facilities in 2005 and 2006. Even at assessment facilities that were not piloting TB/HIV collaborative activities or introducing ART, most TB patients were counseled for HIV testing.

All of the assessment facilities visited provided CPT for HIV-positive patients. Only the pilot facilities and one other hospital visited provided IPT. Table 2 provides an example of the extent of TB/HIV activities available in three geographic areas. A summary of services provided in the facilities assessed is provided in the Appendix.

**Annex 1. Table 2. Number of Public Health Facilities Providing TB/HIV Services**

	Administrative Offices Overseeing Facilities		
	Hadya Zone N = 34	North Gondar Zone N = 18	Gondar Town Woreda N = 2
TB treatment	34	18	2
HIV testing for TB patients	3	11	2
CPT offered to all TB/HIV co-infected patients	3	4	2
CPT routinely offered to eligible HIV-positive patients without active TB	3	4	1
IPT offered to children living in the same household with a newly diagnosed pulmonary TB patient	0	1	1
IPT offered to HIV-positive patients without active TB	1	1	1

### *Human Resources*

Implementing TB/HIV collaborative activities increases the demand for services, and therefore, the workload of the health care providers, both in-service and in health management information systems. Unfortunately, program managers said lower-level health facilities were inadequately or not staffed for position such as pharmacists and medical laboratory technologists. Shortages have been compounded by the high turnover or rotation of staff.

Facilities visited that had well-established TB/HIV collaborative activities also had a TB/HIV focal person or coordinator in place. At a facility where the coordinator had left, collaboration between the service units declined. TB/HIV coordinators at health facilities carry out this duty in addition to their other duties; however, staff appears to find this work rewarding. Zewditu Hospital had no TB/HIV coordinator, but appeared not to need one because both services were provided by one department.

Pharmacy staff had not been trained for TB/HIV collaborative activities. In fact, as mentioned previously, pharmacy staff was often not involved with or aware of TB/HIV collaborative activities, so joint and integrated planning is weak. Even a pharmacist at a pilot site (Zewditu Hospital) indicated that the pharmacy department had never been involved in any of the TB/HIV collaboration initiatives, except ART training, and that little information had been shared about the program planning, and therefore, how the pharmacy could contribute to the collaboration efforts. For example, hospital pharmacies have not been quantifying co-trimoxazole for CPT, but to assure a continuous and sustainable access to co-trimoxazole, involving the pharmacy in collaborative program planning and implementation may help predict the demand, streamline the supply, and reduce unexpected stock interruptions.

## **Managing TB/HIV Pharmaceuticals**

In Ethiopia, the procurement and distribution of all pharmaceuticals and other supplies have been restructured and roles transferred from the Pharmaceuticals Administration and Supply Service to the FMOH's Pharmaceutical Supply and Logistics Department (PSLD). According to the proposed Health Commodities Supply System Master Plan, procurement, storage, and distribution will remain under PSLD, including TB/HIV collaborative pharmaceuticals and supplies. Recently, a TB program staff member responsible for commodity management has been positioned in the Ministry of Health's medicine management unit, rather than in the TB program office, which may promote more effective collaboration in commodity management between the programs.

All pharmaceuticals, including those used for TB/HIV collaborative activities, have to be registered by the DACA or sourced from WHO prequalified manufacturers. Upon arrival at the central warehouse, TB/HIV pharmaceuticals and supplies are physically inspected by PSLD experts against the specifications described in the procurement documents.

The responsibility for quantifying products varies—according to the TB/HIV guidelines, the TB Leprosy Prevention and Control team quantifies co-trimoxazole and isoniazid, while the HIV/AIDS and other STIs team quantifies HIV test kits, reagents, antifungals, and other consumables.

While ARV drugs are dispensed at the ART pharmacy, and TB drugs are dispensed in TB clinics, no formal regulations specify where medicines for collaborative services are to be dispensed. Facilities may decide what is most appropriate for their circumstances. Co-trimoxazole for CPT is usually dispensed at the health facility pharmacy. For TB/HIV co-infected patients, 4 out of 11 health facilities in the assessment also dispensed CPT in the TB clinic. IPT for HIV-positive patients is prescribed and dispensed at the VCT clinic or TB clinic in the health care facilities that offered this service.

## **Managing Information for Monitoring and Evaluation**

The TB/HIV Advisory Committee developed three reporting forms to facilitate the TB/HIV management information system: the VCT register, the TB/HIV register, and the quarterly TB/HIV reporting form. The TB/HIV coordinators at different health system levels are responsible for regularly recording and reporting TB/HIV collaborative information.

The indicators routinely monitored and reported using the three forms are—

- Proportion of TB patients counseled for HIV
- Proportion of registered TB patients who are counseled and tested for HIV
- Proportion of registered TB patients who tested positive for HIV
- Proportion of HIV-positive TB patients who receive CPT during their TB treatment
- Proportion of HIV-positive registered TB patients who begin ART or continue ART during or at the end of TB treatment
- Proportion of HIV-positive patients screened for TB

- Proportion of HIV-positive patients newly diagnosed with TB during screening
- Proportion of newly diagnosed HIV-positive clients who are given IPT

Other indicators that are routinely monitored include the number of TB/HIV trainings provided, the number of trained health care providers, the number of health care facilities with TB/HIV collaborative services, the number of health care facilities reporting TB/HIV data, the number of supportive supervision visits, and the number of health care facilities with uninterrupted supplies of pharmaceuticals and commodities.

*Woredas* collect and compile reports from health centers, health stations, and health posts, and send them to the zonal health department that compiles the reports into one document with data from *woredas* and hospitals. The zonal health department visited as part of the assessment had no complete reports and no reports showing information on CPT and IPT. Recent changes in organizational structure at the zonal level likely contributed to the loss of institutional memory. One department was planning to establish a committee to oversee TB/HIV collaboration at the zonal level.

Health facility visits showed that the VCT register and TB/HIV register are widely used at TB/HIV pilot sites as well as at some non-pilot sites. Otherwise, facilities used a variety of recordkeeping measures including—

- Pre-ART register
- HIV care/ART follow up form
- ART register
- ARV drugs and patient information sheet
- ARV drugs and other opportunistic infections register
- TB log book
- Provider-initiated HIV counseling and testing register
- CPT register

When patients who are not also on ART present with a prescription of co-trimoxazole for CPT, the facility pharmacy does not have records on co-infected patients and pharmacy staff does not know how to categorize the patient who has been prescribed CPT. The pharmacy does not have records of the total number of patients receiving CPT, nor does it have records or reports on patients that stopped CPT due to adverse reactions, unless such records were prepared on their own initiative. Few facilities had prepared their own records to keep track of co-trimoxazole consumption.

In the assessment interviews, some health providers complained of the heavy work load in filling out the different forms. Providers suggested that reducing the number of forms, changing the formats for data recording and reporting, or hiring a clerk to handle the reporting would ease the burden.

## **Supervising TB/HIV Collaboration Activities**

Ethiopia's TB/HIV implementation guidelines stress the importance of having the TB and HIV/AIDS program teams organize regular review meetings at different levels of the health system—twice per year at the national, regional, and zonal levels, and quarterly at the *woreda* level. The meetings are to assess the performance of the collaborative activities, share experiences, and adopt best practices. Two such review meetings were held in 2006. The first meeting included TB and HIV/AIDS coordinators from the regions and the head of the health facility and focal persons for both TB and VCT from each of the nine pilot sites. The second review meeting held in November 2006 focused on implementation of IPT activities.

Program managers reported that teams were also established at different health system levels to supervise TB/HIV collaborative activities. A supervisory checklist was developed to standardize the process that can be modified depending on the purpose and level of supervision. Although regular supportive supervision had been indicated in the implementation guidelines, program managers said that the emphasis so far had been on the expansion of services.

Health centers and hospitals are supposed to be supervised quarterly according to their plans, but this is not done as scheduled for different reasons. However, health facilities do receive supervisory visits from the different partners that support the programs. The supervisory visits that did occur lasted about 30 minutes to one hour on average. Supervisors reportedly made semi-structured observations on services and record-keeping practices rather than using a checklist. The assessment sites reported that program supervisors had not checked on the availability of CPT and IPT supplies as is recommended in the TB/HIV guidelines. However, some respondents thought that stock monitoring was the sole responsibility of the pharmacy unit at each level. Staff interviewed at the zonal health department were not involved in or aware of any program training on TB/HIV activities, plans, or supervisory visits, and they asked that *woreda* and zone level staff be included in training and planning sessions with the facilities.

## **Managing Pharmaceuticals to Implement Interventions**

### *HIV Testing in TB Patients*

HIV testing is the entry point to HIV/AIDS care and treatment services in Ethiopia. Routine counseling of TB patients has been widely established at many facilities, including those that are not part of the TB/HIV collaboration pilot. HIV testing is free to patients receiving VCT or DCT services in public health facilities. However, acceptance of HIV testing among TB patients varies greatly. In the 11 facilities visited, acceptance (meaning not opting out of HIV testing when it is offered) ranged widely. Providers reported that some patients are reluctant to be tested because they believe that TB itself is a deadly disease, and they do not want to add to their burden by being tested for HIV. National-level stakeholders viewed the upward trend in HIV testing among TB patients as an indication that TB patients find HIV testing more acceptable.

The HIV/AIDS program is responsible for providing HIV test kits including those used to test TB patients according to the national guidelines for collaborative activities. All three HIV test kits (screening, confirmatory, and tie breaker) used for VCT and DCT for TB patients are

procured by FMoH using GFATM resources, either through tendering or through an agent such as UNICEF.

Forecasting for HIV test kit requirements is based on the number of HIV test kits previously used plus the estimated number of patients to be counseled and tested during the procurement period. Quantification is done by the HIV/AIDS and other STIs team in close consultation with the Pharmaceutical Supply and Logistics Department. However, if records are kept on TB patients who receive HIV tests, they are collected by the TB clinic (e.g., at Adama and Hosaena) or in the laboratory (e.g., Zewditu), and therefore not used to quantify test kits. Because routine data on the number of TB patients screened for HIV was not yet available, the TB and HIV/AIDS programs did not collaborate on the quantification of HIV test kits. In the future, data to be used for national quantification of HIV test kits will be collected from TB clinics, VCT clinics, and ART clinics, and considered with the trend for service expansion.

The distribution of all HIV test kits used for VCT and DCT follows the same channel as other pharmaceuticals and supplies for HIV/AIDS and TB programs. The distribution of HIV test kits for new sites usually follows a push system (where a set number of kits are sent to the facility), while health facilities with existing patients and data use a pull system (where the facility requests the number of kits they need).

One of the difficulties faced by providers and patients is the inconsistent supply of HIV test kits and related supplies. Facilities also tend to order smaller numbers of HIV test kits because they are expensive and are sometimes delivered with a short shelf life. If the test kits are out of stock, service to patients will be interrupted. The patient may be offered a non-rapid test or asked to come back at another time, which may result in their loss to follow-up and a decrease in credibility in the provider and health system. Provider-initiated counseling of TB patients for HIV testing has increased the number of HIV test kits needed; however, no patients were denied tests because of shortages of HIV test kits. Although shortages occurred, cooperating partners and local NGOs often provided the services or the commodities needed to fill the gaps at the health facilities visited.

### *Isoniazid Preventive Therapy*

IPT for HIV-positive patients without active TB is the policy in Ethiopia. Five of the 11 facilities visited provide IPT, most of them TB/HIV pilot sites. At the VCT clinic, patients are counseled about the use of IPT, and when the patient has no signs of active TB, preventive treatment is initiated. Patients for which active TB cannot be ruled out are referred to the ART clinic or to the outpatient department, where sputum tests are taken and co-trimoxazole is initiated. Patients without active TB collect their monthly supply of isoniazid from the VCT clinic for a period of six months, although the pharmacy may also provide the medicine according to the guidelines. The guidelines also recommend using pyridoxine as an adjunct to isoniazid to prevent peripheral neuropathy; however, pyridoxine was not included in program supplies and none of the facilities visited have it in stock. As pyridoxine was also difficult to obtain from private pharmacies, some health care providers prescribed B-complex as a substitute. Gondar Health Center had decided to quit providing IPT because of the unavailability of pyridoxine as prophylaxis for peripheral

neuropathy. Providers at Zewditu suggested this shortage be alleviated to provide complete services.

The procurement and distribution of isoniazid is done by the TB Leprosy Prevention and Control Team through PSLD. The TB/HIV collaboration has helped pool resources to supply IPT, thereby improving continuity of supply. Since IPT for HIV-positive patients has been implemented, demand for the supply of isoniazid has increased.

Requirements of isoniazid for IPT have been estimated based on the annual risk of HIV infection and the expected case load in the participating health facilities. In the future, quantification will be based on recorded data of the number of HIV-positive clients without active TB who receive IPT in VCT and ART clinics. The TB/HIV coordinators are responsible for collecting and reporting data on IPT. Reporting is expected to improve when all sites routinely collect data, and data managers make quarterly reports using the TB/HIV data form provided.

Record keeping at the facilities is inconsistent on how many patients are screened and on IPT. According to the guidelines, patients on IPT should be captured in the unit register “HIV positive clients without active TB who receive IPT” for the *woreda* TB coordinator to send to the zonal coordinator for compilation, who then sends it to the regional coordinator, who compiles data to send to the TB/HIV collaboration data manager at the central level. The main problem has been incomplete, delayed, or no reporting from health facilities. Since the amount of data reaching the data manager is not sufficient for decision making, the information management system for IPT is not yet operational.

Providers indicated that patients may be willing to take IPT when properly counseled about the benefit of preventive therapy, but providers, themselves, are not convinced of the overall benefit of this intervention, especially in light of the difficulty in totally excluding active TB in patients and fears of increasing resistance to TB medicines. Consequently, facilities that are providing IPT have enrolled only a few patients (e.g., Adama, Bishoptu). In Zewditu, however, 23.8 percent of patients screened for TB were put on IPT in the previous quarter, due in part to accessible X-ray services and greater acceptance by patients. In Zewditu, isoniazid is dispensed directly from the TB/HIV/ART clinic.

An X-ray is required to rule out active disease in patients showing signs of TB. At some facilities, patients have to pay for X-ray services, although services are free when the patient has a poverty certificate from the *kebele* (local government unit). Such a payment policy presents a barrier not only for the provision of IPT, but more importantly, for the detection of patients with active TB. In addition, no shortages of X-ray films were reported because of the increased demand from testing for IPT.

Program managers assumed that adherence monitoring is done during the appointment when patients collect their supplies of isoniazid, however, no records at the national level were available. At Gondar Health Center, patients on IPT were monitored through appointment cards and registers. In addition, patient adherence is checked by asking how many doses patients have missed the previous month. However, these self reports are not recorded in the patient card or in the registers. At Hosaena Hospital, IPT dispensing was noted in a hand-ruled register that clearly

showed patient adherence status to IPT. According to the records, since the start of the program in December 2004 until August 2006, 139 patients (33.8 percent) had discontinued therapy. At Gondar Health Center in 2004, 51 patients were prescribed and completed IPT at the VCT clinic; however, from September 2005 through July 2006, when ART had been introduced, over half of the 61 patients started on IPT quit therapy. The providers speculated that patients adhered well to IPT until they started antiretroviral therapy, which increased their pill burden.

### *Co-trimoxazole Preventive Therapy*

As part of the standard policy in Ethiopia, CPT is indicated for all HIV-positive patients with active TB and adults and adolescents (above 13 years) with symptomatic HIV-related diseases (WHO clinical staging 2, 3, and 4). The duration of therapy is life long in the absence of ART, however, if ART is available, CPT can be discontinued after the patient's CD4 count reaches 500 cells/mm for at least three months.

The TB/HIV implementation guideline states that co-trimoxazole will be funded and managed through the TB program; however, in practice, both the TB and HIV/AIDS programs have procured co-trimoxazole for CPT in the past. Currently, the co-trimoxazole supply comes from the HIV/AIDS and other STIs program. Health facilities have two main sources of co-trimoxazole: through public health programs (TB or HIV) and through the regular pharmaceutical budget from the FMoH. Co-trimoxazole is free to patients.

Quantification of co-trimoxazole has been based on estimates of the expected case load in pilot health facilities. As more data becomes available, estimation will consider the total patient load and the growth trend for TB/HIV co-infected patients and HIV-positive patients. This information will be collected from TB/HIV quarterly reports and the TB/HIV unit register for HIV-positive patients taking CPT, which some health facilities are already using. The data managers and TB/HIV coordinators at different levels will be responsible for compiling this information.

Regions and central referral hospitals are required to report both the number of patients taking CPT and the stock on hand when they order co-trimoxazole from PSLD. This information is collected and compiled from health facilities. Even though the national TB/HIV guidelines specify that procurement and quantification for CPT will be the responsibility of the TB program; both TB and HIV/AIDS programs have filled this responsibility. In the future, the HIV/AIDS program is expected to continue this task as funds have been programmed for this activity.

Quantification of co-trimoxazole is done separately for prophylaxis (CPT) and the medicine is distributed through the same channels as other program commodities to regions or health facilities. According to the TB/HIV implementation guideline, the TB and HIV/AIDS programs prepare distribution plans as soon as reports are received from regions and federal health facilities and forward them to PSLD to implement. PSLD uses a push system of distribution when storage space is limited, co-trimoxazole is near expiry, or new health facilities are starting CPT services. PSLD uses the pull system when regions or health facilities send requests to the program or PSLD. Co-trimoxazole for prophylaxis therapy has separate stock cards from co-

trimoxazole for acute treatment. Regional stores may request co-trimoxazole from PSLD twice yearly; while zones, *woredas*, and health facilities order quarterly.

CPT is usually prescribed monthly by the ART clinic. Patients treated for TB may also receive their prescription for co-trimoxazole at the TB clinic. The medicine is dispensed either from the ART pharmacy or from the general pharmacy at the health facility. However, facility visits indicated that a continuous supply of co-trimoxazole is not assured with the existing supply system, because the demand is not accurately quantified. There were co-trimoxazole shortages in 8 out of 11 health facilities visited, in addition to a national-level shortage. When co-trimoxazole was unavailable for CPT, patients were asked to buy co-trimoxazole from an outside source. Three of the 11 facilities visited indicated using the co-trimoxazole stock for acute care, when available, to fill the gap for CPT.

When patients change from one clinic to another or one facility to another, the continuation of CPT cannot always be assured. For instance, most of the facilities visited provide CPT to TB patients co-infected with HIV, and although the HIV/AIDS clinics could prescribe CPT to the patients after the TB treatment is completed, only the pilot facilities consistently did it this way. TB/HIV co-infected patients who have completed their TB treatment are already on either the pre-ART or ART register and continue their treatment at the HIV/AIDS clinic. None of the pilot sites followed up patients on CPT who transferred between the TB unit and the HIV/AIDS unit, and a spot-check at one facility suggested that there are losses when patients are transferred from the TB to the ART clinic for CPT (out of five TB patients randomly selected at Bole Health Center, three continued CPT at the ART clinic). Co-trimoxazole for CPT is usually dispensed by the facility pharmacy or the ART pharmacy, but at pilot sites, co-trimoxazole for co-infected patients is normally dispensed directly at the TB clinic. The TB/HIV clinic at Zewditu Hospital also prescribed CPT to patients who continue their TB treatment at another facility. Although they kept records of these patients, the facility had no way of knowing if patients that did not collect their prescription there were receiving CPT elsewhere.

Clinics monitor adherence to CPT by keeping track of the patient's appointment at the TB or ART clinic respectively. Health providers said that they ask patients if they have taken all medicines since their last appointment, or if they have delayed taking their medicine. Subjective adherence levels to CPT vary a lot between different health facilities. At Zewditu, providers thought that patients regularly took co-trimoxazole unless they were allergic because the patients see an immediate response from CPT. At other facilities, such as Bishoptu and Hosaena Hospital, non-adherence was suspected to be frequent.

The main challenges faced so far with implementing the TB-HIV collaborative activities include delayed, inconsistent, or lack of data reporting from the health care facilities to the central data management manager and a high turnover of trained staff. Supportive supervisory visits and in-service trainings may bring improvement. In addition, adherence monitoring and measurement is still very weak for CPT.

## **Monitoring and Promoting Treatment Adherence**

The TB clinics use DOT for the intensive phase of TB treatment. There is no directly observed treatment program or modified-DOT (using relatives or other volunteers trained in monitoring adherence) for CPT, IPT, or for ART, but the TB/HIV guideline suggest investigating options for involving the community in supporting TB and TB/HIV patients and observing their medicine intake. Facilities monitor adherence to ART, CPT, and IPT by tracking patients' adherence to regular appointments and through patient self reports. Recall periods for self reports are usually long, because many facilities ask about adherence since the last time the medicine was dispensed, which can be 30 days or more. Some providers also use pill counts to measure patient adherence. Some health care providers from Bishoftu described patients' use of co-trimoxazole as very erratic and indicated that adherence needed attention. Challenges with adherence monitoring were also noted for ART, which was considered even more important. Because adherence to CPT and IPT is not measured, actual adherence levels among the patients in the survey facilities are unknown.

Pharmacy staff in the facilities have become more involved in adherence monitoring, particularly for compliance with regular appointments for ART, and for CPT, when it is provided together with ART. Adherence monitoring at the pharmacy complements rather than replaces adherence monitoring at the clinic. However, pharmacies are not recording adherence data, and pharmacy staff indicated that when their work load is heavy, adherence monitoring decreases. For example, the head of the Adama hospital pharmacy said that with two dispensers, they were able to properly monitor and counsel 1,500 patients on ART and CPT. But when the number of patients increased to more than 2,600, the hospital pharmacy was dispensing CPT to 96 patients per day, six days a week, which allowed no time for monitoring or promoting adherence.

In addition to a shortage of staff to provide counseling, survey participants identified gastrointestinal upset as a frequent adverse reaction to co-trimoxazole, which they suspect has resulted in treatment interruptions. At Hosaena hospital, 30 of the 67 TB/HIV co-infected patients had discontinued CPT since the start of the program primarily because of gastrointestinal upset (based on anecdotal evidence because records were not kept). Different facilities have developed their own strategies to address the issue: some TB clinics advise their patients to take co-trimoxazole at a different time from their TB treatment, while another provider suggested providing co-trimoxazole in capsule form to decrease gastrointestinal upset. The HIV/ART providers in Adama prescribe CPT to be administered every other day to minimize the possible adverse reaction. Ethiopia's DACA requires health providers to report adverse drug reactions (ADRs) observed during treatment at health facilities for all medicines including isoniazid and CPT; however, none of the facilities in the survey had records on the number of patients that discontinued CPT nor on the patients that experience adverse reactions. Increased TB/HIV collaboration may improve provider training and patient education and counseling, which may have a positive impact on detecting and reporting ADRs.

Program managers indicated that health facilities that collect the patient's contact information as well as a relative's information before treatment begins are able to track treatment defaulters, but that adherence monitoring and measurement is not yet practiced in collaborative sites for TB/HIV medicines. All program managers identified adherence monitoring as one of the

weakest performance areas, not only for preventive therapy introduced with the TB/HIV collaboration, but also for ART. They indicated the need for technical support from partners. The International Network for Rational Use of Drugs in Ethiopia expressed interest in providing technical support for antiretroviral treatment adherence.

## **Lessons Learned**

The lessons learned from the two-phase assessment of pharmaceutical management in TB/HIV collaboration in Ethiopia are categorized according to the respective recommendations in WHO's *Guidelines for Implementing Collaborative TB and HIV Programme Activities*.

### ***Establishing Mechanisms for Collaboration***

- A national committee or working groups can effectively plan activities when the group meets regularly and its size is kept to a manageable number.
- Rollout of TB/HIV collaborative activities is facilitated by the simultaneous rollout of ART services.
- High staff turnover requires ongoing retraining for TB/HIV collaborative activities.
- Provider-initiated HIV testing can be rolled out faster than CPT and IPT activities.
- Because of their role in pharmaceutical management and dispensing, pharmacies are an important component in TB/HIV collaborative activities; however, hospital pharmacy staff were often not aware of their hospital's TB/HIV collaborative activities, nor did they participate in the trainings. Including pharmacy staff in the actual planning and management of TB/HIV collaborative activities would make them active stakeholders in the process and increase their commitment to ensuring the availability of necessary commodities through record keeping, quantifying requirements, and advocating for funds, which could decrease treatment interruptions and adherence problems.
- Using multiple and redundant reporting forms is inefficient and creates confusion about which one to follow, which leads to a lack of consistency in the information recorded and reported and may foster underreporting.
- Programs do not usually collect data on patients receiving CPT, so complete records of the total number of patients receiving CPT are unavailable. Even when reporting forms for CPT are available at the TB and HIV/AIDS clinics and at the pharmacy, the data collected may not be useful for quantifying pharmaceutical requirements at the facility if the amount of co-trimoxazole dispensed for all patients on CPT is not tallied.
- When data collection is incomplete, it is inadequate for use in planning and quantification of TB/HIV collaborative activities.
- Having dedicated data clerks strengthens the information management necessary to provide TB and HIV/AIDS services. Data clerks can be used most efficiently and data are more complete when information management services are provided by one department.
- Guidelines that do not give specific information on how to manage pharmaceuticals and commodities for TB/HIV collaboration activities may allow flexibility in providing services such as dispensing and adherence counseling, but can also lead to confusion about details such as where to order a particular commodity.

- TB and HIV/AIDS program monitoring could potentially be combined if supervisors were trained in both areas and equipped with appropriate supervision checklists.
- Although an uninterrupted supply of pharmaceuticals and commodities is an indicator for TB/HIV collaboration success, more concrete guidance needs to be given to assure that the availability of supplies is monitored during supervisory visits.

### ***Managing Pharmaceuticals to Implement Interventions***

#### *Providing HIV Testing and Counseling*

- Shortages of HIV test kits occur mainly because of the short shelf-life and high price of the kits combined with poor inventory management, rather than the increase in demand due to diagnostic counseling and testing services. Shortages sometime occur in the commodities required for conducting the test, rather than in the test kits themselves.

#### *Introducing Isoniazid Preventive Therapy*

- Providing IPT requires other commodities besides isoniazid, such as pyridoxine and x-ray films; therefore, programs need to assure that all supplies are available according to the guidelines. Shortages do not occur when the number of patients served is small, and when the programs collaborate well to assure adequate funding for the commodities required.

#### *Introducing Co-trimoxazole Preventive Therapy*

- CPT significantly increases the workload of pharmacy staff, although not as much as ART does.
- When patients receiving CPT are not also on ART, the pharmacy does not know if the patient is on TB treatment or is a pre-ART patient. Because the pharmacy does not usually keep records of these patient groups, data are inadequate to quantify requirements for CPT.
- A lack of joint and coordinated procurement planning results in stock-outs of co-trimoxazole for CPT. Defining large buffer stocks in the guidelines does not make up for poor quantification at the facilities or a lack of coordination at national level.
- During shortages of pharmaceuticals and commodities at the facility level, local nongovernmental organizations may help bridge the gap.

#### *Monitoring and Promoting Treatment Adherence*

- Medication adherence measurement and monitoring are the weakest areas for TB/HIV treatment.
- Adherence to CPT varies significantly among different facilities. Contributions to poor adherence include insufficient time for counseling, interruption of supplies in public facilities, and adverse drug reactions, such as gastrointestinal upset. Facilities are using different approaches to minimize gastrointestinal upset.

- Adherence monitoring and counseling can be supported by the pharmacy, but suffers when increases in patient load are not met with adequate human resources and infrastructure.
- Adverse drug reactions appear to be rare, however, data on adverse drug reactions are rarely collected.

## **Conclusions**

The results of the assessment showed that Ethiopian health facilities commonly offer provider-initiated HIV counseling and testing for TB patients. In addition, CPT is widely available at all health facilities, although patient follow-up is better managed at TB/HIV pilot sites, where they dispense co-trimoxazole directly at the TB clinic. IPT is not as well accepted among program managers and health providers—besides the pilot sites, only one other hospital had introduced IPT.

The goal of the assessment was to answer a series of questions regarding different pharmaceutical management issues related to TB/HIV collaboration activities—

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

The assessment found that TB/HIV policy documents did not address facility management of commodities required for TB/HIV collaborative activities. This gave the facilities the flexibility to establish pharmaceutical management systems appropriate to their particular situations; however, the lack of guidance may have also contributed to inadequate emphasis on commodity management which resulted in shortages of commodities such as co-trimoxazole and HIV test kits.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense and finance) (1) commodities used by both programs and 2) commodities required for new interventions? What are the conditions that influenced this decision?*

The pharmaceutical management strategy was to make one program responsible for the management of a specific commodity, which would be integrated into that program's regular supply system. Because the programs felt that their respective management structures were working well, they had no interest in merging their programs. Respondents did not indicate that specific conditions guided decisions about which commodities would be provided by which program; it appears as if decisions were based on the historic supply of particular drugs, (e.g., isoniazid by the TB program) or by the sources of funding available (e.g., co-trimoxazole being procured with Global Fund resources and managed by the HIV/AIDS program). Collaboration between the programs worked well in that they had no intention of overlapping their commodity management.

*To what extent have TB and HIV/AIDS programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?*

The TB and HIV/AIDS programs wanted to introduce complementary recording forms for HIV testing and CPT prescribing to simplify data collection. However, such data is not used to quantify requirements at the facility level because consumption data from the laboratory is usually used for HIV test kits, and comprehensive data on the number of patients receiving CPT are not available.

The TB and HIV/AIDS programs did not establish any common procedures to promote treatment adherence; the methods they used mainly depended on available resources. The collaboration has not resulted in better reporting of adverse drug reactions, although a system for reporting adverse drug reactions was already established in Ethiopia.

*Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities in order to increase effectiveness and efficiency?*

The pharmaceutical management system in Ethiopia has recently been restructured, although this was unrelated to the TB/HIV collaboration activities. A TB program staff member responsible for commodity management is now positioned in the drug management unit of the Ministry of Health, rather than in the TB program office, which may promote more effective collaboration in commodity management between the programs.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed for TB/HIV collaboration and pharmaceutical management?*

Because the TB/HIV collaboration has not had much effect on the pharmaceutical management system, little can be said about the advantages and drawback of collaboration in this area. Assessment findings, however, suggest that opportunities exist for improving pharmaceutical management for TB/HIV activities. These include—

- Increasing awareness and commitment of pharmacy staff and supervisors to assure an uninterrupted supplies of commodities by including staff in the planning process and training for TB/HIV collaborative activities
- Improving quantification of co-trimoxazole requirements for both CPT and acute care through more systematic data collection at facility level
- Assuring adequate funding for commodities required for the collaboration
- Investigating the quantities of commodities required to exclude active TB in HIV-positive patients to prevent shortages when IPT is rolled out
- Improving data collection and pharmaceutical management by developing a comprehensive management information system for TB/HIV commodities and providing respective training
- Preventing interruptions or discontinuing CPT services by improving information management and facilitating access to the prescribed medicines
- Increasing service efficiency and reducing patients' waiting time by providing prepackaged medicines for prophylactic therapy

- Improving patient adherence to preventive therapy by investigating and designing simple techniques for adherence monitoring and promotion and involving the community
- Using human resources and computers more efficiently by training data clerks to keep records for collaborating units (e.g., TB and HIV/AIDS clinics and pharmacy)
- Assuring the effectiveness of services and the commitment of health care providers by studying the cost effectiveness of IPT services
- Collecting data on adverse drug reactions to confirm that they are not a problem

## Appendix A. Summary of Services in Assessment Facilities

Activity	PILOT SITES				EXPANSION SITES			NON-COLLABORATION SITES			
	ZWH	KZC	HOH	GOC	GOH	ALH	ADH	BOC	BIH	BTC	BTH
TB patients referred for HIV testing	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Most	Yes	Most
Records used to estimate requirements of HIV test kits	No	No	No	No	No	No	No	No	No	No	No
Shortages of HIV test kits prevented TB patient testing	No	No	No	Yes	Yes	Yes	No	No	No	No	No
HIV+ patients screened for TB	Yes	Yes	Yes	Yes	Yes	Yes	Most	Yes	Yes	No	Yes
Screening for TB: 1. Physical 2. Sputum 3. X-ray 4. Other	1,2,3	1, 2,3	1,2,3	1,2,3	1,2,3,4	1,2,3,4	1,2,3	1,2,3	1,2,3	—	1,2,3
Where HIV-positive patients screened for TB (1) VCT; (2) TB; (3) HIV; (4) Outpatient Dept	2,3	2,3	1	1	1,4	3	3	3	3	—	3
X-ray services available	Yes	No*	Yes	No*	Yes	Yes	—	No*	Yes	No	—
Conditions for VCT referral to TB clinic (1) All patients for TB screening; (2) Patients with suspect TB infection; (3) Patients for IPT; (4) No referral	1	1	2	2	4	2	4	2	4	4	4
CPT routinely offered to all HIV/TB co-infected patients	Yes	Yes	Yes	Yes	Yes	Most	Yes	Yes	Yes	Yes	Yes
Who prescribes CPT to new TB/HIV patients (1) TB clinic; (2) ART clinic	1,2	1,2	1	1	2	2	1	1,2	1	1	2
Where CPT dispensed to TB/HIV co-infected patients	Pharm	TB	TB	TB	TB	Pharm	Pharm	Pharm	Pharm	TB	Pharm
Where CPT dispensed after TB completion	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm		Pharm
Where CPT dispensed to not co-infected patients	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm	Pharm
Shortages of CPT	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Addressing CPT shortages (1) Patients buy (2) General use stock transfer (3) Partners	1,3	1,2	—	1	1	1,2	1,3	1,2	1,3	—	—
IPT prescribed for HIV+ patients	Yes	Yes	Yes	Yes	No	No	—	No	Yes	—	—
Where IPT dispensed to HIV+ patients	TB	VCT	VCT	VCT	VCT	—	HIV	—	TB	—	—
TB clinic staff receives training on TB/HIV collaborative activities	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pharmacy staff receives training on TB/HIV collaborative activities	No	No	Yes	No	No	No	No	No	No	No	No
HIV clinic staff receives training on TB/HIV collaborative activities	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
VCT staff receives training TB/HIV on collaborative activities	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	?	Yes	Yes

ADH= Adama Hospital; ALH = ALERT Hospital; BIH= Bishoftu Hospital; BOC= Bole Health Center; BTC = Butagera Health Center; BTH = Butagera Hospital; GOC = Gondar Health Center; GOH = Gondar Hospital; HOH = Hosaena Hospital; KZC = Kazanchis Health Center; ZWH = Zewditu Hospital

\*Facilities reporting that they do x-ray screening, but also reported no x-ray equipment may refer patients to another facility. The health center level do not do have X-ray equipment but refer patients to other facilities where available for testing.

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## **Appendix C. Data Collector and Key Stakeholders Interviewed**

### **Data collector**

Mr. Tenaw Andualem

### **Key stakeholders**

- Dr. Tesfaye Abichu, FMOH/WHO National TB/HIV Coordinator
- Dr. Getachew Wondimagegn, FMOH, TBLPC team leader
- Dr. Zerihun Tadesse, Head, Disease Prevention and Control Department, FMOH
- Pharmacist Amare, TBLPC/PSLD logistics officer
- Dr. Afework Kassa, HAPCO, HIV/AIDS and other STIs team leader
- Sr. Yetmework Tekle. HAPCO, HIV/AIDS and other STIs team
- Mr. Negussu Worku, FMOH/WHO, National M&E and Data Manager
- Mr. Edmealem Ejegu, Associate RPM Plus/MSH and FMOH
- Sr. Genet Yoseph, Addis Ababa RHB, TB coordinator and TB/HIV focal person
- Sr. Hana Kumsa, Addis Ababa RHB, HIV/ART coordinator
- Pharmacist Ezera Muluneh, Addis Ababa RHB, Pharmacy team leader
- Dr. Zelalem, Ormoia RHB, TB coordinator and TB/HIV focal person
- Pharmacist Tigist, Oromia RHB, Acting head for Pharmaceuticals Administration and Control Services

### **Zewditu Memorial Hospital**

- Dr. Aster wa Amare, head of TB/HIV/ART clinic
- Dr. Addikalu/TB clinic
- Sr. Alma, CT clinic
- Ms. Addlem, VCT data clerk
- Laboratory Head

### **Kazanchis Health Center**

- Sr. Tenage Tadesse, TB/HIV coordinator
- Dr. Haregewoin, ART/OI physician
- Sr. Meseret Abebe, VCT counselor
- Mr. Henock Yezid, pharmacy

### **ALERT Hospital**

- Dr. Eshetu Kebede, TB clinic
- Nurse Ketema Kebede, OPD head nurse
- Pharmacist Ayalew
- Mr. Negash, pharmacy

### **Bole Health Center**

- Sr. Martha Yimer, TB/HIV coordinator
- Dr. Almaz Afersa, ART/OI clinic
- Ms. Ephrah Ibrahim, pharmacy head

### **Bishoftu Hospital**

- Nurse Tesfaye Alemu, TB clinic
- Pharmacist Gezahagn
- Tizeta Assefa, HIV/ART clinic
- Mr. Misgnaw, data clerk

### **Adama Hospital**

- Sr. Melke Tadesse
- Tibka Moges
- Dr. Alemayhu
- Ms Selamwit Zemedede, HIV/ART clinic data clerk
- Mr. Smere Belay, HIV/ART clinic data clerk
- Psychiatric Nurse Fregenet Geletu, VCT clinic
- Pharmacist Alemayehu
- Sr. Almaz Asfaw, TB clinic
- Sr. Laketch

### **Butagera Health Center**

- Nurse Zenebe Gedlu, TB/HIV coordinator and counselor
- Mr. Ibrahim Kemal, pharmacy technician

### **Butagera Hospital**

- Sr. Askale Maru, TB clinic
- Dr. Demes Arega, HIV physician
- Mr. Mohamed Hussein, VCT counselor
- Abdelkaf Said, pharmacy
- Belete Soboka, pharmacy

### **Hosaena Hospital**

- Mr. Tenkir Bankum
- Sr. Yeshe Abebe, HIV/ART clinic
- Sr. Genet Mitiku, VCT counselor
- Mr. Esrael Ayele
- Mr. Fasika Alemayehu

### **Hadya Zone Health Department**

- Mr. Tamre Dutso, HIV coordinator
- Mr. Aylele Lema, Disease Prevention coordinator
- Mr. Petros Anye, VCT coordinator
- Sr. Hirut Bekele, HIV care and support

### **Gondar Health Center**

- Mr. Birku Amara, Head of health center and ART
- Sr. Almaz Lema, TB/HIV coordinator

**Gondar University Hospital**

- Sr. Meseret Senbeto, TB clinic
- Nurse Solomon Guesh, ART clinic
- Sr. Fate Ahmed, VCT
- Mr. Tezera Mekonnen, data manager
- Mr. Elias Geremaw, head of hospital pharmacy

**North Gondar Zone Health Department and Gondar Woreda Health Office**

- Mr. Fasil Chekol, North Gondar Zonal Health Department
- Ms. Azeb Atenafu, Gondar Town Woreda Health Officer



## ANNEX 2.

### MANAGING PHARMACEUTICALS FOR TB/HIV IN COLLABORATION IN KENYA: ASSESSMENT RESULTS

#### Background

Kenya has a large and increasing TB disease burden. With a population of over 33 million, Kenya's incidence of TB cases is estimated at 619 per 100,000 people per year.<sup>16</sup> The case detection rate for smear-positive cases is estimated at 46 percent, while the treatment success rate is 80 percent.<sup>17</sup> The number of cases reported to the National Leprosy and Tuberculosis Control Programme (NLTP) from 1987 to 2004 increased 10-fold from 10,515 to 106,000.<sup>18</sup> This dramatic increase is largely due to the increased prevalence of HIV/AIDS. Most TB patients are in the 15–35 years age group, which corresponds to the age group most affected by HIV; 29 percent of adult TB patients are HIV-positive.<sup>19</sup>

In Kenya, about 6.7 percent of all adults were estimated to be infected with HIV in 2005,<sup>20</sup> and infection rates in women were nearly double that of men, according to the first national HIV prevalence survey, the *Kenya Demographic and Health Survey*.<sup>21</sup> Despite an overall decline, prevalence in some parts of the country is still high. Urban populations generally have a higher prevalence than rural populations (10 versus 6 percent).<sup>22</sup> One of the goals in the fight against the HIV/AIDS pandemic is to reduce prevalence in adults to less than five percent within the next five years.

#### ***Planning for TB/HIV Collaboration in Kenya***

In Kenya, although the TB and HIV programs operate as parallel systems, they work together to maximize resources and establish functional patient referral mechanisms. The essential TB/HIV-related activities requiring commodities as defined by TB/HIV guidelines include—

- Providing co-trimoxazole preventive therapy (CPT)
- Providing diagnostic testing and counseling (DTC) for HIV in TB clinics
- Screening HIV-positive persons for TB
- Providing TB preventive therapy for HIV-positive persons who are negative for TB, where feasible
- Introducing antiretroviral therapy (ART) to TB/HIV co-infected patients

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<sup>16</sup> WHO. (2006). Country Profile for Tuberculosis: Kenya 2004.

[http://www.who.int/GlobalAtlas/predefinedReports/TB/PDF\\_Files/KE\\_2004\\_Detailed.pdf](http://www.who.int/GlobalAtlas/predefinedReports/TB/PDF_Files/KE_2004_Detailed.pdf)

<sup>17</sup> Ibid.

<sup>18</sup> NLTP Annual Report, 2004.

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<sup>20</sup> WHO. (2005). Summary Country Profile for HIV/AIDS Treatment Scale-Up: Kenya.

[http://www.who.int/hiv/HIVCP\\_KEN.pdf](http://www.who.int/hiv/HIVCP_KEN.pdf).

<sup>21</sup> Central Bureau of Statistics (CBS) et al., *Kenya Demographic and Health Survey 2003*.

<sup>22</sup> NASCOP, *AIDS IN KENYA: trends, interventions and impact, 7th Edition, 2005*

To successfully implement these activities, Kenya is collaborating with several bilateral and multilateral partners that are providing technical and financial support. These partners include WHO, the GFATM, and several U.S. government agencies, such as the Centers for Disease Control and Prevention (CDC) and the USAID. To coordinate the implementation of TB/HIV collaborative activities, Kenya created a national TB/HIV steering committee in October 2004 that is guiding the establishment of similar coordinating bodies in provinces and districts. A TB/HIV national coordinator was also appointed from the NLTP to coordinate planning and implementing collaborative activities.

Each program receives separate funding for pharmaceuticals and commodities. The HIV/AIDS program largely depends on financial assistance from the GFATM and the President's Emergency Plan for AIDS Relief (PEPFAR), while the TB program's main funding sources include the Government of Kenya, whose funding has increased over the years to currently about 20 percent<sup>23</sup>, the Global Fund Round 2 grant that will also be used to procure second-line medicines, and Global TB Drug Facility grants.

Collaboration is planned for all levels of the health care system. All provinces and most districts have established functional TB/HIV steering committees, while health facilities are just starting the process. The committees comprise key stakeholders from HIV/AIDS, TB, and nongovernmental/faith-based organization (NGO/FBO) sectors. The role of these committees at every level is to plan for TB/HIV collaborative activities and resource mobilization, coordinate training and other capacity building activities, develop and implement advocacy and communication strategies, promote community participation, and monitor and evaluate the TB/HIV collaborative activities.

## **Study Methodology**

RPM Plus contracted with the International Network for Rational Use of Drugs (INRUD) in Kenya to conduct the study. The investigators were supervised remotely by two RPM Plus staff members in Arlington, Virginia.

The study involved a review of relevant policy guidelines and reports on TB, HIV/AIDS, and TB/HIV collaboration and interviews with key stakeholders at the national level. The investigators used an interview guide developed by RPM Plus to interview the Chief Executive Officer of the Kenya Medical Supplies Agency (KEMSA); the Chief MoH Pharmacist; the Program Manager and TB/HIV Collaboration Manager at NLTP; and the ART Clinical Coordinator and the Program Manager at the National HIV/AIDS and Sexually Transmitted Infections Control Program (NASCOP).

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<sup>23</sup> WHO. (2006). Country Profile for Tuberculosis: Kenya 2004.

## **Assessment Results**

### ***Establishing Mechanisms for Collaboration***

#### *Policies and Guidelines for TB/HIV Collaboration*

Kenya published national policy guidelines on TB/HIV in August 2005. To complement the policy guidelines, the national collaboration committee developed TB/HIV training curriculum (both a participant's manual and facilitator's guide) to build capacity and skills of health workers on how to implement TB/HIV activities and to promote activities' standardization. The training materials comprise seven modules that are used to train health care workers at TB/HIV sites. Logistics management training for TB and HIV program staff is carried out using protocols developed by the MoH in collaboration with partners.

The TB program revised the national TB and leprosy program guidelines in August 2006. The revised manual incorporates TB/HIV activities, including screening HIV-positive patients for TB, nosocomial transmission of TB, provider-initiated diagnostic testing and counseling for HIV in TB patients, co-trimoxazole preventive therapy, ART, and IPT.

The guidelines for ART in Kenya were last revised in December 2005; the guidelines do not contain any specific information on TB/HIV collaborative activities.

#### *Implementation of TB/HIV Collaborative Activities*

Kenya initially implemented TB/HIV collaborative activities in the Nakuru district, collaborative activities were supposed to have been scaled up to 30 districts at the end of 2005. By the time of the study, all districts with high-volume activity and all provincial and subdistrict hospitals were offering DTC. More than 3,000 health workers had been trained to implement TB/HIV collaborative activities.

About 256 sites in Kenya are accredited to deliver ART services, located mainly in national, provincial, and high-volume hospitals. TB services, on the other hand, are decentralized down to the dispensary level, with about 650 diagnostic sites and 1,700 facilities offering TB services. DTC is carried out in all TB treatment and diagnostic sites. Expanding ART services to the dispensaries, which represent the majority of all health facilities and are most accessible to rural, poor patients, has been a challenge. This is because only limited numbers of dispensaries currently function as full-fledged DOTS units offering both TB diagnostics and treatment services. Also, lack of skilled personnel and limited funds for training have also constrained service expansion. Because services are provided at different levels, programs use a jointly developed referral tool (discussed below) to link TB services to ART services and link health facilities to communities.

The TB program is monitoring the success of the collaborative TB/HIV services based on the following three indicators—

- The proportion of TB patients tested for HIV as part of the standard of care

- The proportion of HIV-positive persons screened for TB
- The proportion of TB/HIV co-infected patients who are placed on co-trimoxazole or ARVs or both

The national-level target for the TB program is to test 80 percent of TB patients for HIV/AIDS and to offer CPT to 80 percent of TB/HIV co-infected patients by the end of 2006. At the time of the assessment (November 2006), records showed that about 60 percent of TB patients were tested for HIV/AIDS, and 87 percent of HIV/TB co-infected patients were offered CPT (exceeding the target).

The TB/HIV sites implemented the referral forms to improve patient tracking and to enable committees to properly plan for referral within health institutions and communities where home-based care is available. Although the referral tool was piloted before being introduced at the TB/HIV sites, its use was not properly followed up after implementation. The TB program's area of concern is patients lost through referrals. Available records show that the link to ART clinics is still very weak, as only 30 percent of HIV/TB co-infected patients are referred to TB clinics for treatment.

### ***Managing TB/HIV Pharmaceuticals***

NASCOP and NLTP are responsible for quantifying their own program commodities. However, the TB program now provides data on TB patients who undergo DTC to the HIV program to use in quantification of HIV test kits. Although the ART manual recommends that all HIV-positive patients be screened for TB, little information on this is available since the data forms do not include TB screening as one of the indicators

KEMSA is an autonomous body of the MoH responsible for procurement, port clearance, storage, and distribution of pharmaceuticals for NASCOP, NLTP, and the whole Ministry of Health. Each program determines its own quantities of medicines and supplies that KEMSA should distribute. The TB medicines are distributed to regional warehouses, where the regional TB/leprosy coordinator ensures their distribution to district coordinators who supply them to the health facilities. The TB program noted that district stores and health facilities often have inadequate storage space for commodities.

KEMSA distributes ARVs directly to the pharmacies at treatment sites on a monthly basis using a courier system for sites that are not in the Nairobi area. In addition to the ARVs supplied by NASCOP, the PEPFAR program distributes ARVs through the Mission for Essential Drugs and Supplies (faith-based supplier of essential drugs and commodities); this distribution channel was not part of the assessment.

The pharmacist at ART sites manage and dispense ARVs, while TB medicines are managed in the TB clinics by nurses and clinical officers.

## ***Managing information for Monitoring and Evaluation***

NLTP and NASCOP operate separate information systems that track patient numbers, treatment follow-up, and commodity consumption and requirements. The TB and HIV programs have developed several forms to capture TB and HIV/AIDS information at service delivery points. These forms include—

- Patient referral tool
- TB treatment register (includes information about patients on CPT, IPT, and their CD4 count)
- TB patient record cards
- ARV registers

All TB/HIV sites should be monitoring TB/HIV activities based on these indicators—

- Total number of TB patients registered
- Number of TB patients counseled and tested, and number that tested HIV-positive
- Number of HIV-positive TB patients started on ART
- Number of HIV-positive TB patients started on CPT
- Number of VCT clients tested and the number that tested HIV-positive
- Number of HIV-positive VCT clients screened for TB
- Number of screened VCT clients diagnosed with active TB

The TB program collects and reports information through district coordinators at quarterly TB meetings. Provincial reports are compiled and analyzed before being sent to the central level. Two meetings are held at the central level annually to review these data and program implementation and provide feedback to the provinces. The TB program, however, reports that supervision, monitoring, and evaluation of activities is still inadequate.

In comprehensive care centers (where patients get treatment, care, medicines, and diagnostics for both TB and HIV/AIDS under the same roof), HIV data on TB/HIV co-infected patients are collected routinely; however, the national HIV/AIDS program does not routinely or systematically collect the information because of occasional funding shortages and lack of a continuous feedback mechanism.

### ***Implementing Interventions***

In addition to the TB and HIV program commodities that are used for diagnosing and treating TB and HIV infections, HIV test kits for TB patients, isoniazid for TB preventive therapy in HIV-positive patients, and co-trimoxazole for CPT are needed to effectively implement TB/HIV collaborative activities.

### ***HIV Testing in TB Patients***

Kenya has an opt-out policy for TB patients to be tested for HIV using the DTC process, which was implemented in October 2005. DTC is offered by health care providers as part of the

comprehensive care package for TB. At TB/HIV sites, provider-initiated HIV testing is routinely offered to all TB patients; patients who do not opt out are tested.

TB patients are initially referred to VCT sites and health facility laboratories for HIV testing, but acceptance is minimal. An investigation found that poor training of health workers at VCT sites and long waiting times at the laboratories resulted in poor uptake by the patients. Also, laboratory technicians have to send test results to the physicians who disclose HIV status, and some patients are lost during this time lapse. Now, a trained nurse at the TB clinic does HIV testing. In some health facilities with low case loads, testing may be done in the same room where patients are counseled. In high case load facilities, testing and counseling should be done in separate rooms, but this may not always be possible. Based on a national assessment of DTC acceptance, the TB program recommends that if a TB clinic does not have the capacity to test HIV patients, the preferred option is to refer patients to laboratories for testing. The least preferred option is referral to VCT centers, because more patients are lost through this channel. All provincial, district, and sub-district hospitals provide DTC.

The HIV program procures HIV test kits centrally and distributes them to facilities. Procurement is primarily funded by the GFATM. Shortages of HIV test kits have been reported, mainly because quantification had previously been done based on VCT needs only, without considering DTC consumption. These shortages affected the implementation of collaborative activities at some DTC centers, because health workers lost interest in providing services when HIV testing decreased. The shortages at some sites, however, caused more patients to request HIV testing because they thought health workers were keeping test kits aside for their relatives and friends. Shortages have also occurred at the national level, but mechanisms were quickly put in place to procure emergency stock. Now, the TB program provides data to the HIV program to help quantify test kits.

### *Isoniazid Preventive Therapy*

The NLTP recommends cautious use of IPT in HIV-positive individuals in whom active TB has been excluded. Concerns include the potential for amplifying isoniazid resistance if this valuable drug is given alone in the presence of unrecognized active disease. Kenya would also like to improve TB case finding and strengthen the TB laboratory network before IPT is rolled out to all TB/HIV sites.

NLTP's interim guidelines for IPT in HIV-positive persons recommends limiting IPT use to feasibility studies and for specific, captive populations including prisoners, the military, industrial clinics, and in health care workers. In addition, academic institutions with adequate human resources, and ART clinics (since ARV prescribing is only done by physicians who manage the sites) are allowed to provide IPT. IPT service is part of the comprehensive package of ART treatment offered by public facilities. During the assessment, it was reported that only two NGO programs funded by CDC, Ampath and Eastern Deanery AIDS Relief Program, were providing IPT on a pilot basis. The NGO programs procure, store, and dispense isoniazid at the pharmacy where ARVs are dispensed.

The NLTP is responsible for procuring isoniazid and laboratory commodities, such as x-ray films, using available funding. The TB program has tried to use partners to implement IPT, but adherence levels have been low. Although the national TB/HIV guidelines did not address which clinic (TB or HIV) should be responsible for providing IPT service; the HIV program is currently providing it, and IPT will most likely remain their responsibility.

### *Co-trimoxazole Preventive Therapy*

The national TB/HIV guidelines state that all TB/HIV co-infected patients should receive CPT, but does not discuss how CPT should be used. Patients are also supposed to be monitored for side effects, but the guidelines do not mention how this will be done or how patient adherence to CPT will be followed up. The training modules developed for training health workers on implementing TB/HIV activities do not address CPT issues in depth.

In Kenya, dispensaries, health centers, and hospitals have a particular selection of pharmaceuticals and commodities that are specific to each level of care. The selection of medicines for HIV and TB care both include co-trimoxazole, which is dispensed to patients for CPT free of charge. The selection of medicines for outpatient department care also includes co-trimoxazole used for acute treatment, but it is not available free to patients.

Each program procures and handles its own stock of co-trimoxazole with little collaboration. Because the TB program does not have funds in the budget to procure co-trimoxazole for CPT, funding comes from other sources, such as the GFATM and other donors.

Co-trimoxazole for CPT is dispensed to patients at ART clinic pharmacies, TB clinics, and at the outpatient department general pharmacy. When TB clinics have insufficient co-trimoxazole for CPT, patients get a prescription to fill at the outpatient department pharmacy. Some outpatient pharmacies that have prior arrangements with the NTLTP will provide co-trimoxazole for CPT free to the patients who come with a prescription. For some patients that cannot afford to pay for co-trimoxazole, a wavier system ensures that they get their medicines. No cases were reported of patients not accessing CPT.

At TB sites, co-infected patients receive CPT with their other TB medicines as part of the DOT approach during the intensive phase of treatment. During the continuation phase of treatment, co-trimoxazole is dispensed monthly with other TB medicines until patients complete TB treatment. Patients then transfer to the HIV/AIDS program to continue CPT. However, the TB program loses track of patients' access to CPT after they complete TB treatment. The TB program revised the TB recording and reporting forms to capture information on CPT. This data is reported as part of the TB quarterly reports from districts to the central level. The HIV/AIDS program does not routinely report on the consumption because its data collection tools have not been revised.

Kenya's CPT requirements need to be accurately quantified and a reliable source identified to meet all the demands because most sites (HIV and non-HIV) use the drug.

### *Monitoring and Promoting Treatment Adherence*

The NTLP promotes and monitors patient adherence during the first phase of TB treatment using the DOT approach weekly, and thereafter, monthly. The HIV program counsels patients on ARVs about the importance of adherence before and during the initiation of treatment. Methods used to assess adherence include self reporting, pill count, clinic attendance, and pharmacy records, and clinical and laboratory markers (e.g., CD4 count) that indicate treatment success or failure.

No information is available about adherence to IPT or CPT, other than CPT being included as part of the DOTS during TB treatment for co-infected patients.

## **Lessons Learned**

### ***Establishing Mechanisms for Collaboration***

The TB and HIV programs need to have a reliable referral system, when services are provided at different levels of care. The assessment showed that despite the implementation of referral tools and intensive training of health workers, the loss of patients referred from one service to another was a problem.

### ***Managing Pharmaceuticals to Implement Interventions***

- The TB and HIV programs use existing mechanisms to report TB/HIV data from the facility level to the central level, while using a joint mechanism to monitor and evaluate activities. Even though the TB reporting mechanism is reliably providing routine TB/HIV reports, the HIV program's reporting gaps will affect overall activity of monitoring and evaluation.
- Although the HIV program has had problems with consistent reporting, data reporting from comprehensive care sites where TB and HIV services are provided under one roof has been more reliable, because TB program staff ensure that all TB/HIV reports are collected and reported.
- The success of TB/HIV collaborative activities relies on the motivation of health care workers.
- Kenya included the commodities needed for TB/HIV collaborative activities as part of their supply system for different levels of care. Incorporating the new intervention commodities into the existing supply system will help ensure that the new services are included in program budgets and planning, which will facilitate their implementation.

### ***Providing HIV Testing and Counseling***

- TB patients' acceptance of provider-initiated HIV testing depends on the set-up of counseling and testing services. Acceptance was highest when counseling and testing was done directly by the TB clinic nurse, and was worse when patients were referred to the VCT clinic where they had to wait.
- Nurses can be trained to be good counselors and to conduct HIV testing.

- HIV programs should consider all user groups, (VCT and DTC), when quantifying HIV test kits. The omission of DTC patients in the quantification calculation contributed to stock-outs of HIV test kits.

### *Introducing Isoniazid Preventive Therapy*

IPT has not been widely implemented because it depends on well-trained health providers and laboratory supplies, such as X-rays, to rule out active TB cases.

### *Introducing Co-trimoxazole Preventive Therapy*

- Patients and providers find CPT services highly acceptable.
- As co-trimoxazole financing has been a challenge, the TB program could not always include the medicine in its essential care package. Some patients were required to buy their own medicine for CPT.
- Good coordination and collaboration between the pharmacy and HIV and TB providers at the facility level helps provide a continuous supply of co-trimoxazole for patients on CPT, because programs may be able to exchange stock or may be able to use general supplies in times of shortages. Training health care workers in logistics management also appeared to mitigate shortages. In addition, increasing the awareness and involvement of pharmacy staff at facility level should be beneficial.

### *Monitoring and Promoting Treatment Adherence*

- Incorporating CPT into the DOT approach to TB treatment services was a successful way to monitor CPT while patients are on TB treatment.

## **Conclusions**

The collaboration between the TB and HIV programs needs strengthening; for example, NASCOP had little input into the TB/HIV guidelines published in 2005. Although, there is a general willingness to increase collaboration, it appears to be limited to those involved with clinical activities.

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

The TB and HIV programs operate independently, and collaboration has so far focused on the clinical aspects of patient care and some information sharing on program management. Policies and guidelines on TB/HIV collaboration generally do not address pharmaceutical management; the TB/HIV guidelines published include no guidance on the procurement and management of commodities required for TB/HIV collaborative activities. This could be a result of not including pharmaceutical managers in the guideline development process.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense and finance) (1) commodities used by both programs and (2)*

*commodities required for new interventions? What are the conditions that influenced this decision?*

Most TB sites have successfully scaled-up DTC, however, implementation has been affected by shortages of HIV test kits. Shortages have been attributed to inaccurate quantification that did not consider DTC clients in the calculations. Shortages of co-trimoxazole have also hampered CPT dispensing, but reportedly patients have been able to afford to buy co-trimoxazole from other sources when necessary.

*To what extent have TB and HIV programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?*

Each program manages its own information collection and reporting on program activities, but they are supposed to collaborate on the overall monitoring and evaluation of TB/HIV activities. The two programs are also individually responsible for monitoring patients' treatment adherence and have not adopted any common procedures.

*Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?*

As a result of collaborative activities, health facility infrastructure was reorganized with the introduction of comprehensive care sites. No restructuring has occurred for program commodity management. Pharmacists working in the national AIDS program indicated that better collaboration is needed in the area of quantification, quality assurance, storage and distribution, adherence promotion and monitoring, as well as data collection and information sharing. This collaboration would reduce the duplication of work and improve efficiency.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed for TB/HIV pharmaceutical management?*

Major challenges faced with the implementation of TB/HIV collaborative activities included—

- Limited human resources (training, skills, and motivation)
- Limited funds to train health workers
- Inadequate infrastructure; limited space for privacy in testing of HIV patients at TB clinics
- Inconsistent supply of pharmaceuticals and commodities, particularly test kits and co-trimoxazole
- Limited storage space for medicines and supplies at health facilities
- Inadequate supervision and monitoring and evaluation

## **Appendix A. Data Collectors and Key Stakeholders Interviewed**

### **Data collectors**

- Mrs. Dorine Kagai
- Mr. Julius Ombogo

### **Key stakeholders**

- Dr. Charles Kandie, Chief Executive Office, KEMSA
- Dr. F. M. Siyoi, Chief Pharmacist, Ministry of Health
- Dr. Jeremiah Chakaya, Program Manager, NLTP
- Dr. J. Sitienei, TB/HIV Collaboration Manager, NLTP
- Dr. Sylvia Ojoo, ART Coordinator (Clinical), NASCOP
- Dr. Ibrahim Mohammed, Program Manager, NASCOP



### ANNEX 3.

## MANAGING PHARMACEUTICALS FOR TB/HIV COLLABORATION IN MALAWI: RESULTS FROM A TWO-PHASED ASSESSMENT

### Background

With a population of about 12 million and an incidence of tuberculosis (TB) cases estimated at 409 per 100,000 people per year, Malawi has a case detection rate for smear-positive cases estimated at 39 percent, while the DOTS treatment success rate was 71 percent in 2005.<sup>24</sup> Malawi uses an eight-month TB treatment which is planned to be replaced by a six-month regimen using fixed-dose combinations. A country-wide study indicated that 72 percent of TB patients were HIV-positive.<sup>25</sup> WHO data from 2005 indicated that 50 percent of adult TB patients were HIV-positive.<sup>26</sup> Malawi has had a national TB program since 1964. In the late 1980s and early 1990s, the number of TB cases escalated and case fatality rates increased. Part of the increase in case detection can be attributed to the revitalization of the TB control program, but mainly, the increase was due to the rise of HIV infections. The case detection rates have leveled off since 1995, and DOT coverage has been at 100 percent since then.<sup>27</sup>

With a national prevalence of around 14 percent in 2004, Malawi has one of the highest HIV/AIDS rates in the world.<sup>28</sup> The National AIDS Commission was established in July 2001 to coordinate multisectoral implementation of the national response to the epidemic. As part of the country's larger decentralization process, Malawi established district AIDS coordinators and district AIDS coordination committees. Selected hospitals started supplying ART in 2001, but the government treatment roll-out did not start until 2003, when the first ARV treatment guidelines were published. By the end of 2005, about 38,000 people were receiving treatment at 60 public-sector facilities (central hospitals, district hospitals, and Christian Health Association of Malawi hospitals), with about 1,000 additional patients receiving treatment at 23 private facilities<sup>29</sup>—or about 23 percent of the estimated need.<sup>30</sup> Most health facilities have special ART clinics, which run daily at central hospitals, but only on certain days at district hospitals. The MoH has developed a five-year ART scale-up plan (2006–2010) to reach 245,000 patients by the end of 2010. Shortage of human resources, HIV test kits, infrastructure and funds are challenges to the roll out of ART services.

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<sup>24</sup> WHO. Global Tuberculosis Database. <http://www.who.int/globalatlas/dataQuery/default.asp>. Accessed May 2, 2007.

<sup>25</sup> Malawi Center for Disease Control. 2005. Report of a country-wide survey of HIV/AIDS services in Malawi for the year 2004. national TB program; HIV Unit, MOH; NAC; <http://www.who.int/hiv/Situational-analysis-05.pdf>.

<sup>26</sup> Ibid.

<sup>27</sup> Ibid.

<sup>28</sup> Malawi Ministry of Health. 2006. Treatment Guidelines for AIDS, 2nd ed. Lilongwe, Malawi.

<sup>29</sup> Ibid.

<sup>30</sup> WHO. 2005. Summary country profile for HIV/AIDS treatment scale-up. [http://www.who.int/hiv/HIVCP\\_MWL.pdf](http://www.who.int/hiv/HIVCP_MWL.pdf). Accessed February 2, 2007.

## **Planning for TB/HIV Collaboration in Malawi**

In Malawi, TB/HIV collaboration started with the ProTEST project, which was designed to assess interventions that help interrupt the sequence of events by which HIV infection fuels the tuberculosis epidemic. After the ProTEST project ended in 2002, the Malawi national TB control program had trouble continuing the activities or expanding to other districts. At a major meeting in September 2001, national TB program stakeholders agreed that TB activities should be decentralized to district health offices. In 2002, the national TB program, in conjunction with the National AIDS Commission, developed a three-year plan (2003–2005) for expanding joint TB/HIV activities.<sup>31</sup>

## **Study Methodology**

The study was conducted in two phases: the first phase covers information on activities and experiences on establishing the mechanisms for TB/HIV collaboration at the national and district levels and how pharmaceutical management was addressed in the process. The second assessment phase looked at how the collaboration was being implemented at the facility level. This phase examined the specifics of HIV testing and providing preventive therapies, such as how facilities are managing pharmaceuticals and commodities, monitoring and evaluation, and addressing patient adherence issues.

The first phase of the assessment included a review of relevant policy guidelines and program plans describing TB and HIV/AIDS control, TB/HIV collaboration, and pharmaceutical management of products required for control of the two diseases. The purpose was to examine the rationale and level of TB/HIV collaboration including interventions and approaches to pharmaceutical management.

In addition, staff from Management Sciences for Health's Malawi office interviewed the head of the national HIV/AIDS unit and the Deputy National TB Control Manager, both within the MoH. The goal of the interviews was to investigate the status of collaboration and the perception of stakeholders on the opportunities, challenges, and process of TB/HIV collaboration, especially related to the management of program pharmaceuticals and commodities, such as isoniazid and co-trimoxazole. Specific topics included policy and implementation strategy; program financing; pharmaceutical quantification, procurement, distribution, storage, and dispensing; and information management for monitoring and evaluation.

For the second phase of the study, RPM Plus worked with the national TB program to select public health facilities that are either exclusively supported by the MoH or receive additional support by different international organizations. Four districts were selected: Chiradzulu, Machinga, Ntcheu, and Thyolo. The district health office, the district hospital, and one health center were visited in each of the selected districts. RPM Plus developed the structured questionnaires used for the interviews. At the district hospital, TB and HIV program and pharmacy staff were interviewed.

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<sup>31</sup>TB-HIV Working Group. 2002. *Three year development plan for the implementation of joint TB and HIV services in Malawi*. Geneva: WHO. <http://www.who.int/hiv/3yr-development-plan.pdf>.

## **Assessment Results**

### ***Establishing Mechanisms for Collaboration***

#### *Policies, Guidelines, and Plans for TB/HIV Collaboration*

A national HIV/AIDS policy was released in October 2003 which emphasizes the need for a multisectoral approach, but TB/HIV collaboration was not highlighted specifically.

The national TB program's and National AIDS Commission's three-year plan (2003–2005) for expanding joint HIV-TB activities (mentioned above) proposed a set of nine objectives to fill the gap between the standard TB activities (funded by the national TB program through its five-year development plan) and HIV activities planned as part of the application to the GFATM—

- Provide VCT services for TB patients and the general public
- Provide IPT for HIV-positive persons who do not have TB
- Provide CPT to HIV-positive persons with TB
- Provide care and support to TB patients with HIV-related illnesses
- Provide secondary IPT to HIV-positive patients who complete a course of TB treatment
- Provide ART to HIV-positive TB patients
- Establish and maintain TB/HIV management capacity and coordination
- Establish and maintain relevant TB/HIV operational research
- Ensure TB/HIV collaboration for monitoring and evaluation

In October 2002, the plan was approved by the TB Program Steering Group, which includes MoH representatives and donors. It was then incorporated into the national TB program's five-year development plan (2002–2006) to allow the TB program's traditional donors (U.K. Department for International Development, Norwegian Agency for Development Cooperation, and Royal Netherlands TB Association) to support certain TB/HIV budget lines. WHO and the USAID provided additional financial support. Stakeholders agreed that the expansion of joint TB/HIV activities should fall under national TB program activities. There is no TB/HIV strategic plan for 2006 and beyond, but a new five-year development plan for TB/HIV issues will supposedly be developed. However, policies for TB/HIV collaboration in Malawi are incorporated in the different program's development plans and guidelines.

The 2002–2006 national TB program development plan addresses some pharmaceutical management issues, but not commodities required for TB/HIV collaboration. At the time of the study, the national TB program development plan guidelines were being revised to include TB/HIV collaboration, and the HIV/AIDS unit helped develop the new TB regimen for co-infected patients. The fifth edition of the TB program manual (2002) covers HIV testing of TB patients, CPT in co-infected patients, and TB treatment in HIV-positive patients.

The MoH published its *Five Year Plan (2006-2010) for the Provision of Antiretroviral Therapy and Good Management of HIV-related Diseases to HIV-infected Patients in Malawi* in December 2005. The document calls for co-trimoxazole to be used as prophylaxis; in addition, the second edition of the *Guidelines for the Use of Antiretroviral Therapy in Malawi* were

released in 2006. The guidelines cover ART and pharmaceutical management procedures for ARV medicines at health facilities with a focus on health care workers, and also ART in TB patients and CPT, but they do not address IPT.

In May 2003, the national TB program and the HIV/AIDS Unit and the National AIDS Commission issued guidelines for VCT and CPT in TB patients.<sup>32</sup> In 2005, the MoH developed a new separate policy for CPT. The policy recommends that co-trimoxazole be provided free of charge for preventive purposes for adults and children with HIV/AIDS Stages II, III, or IV, or patients who have a CD4 lymphocyte count of 500/mm<sup>3</sup> or less. The new policy also includes aspects of pharmaceutical management for the CPT intervention.

### *Mechanism for Managing TB/HIV Collaboration*

At the end of the ProTEST project, the national TB program first collaborated with the HIV/AIDS program to plan joint activities. In 2002, the National AIDS Commission was installed as a national umbrella organization, which created a need for an HIV/AIDS unit at the MoH to provide leadership for HIV/AIDS clinical care and support activities at the national and district level<sup>33</sup>— the unit then began collaborating with the national TB program. The TB/HIV working group that developed the first joint TB/HIV development plan dissolved, and now there are no regularly scheduled meetings between the TB and HIV programs.

During the ProTEST project, an MoH TB/HIV coordinator, funded by WHO, facilitated the collaboration between the TB and HIV/AIDS programs at the national level. The TB/HIV coordinator participated in both programs' meetings, such as the HIV/AIDS unit's management meetings and HIV/AIDS Technical Working Group meetings. Both programs were satisfied with this arrangement and considered this mode of collaboration beneficial. However, when the ProTEST project ended, so did the TB/HIV coordinator position, and while other national TB program staff tried to take over the TB/HIV activities, they became overburdened. The TB program director regretted the lack of collaboration between the two programs at the time of the assessment.

The district health offices and health facilities visited during the assessment have no standardized mechanisms for collaboration, despite having successfully implemented some TB/HIV activities. Respondents at the district offices defined their collaboration through the joint program activities, including follow-up visits of patients to the TB clinic and HIV clinic being held at the same day.

### *Implementation of TB/HIV Collaborative Activities*

According to the three-year development plan for TB/HIV collaboration, activities should have started in seven districts in the first year (2003), followed by another seven districts in the second year, with full country coverage in the final year. In 2003, 15 hospitals were selected to

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<sup>32</sup> Malawi TB-HIV Unit of the national TB program; HIV/AIDS Unit of the Department of Clinical Services; National AIDS Commission. 2003. *Voluntary Counselling, HIV Testing and Cotrimoxazole Prophylaxis for TB patients*. Lilongwe, Malawi. <http://www.who.int/hiv/VCT-CTX-guidelines.pdf>.

<sup>33</sup> Five Year Development Plan of the national TB program, December 2001.

implement TB/HIV collaborative activities, starting with HIV testing and CPT to TB patients to those patients who tested positive. The collaboration's major achievements have been the countrywide implementation of opt-out HIV testing of TB patients and the provision of CPT for HIV-positive TB patients. At the four district hospitals visited as part of the assessment, TB patients were routinely tested for HIV, and TB patients who are HIV-positive were offered CPT. However, HIV-positive patients who were not co-infected were rarely provided with co-trimoxazole for CPT, and IPT services were not offered in the public sector.

VCT clinics refer patients for TB testing only when they have suspected TB. Ntcheu district hospital was the only facility that routinely screens newly identified HIV-positive patients and refers them to the TB clinic for a sputum test. At the other hospitals, suspected TB cases (i.e., cough for three weeks or more) are sent to either the ART clinic or the outpatient department for initial sputum tests and then referred to the TB clinic as appropriate.

TB patients are admitted to a hospital for the first two weeks of treatment. Thereafter, the patients receive the TB medicines for their remaining 30 weeks of treatment from the TB ward to take to the health facility closest to home. Patients can choose to have their medicine intake observed at the health facility or by a guardian at home, and most patients choose a guardian. TB patients who are HIV-positive are automatically eligible for ART, but their acceptance into the program is not necessarily expedited. TB patients usually do not start ART before they complete the initiation phase of TB treatment. The national TB program plans to replace the current eight-month TB regimen with a six-month regimen using fixed-dose combinations. The new regimen has already been implemented in the Thyolo and Chiradzulu districts.

Health facilities in Malawi usually provide TB and HIV/AIDS services separately. ART clinics do not offer comprehensive care that includes TB treatment; therefore, if an HIV-positive patient has TB, then he or she will be referred to the TB clinic. This has resulted in patients having to come to the hospital more than once to pick up their different prescriptions.

The district hospitals have tried different approaches (Table 1) to improve TB/HIV services—

- Chiradzulu was the only facility visited that had implemented a one-stop service for patients co-infected with TB and HIV. TB patients receive ARV and TB medicines in the same clinic.
- Thyolo and Chiradzulu have started to offer ART to TB patients within the first two weeks of TB treatment during which TB patients are hospitalized. Thereafter, patients continue with home-based care.
- Ntcheu was the only hospital visited that indicated that it conducts routine TB screening at the ART clinic.
- Machinga hospital provides routine HIV counseling and testing for TB patients within the first two weeks of TB treatment, while TB patients are hospitalized.

Most TB patients referred from district hospitals to health centers had already been tested for HIV, and the patients' HIV status was either indicated on the patients' treatment card or assumed when patients bring their supply of co-trimoxazole to the health center. Two of the health centers visited in the assessment also offer ART through mobile services that the district hospital provides.

**Table 1. Health Center Services for TB and HIV/AIDS**

	<b>Chiradzulu</b>	<b>Machinga</b>	<b>Ntcheu</b>	<b>Thyolo</b>
<b>Services provided</b>	<ul style="list-style-type: none"> <li>• Continuing TB treatment</li> <li>• HIV testing</li> <li>• ART (mobile service)</li> <li>• CPT for TB patients through mobile clinic</li> </ul>	<ul style="list-style-type: none"> <li>• Continuing TB treatment</li> <li>• HIV testing</li> <li>• CPT for TB patients</li> </ul>	<ul style="list-style-type: none"> <li>• Continuing TB treatment</li> <li>• HIV testing</li> <li>• CPT for TB patients</li> </ul>	<ul style="list-style-type: none"> <li>• Continuing TB treatment</li> <li>• HIV testing</li> <li>• ART (mobile service)</li> <li>• CPT for TB patients</li> </ul>

### ***Managing TB/HIV Pharmaceuticals***

Most of the objectives listed in the implementation plan for TB/HIV collaborative services require the availability and effective management of specific supplies, such as medicines and diagnostics.

Program officers identified HIV test kits and co-trimoxazole as the main commodities required for both programs, possibly because they saw the referral of TB patients to counseling and testing and the provision of co-trimoxazole as the biggest successes of the collaboration. (IPT has not been fully implemented, and providing ART has remained the full responsibility of the HIV/AIDS program.) VCT sites are not yet consistently screening TB patients, but an HIV/AIDS program manager recommended it as a useful intervention.

For medicines required for collaborative activities, the programs decide which of them should procure which commodities. Programs tried to include important collaborative services in the national Essential Health Package, so they would be funded through the sector-wide approach (SWAp) to health financing in the future. For example, co-trimoxazole for CPT and HIV test kits are included in the Essential Health Package.

In Malawi, the CMS is the single-source supplier for all public health facilities. The CMS procures and distributes medicines to all three regional medical stores (RMS), which supply the hospitals and health centers in the districts. At public health facilities, pharmaceuticals are dispensed without charge. The HIV program and TB program use the CMS/RMS distribution system for some commodities, but for others, such as antiretrovirals, alternative procurement and distribution systems are in place. For example, the GFATM funds ARVs, and in 2006, also provided funds for co-trimoxazole for CPT. All commodities funded by the GFATM are procured by the United Nations Children’s Fund (UNICEF). UNICEF contracts with a private company to distribute ARVs directly to the health facilities, while HIV test-kits and pharmaceuticals for opportunistic infections (including future supplies of co-trimoxazole) are distributed through the CMS/RMS system. The national TB program’s central unit directly procures most TB medicines, reagents, and other supplies through an external procurement agent appointed by the U.K.’s Department for International Development. TB medicines are distributed through the CMS/RMS system to the district hospitals.

The HIV/AIDS unit worked closely with the national TB program to develop the structures for managing antiretroviral medicines based on the program’s structure for antituberculosis

medicines. The TB program uses the morbidity method to quantify medicine requirements, basing the calculation on requirements for existing patients, plus requirements for an estimated number of new patients. For ARVs, the HIV/AIDS unit is responsible for the quantification of medicine allocation to the individual facilities. The HIV program uses the planned scale-up figures for ART services; districts are given quotas of patients that can start ART per month. The HIV/AIDS unit, with support from partners, supervises ART implementation sites every quarter and also quantifies supplies and monitors stock status and storage of ARV medicines. Within the framework of the TB/HIV collaboration, the programs work together to conduct surveys to project the number of patients requiring treatment, which maximize available resources.

Currently, the TB and HIV/AIDS programs jointly plan where pharmaceuticals and supplies overlap program responsibilities. Although programs prepare individual procurement lists, they collaborate on the quantification of items used by both programs, which avoids double counting. Although program collaboration has helped improve the quantification of medicines, it still remains a major challenge for the HIV/AIDS program. The HIV program manager expects that a computerized system for forecasting and quantification would be beneficial.

With the implementation of the SWAp and decentralization in the health sector, ordering and procuring TB commodities will change over time. The national TB program will continue to conduct national procurement for the first two years. In the long term, however, the CMS will take responsibility for procuring and distributing TB medicines and supplies based on the projected requirements outlined in the district health plans.

### ***District Hospital Pharmacy Activities in TB/HIV Collaboration***

TB program commodities are stored at the pharmacy, but the program monitors stock levels and quantifies requirements. During quarterly visits, the TB officer checks stock cards for stock levels and consumption. Since TB/HIV collaboration has been introduced, the pharmacy keeps separate co-trimoxazole stock cards for CPT and for general use. While CPT for co-infected patients is dispensed at the TB clinic, some pharmacies dispense co-trimoxazole to HIV-positive patients not co-infected with TB that have received prescriptions from their clinicians. Pharmacies that do dispense CPT (Ntcheu, Machinga) do not monitor patients to see if they collect their CPT regularly, nor are any pharmacies involved in adherence monitoring. ARV medicines are also stored at the pharmacy, but monitored and dispensed by the ART nurse.

Individual pharmacies reported shortages in pharmacy staff. Suggestions to serve patients faster included pre-packaging co-trimoxazole for CPT and not registering CPT patients in the health management information system. The staff at Thyolo felt that pharmacy services had benefited from improved record keeping and prompt physical stock checks at the pharmacy. Pharmacy staff suggested that combining TB and ART orders and establishing a one-stop clinic for ARVs, TB medicines, and co-trimoxazole would maximize human resource efficiency.

Most pharmacy staff at the district hospitals who participated in the assessment did not perceive themselves as being involved in TB/HIV collaborative activities. Pharmacy staff were not trained in TB/HIV activities, but they got a briefing on CPT. Pharmacy staff identified training needs in CPT for TB/HIV patients, record keeping, and monitoring patient treatment adherence.

## ***Managing Information for Monitoring and Evaluation***

The TB program bases its information management system on quarterly cohorts, and the program uses quarterly reporting and supervision for monitoring program activities and supplies. At health facilities, the pharmacy stores TB medicines, but the TB program closely monitors available stock (e.g., by using shadow files for TB program supplies). There have reportedly been no stock-outs of TB drugs in recent years. The national TB program system of reporting on quarterly cohorts served as a model for the registration and monitoring system of patients receiving ARV medicines, but the TB and ART clinics do not collaborate on record keeping.

The HIV/AIDS program maintains a manual record-keeping system for ARV drugs. Clerks and nurses maintain registers and records at the ART clinic. Each patient on ART receives a patient ARV identity card, and the clinic keeps a patient master record card for ARVs. The ART clinic team completes a quarterly ARV cohort analysis form and a cumulative analysis form for monitoring patients. Details are checked during supervisory visits. The cumulative form provides the HIV/AIDS unit at the MoH with regular updates on the number of patients on first-line treatment who have substituted, switched, defaulted, stopped, transferred out, or died, as well as the number of patients reaching 95 percent adherence (based on pill counts).

The programs do not collaborate on monitoring and supervision for TB and HIV program activities at the district hospitals and health centers, even though both programs sometimes see the same patients. The frequency and duration of supervisory visits differs between the programs and the facilities visited. According to one of the assessment interviewees, the programs collaborated on the supervision of TB and HIV/AIDS activities at peripheral facilities, but when HIV/AIDS program activities scaled up and became more cumbersome, the programs separated their supervisory activities. At health centers, TB and HIV activities are also supervised by the TB and HIV/AIDS programs respectively. During their visits, the programs often use checklists that cover the availability of supplies or order quantities. Quarterly supervisory visits at ART clinics use a pharmaceutical security checklist and a comparison of medicine consumption records with medicine usage at the treatment unit. Supervisors also check HIV testing, referrals, information, education, and communication activities, and they quantify program commodities, particularly ARVs and HIV test kits.

## ***Managing Pharmaceuticals to Implement Interventions***

### ***HIV Testing in TB Patients***

HIV counseling and testing is the entry point to TB/HIV collaborative activities. Those interviewed said that the referral mechanism had been fully implemented. Counseling and testing officers work with TB officers to refer clients with TB to VCT sites.

The facilities visited as part of the assessment monitor HIV testing of TB patients through the TB register and sometimes through the VCT register, which shows how many patients are on TB treatment and ART. Data were available to calculate the percentage of new TB patients that are tested for HIV. District health officers and TB providers indicated that acceptance of HIV testing had been high in the previous quarter (up to 98 percent in two districts). These figures were,

however, not used to quantify commodities for HIV testing. Only the Ntcheu district TB officer was involved in the quantification of HIV test kits, because some TB officers also provide HIV counseling and testing.

Three of the four districts had experienced shortages of HIV test kits, which was likely to have hampered HIV testing in TB patients; however, the number of test kits used for TB patients is small compared to overall requirements. For instance in 2005, 482,364 HIV tests were performed in the country, and yet, of the 26,019 new TB patients that year, 12,243 (47 percent) had been tested for HIV, or 2.5 percent of the total. At the MoH, the HIV/AIDS unit is responsible for the quantification and supply of HIV test kits. The supply system for HIV test kits was revised in 2005 to better monitor requirements and use. Shortages of HIV test kits, human resources, infrastructure, and financial gaps are the major challenges for rolling out collaborative services according to the HIV/AIDS program manager.

### *Co-trimoxazole Preventive Therapy for Co-infected Patients*

In 2002, the MoH endorsed a policy that offered HIV counseling and testing and CPT to all eligible TB patients in Malawi. This package, which applied only to TB patients, was to be phased in over three years. Malawi had conducted operational research in two rural districts (Thyolo and Karonga) and one urban district (Blantyre) and found that providing a package of HIV counseling and testing to TB patients, plus co-trimoxazole for those who were HIV-positive, was feasible to implement routinely.<sup>34</sup> National guidelines on VCT and CPT were developed, and public facilities began providing CPT to TB patients in the third quarter of 2003. CPT for co-infected TB patients has been implemented in all sites including the Christian Health Association of Malawi facilities.

As an agreement of the collaboration, the TB program supplies co-infected TB patients with co-trimoxazole during TB treatment—thereafter it was hoped that patients would receive their co-trimoxazole from the district health office. TB patients first receive CPT as an inpatient, then as part of home-based care. After the initial hospital-based treatment, the TB units at health facilities provide the TB patients with TB medication and co-trimoxazole for the remaining months of TB treatment. The patient brings the medicine to the health center close to his or her house. The patient then collects monthly supplies of TB medicines and co-trimoxazole from the respective health facility (Table 2).

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<sup>34</sup> Chimzizi, R.B. et al. 2004. Counselling, HIV testing and adjunctive cotrimoxazole for TB patients in Malawi: From research to routine implementation. *Int J Tuberc Lung Dis.* 8(8):579-585.

**Table 2. Co-trimoxazole Dispensing Practices for HIV Co-infected TB Patients in Four Districts**

	<b>Thyolo</b>	<b>Chiradzulu</b>	<b>Ntcheu</b>	<b>Machinga</b>
<b>TB initiation phase</b>	TB ward (TB nurse)	TB clinic	TB clinic* pharmacy dispensary	TB clinic*
<b>TB continuation phase</b>	TB clinic	TB clinic through mobile services	TB clinic	TB clinic
<b>After completion of TB treatment</b>	Not provided	Not provided	Pharmacy	Not provided

\* Inpatients receive from the ward

The national TB program provides co-trimoxazole to TB patients that are HIV positive. When the guidelines for VCT and CPT in TB patients were issued,<sup>35</sup> the planners thought that it would not be feasible for the national TB program to procure co-trimoxazole, so the plan was to provide the CMS and health facilities with funds to procure additional co-trimoxazole. However, practice showed that keeping stocks of co-trimoxazole separate from those for general use was difficult. With insufficient supplies of co-trimoxazole being procured for general use, stock-outs and treatment interruptions of patients on CPT occurred, and the national TB program had no means to determine the use of co-trimoxazole at district level. As a result, the national TB program reconsidered and decided to procure the medicine as a line item of the TB program. Co-trimoxazole was included in the TB requisition form for the RMS and is distributed through the same CMS and RMS channels as other public health commodities. This way, most health facilities use separate stock cards for co-trimoxazole provided by the national TB program. Stock-outs of co-trimoxazole at the RMS between June 2005 and June 2006 led to stock-outs of up to one month at health facilities. One district received supplements from an international nongovernmental organization to fill the gap. However, public health facilities without external support have no means of ensuring patients' long-term access to CPT when stock-outs occur at the CMS/RMS.

The referring hospitals may follow up on the TB patients treated at the health centers. For example, the Chiradzulu district hospital receives a referral form once the patient has reported at the health center to continue treatment. However, Machinga and Ntcheu health centers had no feedback mechanism for CPT, or the centers only let the hospital know if there were problems, such as the hospital giving the patient an inadequate supply of co-trimoxazole to complete treatment.

At the health center, the TB office usually stores co-trimoxazole for CPT, which patients bring when they transfer from the hospital. Each patient's supply is kept in a separate pill bag. Only one health center regularly counted to see if patients brought sufficient supplies for their full TB regimen, and at three of the four health centers visited, some patients had not brought the full quantities needed to complete CPT during their TB treatment. In those cases, the health center either followed up with the referring hospital, used co-trimoxazole from the general use stock, or got additional co-trimoxazole from the district TB officer. Health center staff noted problems

<sup>35</sup> Malawi TB-HIV Unit of the national TB program; HIV/AIDS Unit of the Department of Clinical Services; National AIDS Commission. 2003. *Voluntary Counselling, HIV Testing and Cotrimoxazole Prophylaxis for TB patients*. Lilongwe, Malawi. <http://www.who.int/hiv/VCT-CTX-guidelines.pdf>.

with the lack of continuous co-trimoxazole supply for the duration of TB treatment, the lack of training of health center staff, and the lack of patient follow-up. In addition, providers indicated that co-trimoxazole was shared at home with family members and sometimes stolen. In addition, the health center was not directly involved in dispensing, but only served as a storage area for co-trimoxazole, which was a problem.

The TB clinics keep track of CPT for co-infected patients in the TB register, but do not track treatment interruptions. When shortages of co-trimoxazole occurred at Thyolo, patients were told to buy the medicine themselves, but none could afford it. When there were shortages at Ntcheu, staff placed emergency orders at the RMS.

The national TB program hoped that patients could continue to receive their co-trimoxazole from the health facility post-TB treatment, but CPT is often interrupted because of stock-outs of co-trimoxazole from the general supply. Three of the four districts indicated that they do not provide CPT after TB treatment has ended because of inadequate co-trimoxazole stock and because post-TB treatment CPT is not part of the policy. One district, Ntcheu, reported that CPT is provided after completion of TB treatment, but no records were available, and no monitoring system or follow-up was in place.

#### *Co-trimoxazole Preventive Therapy for HIV-positive Patients not Co-infected with TB*

A new policy was approved in 2005 with the goal of providing all eligible HIV-positive patients with CPT, but the policy had not yet been implemented at the time of the assessment. The HIV program has applied to the GFATM for funding for co-trimoxazole for this policy; the application was approved, but funding was not yet available.

Although ART clinics do not routinely provide CPT services to HIV-positive patients not co-infected with TB, some clinicians prescribe CPT to selected HIV-positive patients (e.g., for secondary prophylaxis after opportunistic infections). The ART clinics do not usually keep track of the number of patients receiving CPT. The patients collect the medicine from the pharmacy on a monthly basis, and the pharmacy indicates the amount of co-trimoxazole issued in the patients' health passport, which could be used to monitor treatment. Co-trimoxazole prescribed by the ART clinic is usually taken from general supply. The HIV/AIDS program communicates with the pharmacy about stock levels, and in Machinga and Thyolo, the ART clinic checked stocks in the pharmacy once a week.

Because the HIV/AIDS program was not yet providing co-trimoxazole, and therefore supplies for general use were insufficient, the TB program regularly provided CPT only to TB patients who are HIV-positive. The TB/HIV coordinator estimated that only about 30 percent of eligible HIV-positive patients receive CPT because of supply shortages. Only the ART clinic in Thyolo indicated that the HIV/AIDS program supplied co-trimoxazole. Thyolo regularly offers CPT to patients on ARVs who also have opportunistic infections. Machinga hospital provides routine CPT for children between 6–14 years who are HIV-positive, but not on ARVs. In Ntcheu, patients with a history of having received CPT are provided with one week of medicine, after that they must buy their own medicine.

The new policy for CPT envisions that once assigned a disease stage by a clinician, the patient will receive a three-month prescription of co-trimoxazole to fill at the pharmacy. Follow-up will occur in the general outpatient department, unless health care facilities run HIV/AIDS care clinics. The pharmacy will keep a CPT register that includes the patient's unique co-trimoxazole registration number, name, age, sex, and the date they receive the medicine. Pharmacy staff will monitor the number of patients starting and continuing on CPT through regular checks of the health facility pharmacies' CPT register. The MoH's HIV/AIDS unit will organize training for pharmacy technicians on how to monitor co-trimoxazole use and how to fill out the registers. When the new policy is introduced, the TB clinics will continue to provide CPT for TB patients; the ART clinic will dispense CPT to patients who receive ART; and patients not on TB treatment or ART will collect their co-trimoxazole from the facility pharmacy.

The national TB program and HIV/AIDS programs are convinced that CPT for HIV-positive patients is effective, but so far, this intervention has only been consistently implemented for co-infected patients. The TB clinics keep track of CPT for co-infected patients through a variety of registers and treatment cards; however, treatment interruptions are not tracked. The lack of policy and financing for co-trimoxazole procurement have hindered the wider implementation of CPT in HIV-positive patients without TB.

### *Isoniazid Preventive Therapy*

Providing IPT to HIV-positive patients without TB was one of the core interventions piloted by the ProTEST project. However, the Ministry of Health is not supporting the intervention until the national TB program gathers information about IPT from other countries. Because IPT for HIV-positive patients is not yet policy in Malawi, the HIV/AIDS unit is not implementing the intervention, nor are former ProTEST sites providing it. The ART guidelines from 2003 included a form that asked for the number of patients on IPT, as well as the number of patients that have completed IPT. However, this form is not in the second edition of the ART guidelines (2006).

For many years in Malawi, IPT has been recommended for children living in the same household with a newly diagnosed pulmonary TB patient; however, anecdotal reports suggest that IPT is not given to all children who should get the intervention. At the time of the assessment, IPT for children was not included in any regular recording forms at the TB clinic, so it was difficult to assess the current practice.

### *Monitoring and Promoting Treatment Adherence*

TB patients are admitted to the hospital for the first two weeks of treatment, where nurses monitor adherence. Thereafter, patients' medicine intake can be observed by a guardian or a health worker, and most patients chose a guardian. Guardians monitor adherence throughout the continuation phase of TB treatment, but do not record their observations. Guardians are also not asked to observe patients taking co-trimoxazole for CPT, but facilities reported that the same directly observed treatment system is used for CPT for co-infected patients throughout their TB treatment. Health center staff monitors the monthly collection of TB medication and co-trimoxazole. Patients are also asked to bring back any remaining drugs to their next visit, but

they do not always do so. The table below shows the methods of adherence monitoring for TB and CPT applied in the four districts visited according to the facility respondents.

**Annex 3. Table 3. Adherence monitoring of TB and CPT in co-infected patients**

	<b>Thyolo</b>	<b>Chiradzulu</b>	<b>Ntcheu</b>	<b>Machinga</b>
<b>TB initiation at hospital</b>	DOT	DOT	DOT	DOT
<b>TB initiation phase (two months)</b>	DOT	DOT	Guardian at home-based care	DOT
<b>TB continuation phase</b>	Pill count	Home-based care	Observe monthly supply or consumption	Guardian

HIV/AIDS guidelines recommend that every patient be monitored for adherence to ART, either by pill count or patient self-report. Because the ART adherence program was based on the TB treatment design, a guardian also observes adherence to ART; however, this practice is not strictly enforced, and patients are not denied treatment if they do not come to the clinic with a support person.

## **Lessons Learned**

The lessons learned from the two-part assessment of pharmaceutical management in TB/HIV collaboration in Malawi are categorized according to the respective recommendations in WHO's *Guidelines for Implementing Collaborative TB and HIV Programme Activities*.

### ***Establishing Mechanisms for Collaboration***

- Conducting regular TB/HIV committee meetings at national level was difficult. A working group successfully prepared a three-year TB/HIV development plan, but it was difficult to maintain regular meetings over time. No formal committees were in place to facilitate ongoing TB/HIV program collaboration.
- Appointing an HIV/TB coordinator who attends meetings of both programs can significantly help facilitate the collaboration at national level. The coordinator will be more efficient if he or she has no other major program responsibilities.
- TB/HIV collaboration may be more challenging at district level because TB and HIV services are often not provided in the same clinic, and no structures are in place to support the collaboration.
- Defining the program responsibilities for the specific TB/HIV activities is important. In Malawi, program responsibilities were clearly defined, resulting in the successful implementation of HIV testing and CPT for TB patients throughout the country.
- The lack of specific guidelines for managing commodities led to health facilities using different management approaches. For example, pharmacies did not receive guidance on how to store co-trimoxazole for CPT; therefore, some stored it separately as a program commodity, while others stored it together with co-trimoxazole for general use, using the same stock card.

- Because there was no collaboration between the programs and no involvement of the facility pharmacies, each program quantifies its own pharmaceutical requirements.
- HIV/AIDS programs may adopt reporting structures from the TB program to manage ARVs, but there are limitations to that approach because ART is life-long.
- The TB and HIV programs can maximize human resource efficiency by conducting common supervisory visits. The benefit of collaborating will depend on the frequency of visits and the work load of each program. Sharing transport for scheduled quarterly visits is cost efficient and fosters program communication and collaboration, especially for remote facilities.

### ***Managing Pharmaceuticals to Implement Interventions***

#### *Providing HIV Testing and Counseling*

- HIV counseling and testing is considered the entry point for collaborative activities, and HIV testing of TB patients has been implemented successfully in Malawi.
- HIV test kits are managed by the HIV/AIDS program, and the TB program is not involved in quantification because the number of tests required for TB patients is a small percentage of the total. However, shortages of HIV test kits, which have occurred previously, would affect collaborative activities.

#### *Introducing Isoniazid Preventive Therapy*

- IPT was piloted under the ProTEST project, but the government did not endorse a policy for IPT provision in HIV patients, and the intervention could not be scaled-up.

#### *Introducing Co-trimoxazole Preventive Therapy*

- Sufficient funding is needed to procure co-trimoxazole for all patients. Although both programs consider the provision of CPT to co-infected TB patients a success, eligible HIV patients not infected with TB are not routinely receiving CPT, except in some pilot districts, because of a lack of program funding for procurement and little effort at the district level improve pharmaceutical management practices that would assure uninterrupted supply.
- To ensure that sufficient stock is on hand, more accurate quantification of all patients that may use co-trimoxazole in the health system must be done because the drug is used for both CPT and acute infections.
- If appropriate quantities of co-trimoxazole are available for CPT, TB patients may still suffer treatment interruptions if facilities use the co-trimoxazole stock for general care.
- Obstacles to expanding CPT for TB and HIV patients can include the centralized diagnosis of TB cases, which is only done at the district hospital, which means that many patients need to travel long distances to collect co-trimoxazole.
- Medicine sharing in the villages and insecure storage that does not prevent theft of co-trimoxazole can present pharmaceutical management challenges.
- District officers made suggestions to improve the management of co-trimoxazole to improve the provision of CPT to TB and HIV/AIDS patients—
  - Make one program responsible for procuring the co-trimoxazole.

- Put sound monitoring mechanism in place for CPT to improve quantification information.
- Train health center staff on how to manage, store, and dispense co-trimoxazole.
- Staff from the ART clinics in Ntcheu and Thyolo also made suggestions to improve co-trimoxazole management—
  - Store and dispense co-trimoxazole for HIV/AIDS patients in the ART clinic to assure that HIV-positive patients have adequate supply (to avoid pharmacy rationing).
  - Give the responsibility for procuring co-trimoxazole to the HIV/AIDS program.
  - Train health care workers and pharmacy staff on the importance of CPT.
  - Clarify the policy on which HIV-positive patients are eligible to receive CPT.

### *Monitoring and Promoting Treatment Adherence*

- Modeled on the TB program, the HIV/AIDS program adopted the use of a guardian to monitor treatment adherence, although if patients do not indicate a guardian, they are not excluded from starting or continuing ART.

## **Conclusions**

The results of the assessment showed that health facilities in Malawi commonly offer provider-initiated HIV counseling and testing for TB patients. CPT has been introduced for TB patients who collect co-trimoxazole with their TB medication from the TB clinic. IPT is not yet provided at public health facilities, and TB screening of HIV-positive patients at VCT is limited to checking for prolonged cough.

The goal of the assessment was to answer a series of questions regarding different pharmaceutical management issues related to TB/HIV collaboration activities—

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

The assessment found that pharmaceutical management was addressed in some guidelines; for example the ART guidelines indicate how ARVs are managed, including those for TB-co-infected patients. The management of co-trimoxazole for CPT was described in the new CPT policy, but this was not implemented at the time of the study.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense and finance) (1) commodities used by both programs, and (2) commodities required for new interventions? What are the conditions that influenced this decision?*

The two programs continued to manage the products that they had historically managed. For example, the HIV/AIDS program carries out HIV tests, provides ART to co-infected patients, and manages HIV test kits and ARV medicines. HIV test kit management practices have been reviewed to improve the availability of test kits at the user point. Although these efforts should also benefit the implementation of TB/HIV activities, the review was not an TB/HIV

collaborative activity because the TB program was not involved. The TB program offers TB treatment for co-infected patients and manages TB drugs and co-trimoxazole for TB patients.

For CPT, which was a new intervention at the time of the assessment, each program was responsible for the patients they serve, because no one funding source covered all patients in need of CPT. The TB program manages co-trimoxazole for co-infected patients as long as patients are on TB treatment. Thereafter, the district health services should begin providing co-trimoxazole to TB patients as well as HIV patients who are not co-infected. At the time of the assessment, the HIV/AIDS program was advocating for funds to procure co-trimoxazole and to monitor CPT services. Shortages of co-trimoxazole were widely attributed to limited funding and the lack of a mechanism that assured that co-trimoxazole earmarked for CPT was used only for this purpose.

*To what extent have TB and HIV programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?*

The ART program was modeled after the TB treatment program and uses similar quarterly cohorts as a basis for program monitoring and pharmaceutical management planning. Both programs use morbidity data for the quantification of requirements, and both also monitor supply management during supervisory visits.

Both programs promote the use of patient guardians to support treatment adherence. In TB patients, CPT is monitored along with TB treatment.

*Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?*

TB/HIV collaboration has not led to a general restructuring of the pharmaceutical management system in Malawi. The country is, however, undergoing a process of decentralization and as more responsibility is given to the districts, they will become more involved in program planning and managing the pharmaceuticals and supplies needed to implement TB/HIV collaborative activities.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed for TB/HIV collaboration and pharmaceutical management?*

The collaboration worked well to implement HIV/AIDS counseling and testing and provide CPT to TB patients. Record keeping and monitoring of program activities and supplies of both programs have benefited from the structured approach based on quarterly cohorts. Collaboration in the clinical management of TB/HIV co-infected patients appears to work well at some facilities. In addition, using patient guardians to monitor treatment adherence to ART and TB treatment as well as preventive treatment, such as CPT, can help reduce the work load of the health facility staff and improve adherence.

Limited human resource capacity, shortages of some pharmaceuticals in the public supply system, and lack of a national policy for IPT have limited the expansion of collaborative activities.

## **Appendix A. Data Collectors and Key Stakeholders Interviewed**

### **Data collectors**

- Mr. Enock Kajawo'
- Mrs. Cynthia Kamtengeni

### **Key stakeholders national-level program**

- Dr. Rhehab Chimzizi, national TB program
- Mr. John H. Kwanjana, Deputy National TB Control Manager, Ministry of Health
- Dr. Edwin Libamba, Head of HIV/AIDS Unit

### **District-level health offices**

- Mr. Lipenga, VCT coordinator
- Mr. Nkhata, District Technical Officer
- Mr. Matapila, pharmacy technician
- Mr. Makhalira, District TB Officer;
- Mr. Kawale, District AIDS Coordinator
- Mrs. Mkombe, nurse in charge of pharmacy

### **Nsipe Health Center, Cham facility**

- Patrick Kabambe
- Anthony Chilikutali
- Benito Lekela

### **Bvumbwe Health Center**

- Mr. Koloviko, HIV/AIDS focal person
- Mr. Majoni, TB focal person
- E. Mambala, TB focal person

### **Ntaja Health Center**

- W. Ruben
- D. Milanzi, TB focal person

### **TB and HIV health facilities**

- Mrs. Matapila, pharmacy technician
- Juma Mizati, pharmacy technician
- D. Mkombe, nurse in charge of pharmacy
- Charles Mnyolo, AIDS Coordinator
- F. Gondwe
- Chandla
- Z. Kawale
- Mr. Makhalira

## ANNEX 4. MANAGING PHARMACEUTICALS FOR TB/HIV COLLABORATION IN TANZANIA: ASSESSMENT RESULTS

### Background

With a 2004 population of about 38 million and TB incidence of 347 per 100,000 population,<sup>36</sup> TB remains a public health problem in Tanzania more than 20 years after the country launched the National Tuberculosis and Leprosy Program. Tanzania is still striving to achieve WHO targets of detecting 70 percent of infectious TB cases and achieving a treatment success rate of 85 percent; in 2004, the estimated case detection rate for smear-positive TB was about 47 percent, while the treatment success rate for 2003 was 81 percent.<sup>37</sup> Although Tanzania is approaching the WHO target for treatment success, the 2003 death rate was 10 percent, and the number of TB cases has steadily increased from 11,753 in 1983 to 65,665 in 2004.<sup>38</sup>

Since 1983, when the first three AIDS cases were identified in Tanzania, the HIV epidemic has spread widely to all districts and communities. By the end of 2005, an estimated 1.4 million people were HIV positive<sup>39</sup> with about 260,000 living with AIDS.<sup>40</sup> According to UNAIDS, the prevalence of HIV in the adult population is about 6.5 percent, and about 7 percent of those infected are receiving ART.<sup>41</sup> Although the HIV prevalence is higher in urban areas, the number of new HIV infections in rural areas may be double that of urban areas by 2010, because three-quarters of the population lives in rural areas.<sup>42</sup> The large percentage of rural dwellers makes access to services and treatment scale-up a challenge.

The HIV epidemic has greatly increased the incidence of TB and mortality rates in Tanzania. About 36 percent of TB patients between the ages of 15–49 years are co-infected with HIV.<sup>43</sup>

### ***Planning for TB/HIV Collaboration in Tanzania***

In Tanzania, TB and HIV prevention and control programs are organized as separate entities operating in parallel. A five-year TB/HIV collaboration plan to scale-up voluntary counseling and testing (VCT), care, and support services for HIV/AIDS and related TB in 45 districts in mainland Tanzania was developed in 2003. This implementation plan was incorporated into the national HIV/AIDS strategy, which was submitted and approved by the GFATM for Round 3

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<sup>36</sup> WHO. 2006. *Country profile: United Republic of Tanzania*.

<http://www.stoptb.org/countries/GlobalReport2006/tza.pdf>

<sup>37</sup> The United Republic of Tanzania Ministry of Health and Social Welfare. 2006. *Manual of the National Tuberculosis and Leprosy Program in Tanzania*. 5th ed.

<sup>38</sup> Ibid.

<sup>39</sup> UNAIDS Epidemic Update, November 2006. Available at:

[http://data.unaids.org/pub/EpiReport/2006/2006\\_EpiUpdate\\_en.pdf](http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf)

<sup>40</sup> IRIN PlusNews Treatment Map: Tanzania, January 2006.

<http://www.plusnews.org/profiletreatment.aspx?Country=TZ&Region=EAF#>

<sup>41</sup> UNAIDS. 2006. *Report on the global AIDS epidemic 2006*.

[http://www.unaids.org/en/HIV\\_data/epi2006/default.asp](http://www.unaids.org/en/HIV_data/epi2006/default.asp)

<sup>42</sup> IRIN PlusNews Treatment Map: Tanzania, January 2006.

<sup>43</sup> WHO. 2006. *Country profile: United Republic of Tanzania*.

funding in 2004. According to the implementation plan, activities included VCT, IPT, CPT, treatment of sexually transmitted infections and other opportunistic infections, DOTS for TB, home care services, and psychological support. The plan proposed TB centers to provide comprehensive management of TB and HIV/AIDS treatment services.

The Korogwe, Iringa, and Temeke districts initially implemented TB/HIV collaborative activities in 2004 using resources from the GFATM and with assistance from WHO. Other supporting partners include PEPFAR, CDC, and PATH. Currently, partners are supporting the collaborative activities in 23 districts (out of 120 mainland districts). However, activities are not being implemented in all health facilities earmarked to provide TB/HIV services, nor are all interventions being implemented in all districts. To fill these gaps, the government of Tanzania provides some services using GFATM resources. Other districts are also implementing some components of the collaborative activities, such as recording and reporting, but these activities are not done systematically.

In November 2005, a workshop for 18 Ministry of Health representatives and TB/HIV stakeholders was conducted to discuss recommendations coming from an assessment of TB/HIV activities.<sup>44</sup> An assessment team comprising international health experts visited Tanzania in September 2005 to review collaborative TB/HIV activities, including diagnostic counseling and testing. During the workshop, participants reached consensus on an outline for policy and guidelines to implement TB/HIV activities in Tanzania, and a committee was established to coordinate national-level TB/HIV collaboration. This committee formed a subcommittee to develop the national policy on TB/HIV collaborative activities. The subcommittee finalized the TB/HIV policy document and submitted it to the MoH for approval in the last quarter of 2006.

## **Purpose of the Study**

MSH/RPM Plus Program designed a study to investigate commodity management in support of TB/HIV collaboration as described by WHO's *Guidelines for Implementing Collaborative TB and HIV Programme Activities*. This assessment focused on two issues—establishing the mechanisms for collaboration, which included planning and information management for monitoring and evaluation, and the management of pharmaceuticals needed for clinical interventions, such as HIV testing and counseling for TB patients, IPT, CPT, and treatment adherence.

This study report describes the implementation of TB/HIV collaborative activities in Tanzania and how pharmaceutical management has been addressed in policies, working documents, and in practice. The study addressed the following questions—

- To what extent has pharmaceutical management been addressed in the national TB/HIV policy?

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<sup>44</sup> The United Republic of Tanzania Ministry of Health, Workshop to Outline Implementation of WHO/CDC/KNCV Assessment Recommendations For TB/HIV Activities In Tanzania. Bagamoyo, 10 November 2005.

- What strategy has been proposed or implemented to manage (1) commodities used by both programs and (2) commodities required for new interventions? What are the conditions that influenced this decision?
- To what extent have TB and HIV programs adapted common procedures, such as for adherence promotion and information management?
- Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?
- What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed?

## **Study Methodology**

RPM Plus contracted with three consultants from Muhimbili University to conduct the TB/HIV study on pharmaceutical management in Tanzania. The consultants used an interview guide developed by RPM Plus to collect data from stakeholders at the national level.

Stakeholders included—

- Head of Care and Treatment Unit, National AIDS Control Programme
- Pharmacist, Care and Treatment Unit, National AIDS Control Programme
- Chief pharmacist, MoH
- Procurement pharmacist, Medical Stores Department (MSD)
- Participants in the 2005 TB/HIV workshop
- Staff members of the government's TB/leprosy program
- TB and HIV clinicians at PASADA (the Catholic Relief Services HIV/AIDS project in Dar es Salaam)

The consultants also visited five health facilities in Dar es Salaam, including one TB/HIV implementing site, to verify findings from the stakeholder interviews and to learn about the challenges faced at the facility level. The five facilities were the Muhimbili National Hospital, Amana District Hospital, Lugalo Military Hospital, Mwananyamala District Hospital, and Temeke District Hospital.

Areas addressed in the assessment included—

- TB/HIV national policies and guidelines, areas of collaboration, and roll-out plans
- Policies and plans on pharmaceutical management in support of TB/HIV collaboration
- Pharmaceutical management structures of the TB and HIV/AIDS programs and for the coordination of TB/HIV services, including information management and human resources
- Procedures used by the programs to select, quantify, procure, distribute, store, dispense, and finance pharmaceuticals and commodities
- Adherence monitoring and adherence promotion activities
- Perceptions of stakeholders on the opportunities and challenges of TB/HIV collaboration

## **Assessment Results**

### ***Establishing Mechanisms for Collaboration***

#### *Policies and Guidelines for TB/HIV Collaboration*

The National TB and Leprosy Program manual was revised in 2006 to incorporate a section on TB/HIV collaborative activities, including CPT for co-infected patients, IPT for HIV-positive patients without active TB, HIV counseling and testing for all TB patients, ART for TB patients, and treatment for HIV-positive patients with active TB. The TB program invited the HIV team to participate in the revision. TB recording and reporting forms at the district and facility levels were also revised to incorporate TB/HIV collaboration information. The revised manual and records have been endorsed by the Ministry of Health and disseminated to all the districts, but not all health workers in the country have been trained to use the new records. The non-TB/HIV sites are reporting limited data to the national level, and reporting is not done systematically.

The *National Guidelines for the Clinical Management of HIV and AIDS*, revised April 2005, provides information on CPT, IPT, and TB treatment in HIV co-infected patients. However, the guidelines address only the management of ARV medicines, not other pharmaceuticals or commodities needed for TB/HIV collaborative activities. In addition, a booklet called *Chronic HIV and TB Basic Care with ARV Therapy: Integrated Management of Adolescent and Adult Illnesses* was approved in March 2006. These guidelines, developed for health workers at dispensaries, health centers, and district outpatient clinics, provide clinical guidance for TB testing and co-trimoxazole and fluconazole prophylaxis.

#### *Basis for TB/HIV Collaboration in Tanzania*

The TB program receives funding from the Tanzania government, Royal Netherlands government, Irish Aid, the World Bank, and others. The HIV/AIDS program is funded in part by the Tanzanian government and international partners, such as the PEPFAR and the Clinton Foundation. TB/HIV collaborative activities are financially supported by the GFATM and other partners. Funds from donors who support TB are used strictly for TB activities and funds for HIV/AIDS are used strictly for HIV/AIDS activities. Although most donors have indicated a willingness to support TB/HIV collaboration, much more work has to be done to establish the areas and extent of collaboration.

TB/HIV coordinators have been recruited for 21 of the 23 districts that are supported by partners for implementing collaborative services. One person coordinates two small neighboring districts. The coordinators are responsible for compiling TB/HIV data, tracking patients, coordinating trainings, ensuring that TB patients have access to HIV/AIDS care and treatment centers (CTCs), and that HIV patients have access to TB services, and are supervising and monitoring collaboration. There is a national TB/HIV coordinator who spearheads collaborative activities.

At the health facility level, collaborative activities are coordinated through patient referrals between the TB and HIV/AIDS CTCs. ART services are provided only at secondary care-level facilities that have the capacity to manage ARVs, while TB services are mostly provided at the

primary health care level. However, some facilities have started providing both TB and HIV/AIDS services, although they are coordinated by the two separate programs.

Inadequate human resource for implementing TB/HIV collaboration is a limiting factor because the individual programs' personnel are already stretched thin, and collaboration will require additional staff.

The TB and HIV/AIDS programs work independently. Although the two programs are looking into areas of collaboration, the TB program management is concerned that if TB and HIV/AIDS activities merged, the TB program would be incorporated into the HIV program, thereby losing too much autonomy.

### ***Managing TB/HIV Pharmaceuticals***

The MSD is responsible for procuring and distributing all public-sector medical commodities, including those for TB and HIV/AIDS programs. Three MSD procurement managers are assigned to procurement for either the TB, HIV, or essential medicines program. The supply chain for commodities starts at the MSD main office, then the distribution is to zonal offices, then to regional offices, then to facilities. Depending on the products and their respective programs, distribution to facilities is based on a pull system (required quantities are calculated by the treatment sites) or a push system (required quantities are calculated at the central level).

For ARVs, the first allocation is made through a push system; for follow-on supplies, the pull system is used. A pull system is also used for HIV test kits. The MSD procures ARV medicines for the National AIDS Control Programme and distributes them to all accredited health facilities across the country. Health facilities order a three-month stock of ARV drugs from MSD. MSD procures co-trimoxazole for the essential medicines program while HIV test kits and ARVs are procured for the HIV program. However, the HIV test kits are distributed to VCT and CTCs as well as to TB clinics.

TB program commodities are quantified by the TB coordinator and district medical officer. TB clinics make quarterly orders using the number of TB cases notified in the previous quarter.

HIV commodities, including ARV medicines are quantified by the ART pharmacist and other pharmacy staff at the health facility; however, co-trimoxazole is still provided through the Essential Medicines Program rather than through the HIV program. Test kits are quantified by a laboratory technician responsible for HIV/AIDS care. ARV order quantities are based on the simplified consumption formula using stock on hand and the consumption rate—not on morbidity data. Data sources for quantification include the ARV dispensing register, ART report, and commodity request form. Quantification of requirements for newly established sites is done at the national level because of the lack of historical data.

The TB and HIV/AIDS programs do not intend to merge their distribution channels, because they feel that merging could weaken one or both of the programs.

Currently, TB medicines are stored in the hospital or clinic store managed by the pharmacist who works closely with the TB/leprosy program coordinator of the facility. TB medicines are dispensed at TB clinics, while ARVs are dispensed at the pharmacy. ARVs are kept at high-security stores, where one pharmacist is responsible for stock. The physical stock is checked every month. At some facilities, TB drugs are kept with the ARV drugs in the higher-security storage area because of cases of TB drug theft. At the facilities where TB and HIV/AIDS services are both provided, TB and HIV/AIDS drugs are stored at the pharmacy.

Co-trimoxazole for CPT and acute care are stored together in the main pharmacy. No records are kept on dispensing CPT at the pharmacy.

### ***Managing Information for Monitoring and Evaluation***

The TB and HIV/AIDS programs collect information on their respective program commodities. However, no data related to indicators for monitoring and evaluating the TB/HIV collaborative activities at health facilities were reported.

The TB program's information system is comprised of quarterly reports of TB cohorts sent by participating TB health facilities, both public and private (which have to qualify to receive TB medicines from the program). These data are used to quantify TB medicines needs. The TB program revised its TB recording and reporting forms for district and health facilities in February 2006 to incorporate data gathering for TB/HIV collaborative activity indicators. New information captured in the TB forms includes the patient's HIV status, if the patient is on CPT, ARVs, or pre-ART care, and the date started. Data are also available on the number of TB patients referred or tested for HIV. Revised recording forms have been disseminated to all DOTS sites in the country, but recording and reporting of collaborative information is still not routine, because not all sites have received training on providing TB/HIV collaborative services. Information derived from these records is not used for co-trimoxazole quantification, and there is no incentive to use the data, because no additional funding is available for the procurement of co-trimoxazole for CPT.

The HIV program has recently revised its recording and reporting forms to include TB/HIV information, but new forms have not yet been disseminated to CTCs. The HIV/AIDS program is responsible for providing data on the number of HIV-positive patients screened for TB and the number that were smear-positive, but these data are not routinely reported except as part of special studies.

Example of records kept at the CTC include—

- ART reporting form—in addition to ART data, this form also includes TB/HIV collaborative information, such as if the patient is a confirmed new TB case and if the patient is on CPT
- ART report and request form—this form is used for quantifying medicine needs at treatment facilities using the consumption method (collects data for ARV drugs only)
- Patient record form—this form includes TB/HIV collaboration data to determine if patient is a confirmed new TB case, on CPT, or on isoniazid
- ART dispensing register—this register documents dispensing information for ARVs

Information exchange was found beneficial for patient management. In view of drug interactions with rifampicin and high pill burden, the TB and HIV program decide together when to start ART in HIV-positive patients co-infected with TB.

### ***Implementing Interventions***

The products needed for the interventions described in Tanzania's plan for TB/HIV collaboration mainly include commodities for HIV testing and co-trimoxazole for CPT because IPT for HIV-positive patients is not yet recommended in Tanzania's national policy. One of the TB/HIV facilities (Temeke) is providing ARVs at the TB clinic on a pilot basis. This service will also be scaled up if the pilot is successful, but currently TB/HIV co-infected patients on ARVs are referred to HIV clinics to collect their medicines.

#### *HIV Testing in TB Patients*

Provider-initiated (opt-out) diagnostic counseling and testing (DCT) is offered at sites providing TB/HIV collaborative services, where health workers have been trained using the CDC training package for DCT. At TB clinics providing this service, the nurse counsels and tests patients for HIV infection. This service has been phased in by collaborative districts during 2006, while the original three districts have been implementing DCT for two years. However, not all TB clinics routinely test patients for HIV, and some patients are still referred to HIV/AIDS CTCs or VCT clinics for HIV testing. In addition, some nurses are still not confident in their ability to test for HIV, so they collect blood samples and send them to the CTC or VCT clinic for testing.

Acceptability of DCT by TB patients is reportedly very high—80 percent in 2006—according to the TB/HIV coordinator. An external evaluation of DCT for TB patients at selected implementing sites in September 2005 also reported high acceptance of DCT by patients that resulted in high referrals to HIV/AIDS CTCs, but there was limited access to CTCs for TB patients referred because the centers are overwhelmed with patients. Consequently, there has been discussion of incorporating CTCs at the TB clinics that have enough qualified human resources. In non-implementing sites, TB patients are sometimes advised to go for voluntary HIV counseling and testing, but not all patients follow this advice.

Supply of HIV test kits has been fairly regular, but a shortage of test kits between May and August 2006 affected TB/HIV services. Some bigger hospitals purchased their own test kits using money from a cost-sharing program and kept the tests free for patients.

#### *TB Testing in HIV-Positive Patients*

Health workers at HIV/AIDS counseling and testing centers are trained to screen for TB infection in HIV/AIDS patients. TB screening comprises a set of questions about TB symptoms and collecting the patient's sputum and sending it to the health facility laboratory. If a sputum smear is positive for TB, the patient is referred to the TB clinic for treatment. A concern raised by the TB program was that smear-negative patients are not followed up, despite them being an important group to monitor.

CTC services are provided at district and higher level health facilities; they have not been decentralized down to the health center or dispensary level, where TB treatment is more widely available. A long-term plan is to make TB clinics referral centers where HIV patients can also collect their ARV medicines. The provision of ART is being piloted at one TB site.

CTC staff do not always have time to screen patients for TB. The proposed solution is for CTC staff to participate in regular TB program meetings as a way to track patients. For example, during TB quarterly data exchange meetings, district coordinators come with TB records to track patients to prevent double counting; in addition, CTC records will be reviewed when CTC staff joins the meetings to determine the number of HIV-positive patients screened for TB and the number that are TB-smear positive.

### *Isoniazid Preventive Therapy*

IPT is not implemented in public health facilities in Tanzania due to difficulties in ruling out active TB, monitoring treatment adherence, and the challenge of patients completing six months of medication. There are also concerns about the spread of microbial resistance if IPT were adopted nationwide and about the period that patients will remain TB free after completing a course of IPT. In a country with 1.4 million people living with HIV, one study respondent suggested that over one million would theoretically need IPT. Finally, the TB program has been reluctant to release isoniazid as single drug because of concerns about developing drug resistance.

The national policy on TB/HIV collaborative activities does not yet require the National TB and Leprosy Program to implement IPT service.

### *Co-trimoxazole Preventive Therapy*

CPT is initiated in both HIV-positive patients and TB/HIV co-infected patients who meet the eligibility requirements for CPT and not on ARV therapy. For patients starting ART, CPT can be discontinued when the patient's CD4 count is greater than 200 cells/mm.

Co-trimoxazole is also largely used as a common antibiotic for acute treatment of bacterial infection. The essential medicines program procures co-trimoxazole nationally for both acute treatment and for CPT purposes. Health facilities purchase co-trimoxazole using their health facility budgets, and do not allocate additional funds for procuring co-trimoxazole used for CPT. Tanzania included co-trimoxazole for CPT procurement as a line item in the Global Fund round 3 HIV/AIDS program proposal. The plan is for the HIV program to procure co-trimoxazole for CPT when funds become available to be distributed to all HIV care and treatment centers.

Quantification of co-trimoxazole is not based on actual requirements but on available budget. Information collected through the revised TB and HIV program reporting and recording forms is not used to quantify medicine needs. As a result, occasional stock-outs of co-trimoxazole at health facilities force patients to buy their medicines from other sources, such as private-sector pharmacies. One of the health facilities visited in Dar es Salaam had co-trimoxazole stock-outs

for a total of 75 days between June 2005 and May 2006. They were attributed mostly to the inaccurate quantification, based on budget and not on actual need.

CPT is prescribed at the HIV clinic and dispensed monthly at the hospital pharmacy. In the three TB/HIV collaboration districts, TB staff have been trained to prescribe CPT for co-infected patients; however, dispensing is still done at the ART pharmacy. The plan is to scale-up this activity to allow other TB clinics to prescribe CPT.

The main problem with CPT implementation in the country is that uptake among TB patients has been very low, about 30 percent, according to one of the stakeholders interviewed. The reason for the low uptake has not been studied, but TB program managers suspected that providers pay more attention to prescribing ARVs than co-trimoxazole, which is required for eligible patients that have no access to ARVs. Also, CPT is supposed to be free for the patient, but at some facilities, eligible patients pay for their co-trimoxazole prescription using the country's cost-sharing approach to health care financing. Access to CPT is sometimes affected by the patient's ability to pay out-of-pocket for the medicine. CPT implementation is not formally monitored at health facilities.

### *Monitoring and Promoting Treatment Adherence*

Like the other activities, adherence monitoring for TB medicines and ARVs is done independently by the respective programs, even at sites where both services are provided.

Adherence monitoring and promotion for the TB program follows the DOT approach for the first two months of TB treatment (initiation phase). A combination of different approaches, depending on the facility's location, funds, and human resources, is used to monitor and promote adherence for the last four months of TB treatment (continuation phase). Examples include the use of volunteers (former TB patients) and home-based care givers.

Methods used to monitor patient adherence to ART include pill count, patient self-report, CD4 count, and tracking appointments. How the facilities promote ART adherence depends on the availability of funds, human resources, and the collaborating partner supporting the facility. Examples of some of the promotion strategies include the use of home-based care givers, telephone calls, patient calendars, and recruiting family and community members.

The *Guidelines on Chronic HIV and TB Basic Care* (March 2006) recommend that patients need special adherence support during the first weeks of combined TB and ARV treatment when adverse reactions typically occur, for second-line treatment, and for patients living under difficult socioeconomic conditions. If the patient is on TB and ARV treatment, daily TB directly observed treatment should be combined with the morning dose of ARVs. Flexibility in designing directly observed treatment for ART is recommended because this is a life-long therapy. All ART patients are encouraged to have an adherence assistant help them with ART medication.

The stakeholders interviewed reported that no adherence monitoring is done for CPT, and none was observed at the five health facilities visited.

## **Lessons Learned**

### ***Establishing Mechanisms for Collaboration***

- Good administrative structures in the existing TB and HIV/AIDS programs provide a solid basis for collaborative activities. The experience from TB/HIV collaboration in three pilot districts showed the willingness of the two programs to work together and of donor agencies to support collaboration. Advocacy for such activities can increase funding and attention for the TB program.
- Although two programs may be willing to collaborate, each may worry that some of the vital program activities and donor assistance might be taken up by the other program. Emphasis from the MoH regarding each program's independence can provide reassurance.
- Human resource capacity is a major challenge for implementing collaborative activities at different levels, such as conducting needs assessments, developing the policy for TB/HIV collaboration, conducting training, and providing services.
- Despite limited human resource capacity, a collaboration can produce effective clinical guidelines. In Tanzania, both TB and HIV/AIDS programs incorporated collaborative activities into their guidelines, and the two programs also developed a joint clinical guideline for implementing TB and HIV/AIDS activities at dispensaries, health centers, and district outpatient clinics.
- Training can often be haphazard for different health provider cadres, especially when no standardized training curricula exists. At the time of the assessment, the National AIDS Control Programme trained health workers from TB clinics in TB/HIV management; however, training does not cover pharmaceutical management, although medicines from both programs are available in the same health facility.
- Establishing organizational structures within different levels of the health system to foster TB/HIV collaboration is important. A national committee effectively developed a national policy on TB/HIV collaboration. Putting district coordinators in place to synchronize operations made it possible to track patients referred from one clinic to another. This function may later be replaced by district coordinating committees. Tanzania also planned to establish coordinating committee at all levels of the health care system despite initial concerns regarding the sustainability and financial implications.
- Well defined pharmaceutical management structures are often in place for ARV drugs and TB drugs, but not for co-trimoxazole used by both programs. The lack of an established quantification procedure between the two programs and the use of the regular health facility budget to procure co-trimoxazole contributes to co-trimoxazole stock-outs at facilities.

### ***Implementing Interventions***

- When referral systems are working well, patients benefit from getting a combined package of care.
- Information exchange between the two programs was found beneficial when deciding on the start of ART for patients co-infected with TB.
- Some TB providers do not feel confident initiating HIV testing in TB patients.
- Providing TB/HIV collaborative services in Tanzania is hindered by the fact that many facilities provide either TB or ART services, but rarely both. Working to provide both services

at the same facility is a major step toward achieving more effective patient care and treatment. An assessment of collaborative activities at the three pilot districts in September 2005 resulted in the recommendation that HIV/AIDS care and treatment services should be expanded to the subdistrict level.

### ***Providing HIV Testing and Counseling***

- HIV test kits need to be managed more effectively to avoid the stock-outs that decrease TB patients' access to TB/HIV services.
- Provider-initiated counseling and testing for HIV is accepted by most both health care providers and TB patients in Tanzania.

### ***Introducing Isoniazid Preventive Therapy***

- When providers do not feel that they can reasonably exclude patients with active TB or properly monitor adherence to treatment, they are reluctant to implement IPT. Because the majority of HIV-positive patients would be eligible for IPT in Tanzania, the burden of providing this intervention could be considerable.
- Tanzania is investigating the cost-effectiveness of IPT by introducing it in prisons.

### ***Introducing Co-trimoxazole Preventive Therapy***

- When health facility budgets are not sufficient to procure enough co-trimoxazole to assure uninterrupted access, co-trimoxazole stock-outs occur in facilities.
- CPT was not well accepted in Tanzania. Contributing factors may have been health care providers giving preference to ART over CPT (they are not usually given concurrently) and some facilities requiring co-payments. Also, patients usually need to collect CPT prescriptions at the HIV/AIDS CTC, which is often overburdened with patients and makes this service less accessible.

### ***Monitoring and Promoting Treatment Adherence***

- Open spaces of TB clinics are usually not private enough for confidential HIV/AIDS counseling and testing. However, converting the infrastructure of the regular TB clinics to accommodate HIV activities can be a challenge.
- Stigma among patients presents a barrier to accessing services at the HIV/AIDS CTCs.
- Adherence monitoring is not given much attention. Health care providers are supposed to use pill count to monitor ART and CPT. However, pill counting is not done consistently for ART and was not observed for CPT at the five hospitals visited in Dar es Salaam. The TB program used directly observed treatment, and TB program planners thought using directly observed treatment methods to monitor CPT was feasible; however, it was not in practice because co-trimoxazole is not distributed through the TB program.

## Conclusions

In Tanzania, TB/HIV collaboration is in an early phase. Although a national policy for TB/HIV collaboration has not yet been disseminated, activities are already being implemented in 23 districts. TB clinic staff in these districts conduct provider-initiated counseling and testing, but not all nurses felt confident enough to carry out the HIV test. In addition, the CTC staff did not always screen patients for TB because of time constraints. CPT is also provided, but acceptance of this service has been low, possibly due to preference given to ART services. IPT is not yet offered.

The goal of the assessment was to answer a series of questions regarding different pharmaceutical management issues related to TB/HIV collaboration activities—

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

Pharmaceutical management is not clearly addressed in the existing guidelines. As interventions are scaled-up, it is clear that pharmaceutical management needs to be addressed to ensure consistent availability of commodities.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense and finance) (1) commodities used by both programs, and (2) commodities required for new interventions? What are the conditions that influenced this decision?*

No particular strategy was developed to manage pharmaceuticals and commodities required for TB/HIV collaborative services. The individual programs manage collaborative commodities with their other program commodities. However, the HIV program alone is responsible for procurement and distribution of HIV test kits, including those used by TB clinics.

*To what extent have TB and HIV programs adapted common procedures in pharmaceutical management, such as for treatment adherence and information management?*

Both TB and HIV/AIDS programs have incorporated information for TB/HIV collaborative activities into their respective program guidelines; in addition, the two programs have worked together to draft a policy guideline for TB/HIV collaboration and to develop a joint clinical guideline for implementing TB and TB/HIV activities at dispensaries, health centers, and district outpatient clinics in Tanzania. These guidelines suggest a flexible approach for using treatment supporters to monitor TB and AIDS treatment. Adherence to CPT was not usually monitored.

*Has program collaboration in TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities to increase effectiveness and efficiency?*

The pharmaceutical management system was not restructured for to TB/HIV collaborative activities, and the programs were not interested in merging program activities.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed for TB/HIV collaboration and pharmaceutical management?*

As the introduction of TB/HIV collaborative activities is in an early stage, experiences with advantages and drawbacks of the pharmaceutical management collaboration are limited. The biggest advantage appears to be the potential for more efficient use of human resources, such as, providing co-trimoxazole directly at the TB clinic. Also, if the pilot test of a TB clinic providing ARVs in Temeke district is successful, the TB program can contribute to an increase in the number of HIV patients receiving ART. The limitations lie in the availability of trained staff, because HIV testing is already a challenge to some nurses. Adherence monitoring could also benefit from the collaboration, when adherence to CPT is monitored directly at the TB clinic together with TB directly observed treatment

TB clinics could access HIV/AIDS program commodities through the MSD, which stores TB and HIV/AIDS program supplies. However, this arrangement would require district offices, such as the district TB/HIV coordinator, to assume a bigger role in coordinating quantification of supplies for both programs.

Finally, secure storage areas for ARV drugs have sometimes been used to store TB drugs at health facilities where leakage has been a problem. This may also become an attractive option for storing more expensive drugs used for multidrug resistant TB.

## **Appendix A. Documents Reviewed**

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4. WHO/CDC/KNCV. 2005. Workshop proceedings outlining implementation of WHO/CDC/KNCV assessment recommendations for TB/HIV activities in Tanzania. Bagamoyo, Tanzania.
5. The United Republic of Tanzania. Ministry of Health. 2005. National Guidelines for the Clinical Management of HIV and AIDS. National AIDS Control Programme. 2nd ed.

## **Appendix B. Data Collectors and Key Stakeholders Interviewed**

**Data collectors** (academic staff members at Muhimbili College of Health Sciences)

- Dr. O. M. S. Minzi
- Dr. A. R. Kamuhabwa
- Dr. G. A. B. Kagashe

### **Key Stakeholders**

- Dr. Eluid, TB/HIV coordinator for national TB program
- Dr. Bwijo A Bwijo, head of Care and Treatment Unit at National AIDS Control Program (NACP)
- Ms. Emma Lekashingo, Pharmacist at Care and Treatment Unit at National AIDS Control Program
- Mr. Nicholas Fredrick, Procurement Pharmacist at Medical Stores Department
- Turka, Pharmacist at Lugalo Military Hospital
- Dr. Stela Chale, WHO/NACP HIV/AIDS Technical Officer
- Mr. Joseph Muhume, Chief Pharmacist, Ministry of Health
- TB Coordinator and Pharmacist in charge, Lugalo Military Hospital
- TB Coordinator, Temeke District Hospital
- Participants of TB/HIV workshop in November 2005
- Pharmacist in charge, Muhimbili National Hospital
- TB Clinician and Coordinator, Muhimbili National Hospital
- Staff members of TB/Leprosy program at MoH
- TB and HIV clinicians at PASADA



## ANNEX 5. MANAGING PHARMACEUTICALS FOR TB/HIV COLLABORATION IN UGANDA: ASSESSMENT RESULTS

### Background

Uganda, with a population of about 28 million, had an annual TB incidence rate of 402 cases per 100,000 in 2004—the fifteenth highest burden in the world.<sup>45</sup> Uganda, like most other countries in the high-burden category, is still working towards meeting the WHO TB global targets of 70 percent case detection rate and 85 percent treatment success rate. The 2004 detection rate of sputum smear-positive cases was 43 percent with a treatment success rate (treatment completion and cure) of 68 percent.<sup>46</sup>

Based on the UNAIDS report on AIDS, the prevalence of HIV infection among adults in Uganda was estimated at about 6.7 percent in 2005.<sup>47</sup> Approximately one million people have HIV infection and about half of the people eligible for antiretroviral therapy (ART) were receiving it in 2005 with treatment scale-up ongoing.<sup>48</sup> According to the Ugandan MoH, about 50 percent of tuberculosis patients were co-infected with HIV,<sup>49</sup> and an estimated 30 percent of all deaths in people living with HIV/AIDS has been attributed to TB<sup>50</sup>; however, Stop TB Partnership figures from 2005 estimated that 19 percent of TB patients in Uganda were co-infected.<sup>51</sup>

### *Planning for TB/HIV Collaboration in Uganda*

TB/HIV collaborative activities were first implemented in Uganda through a few public facilities and NGOs) including AIM (AID/HIV Integrated Model district program), AIDS information Center (AIC), Mbuya Reach Out, Nsambya, and The AIDS Support Organization (TASO). Because no national policy existed at that time to guide TB/HIV collaboration, activities were not standardized and depended largely on the knowledge and motivation of individual health workers or counselors. An external evaluation of the TB program conducted in May 2005 revealed that limited TB/HIV collaborative activities were ongoing, but that the approaches were not always technically sound.<sup>52</sup>

To better coordinate and implement a national approach for collaborative activities, the MoH established a national coordination committee for TB/HIV collaboration in January 2005. The

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<sup>45</sup> WHO. Global Tuberculosis control “Country Profile: Uganda.” WHO website <http://www.stoptb.org/countries/GlobalReport2006/uga.pdf> (accessed September 22, 2006).

<sup>46</sup> Ibid.

<sup>47</sup> UNAIDS. 2006. *Report on the global AIDS epidemic*. Geneva, UNAIDS.

<sup>48</sup> WHO. 2005. Summary Country Profile for HIV/AIDS Treatment Scale-up: Uganda; MOH ART Policy, 2003; MOH TB/HIV Policy, 2005; Egger M et al, 2005).

<sup>49</sup> Ibid.

<sup>50</sup> Uganda Ministry of Health. 2006. *National Policy Guidelines in for TB/HIV Collaborative Activities in Uganda*. Kampala, Uganda.

<sup>51</sup> WHO. Global Tuberculosis control “Country Profile: Uganda.” WHO website <http://www.stoptb.org/countries/GlobalReport2006/uga.pdf> (accessed September 22, 2006).

<sup>52</sup> Uganda Ministry of Health. 2006. *National Policy Guidelines in for TB/HIV Collaborative Activities in Uganda*. Kampala, Uganda.

committee comprises representatives from the National TB and Leprosy Programme (NTLP); the National AIDS Control Programme (NACP); WHO; development agencies; civil society organizations; NGOs; academic institutions; special groups, such as the army and police; people living with HIV/AIDS; patient support groups; activists; and district representatives who are charged with the overall coordination of TB/HIV collaborative activities in the country. This committee coordinates activities through four working groups (1) policy and guidelines; (2) district implementation; (3) advocacy, communication, and social mobilization; and (4) monitoring and evaluation.

To coordinate overall TB/HIV activities in the country, Uganda recruited two TB/HIV coordinators; one under NTLP and the other under the NACP. According to the TB/HIV policy guidelines, TB/HIV coordinators should be established at different levels of the health system to facilitate planning, monitoring, and communication between the programs. Collaborative activities are provided in 28 of the 42 districts in the country. Sixteen of the 28 districts, with support from the USAID had been carrying out some collaborative activities before the national policy was released. Since the national policy was published in 2006, WHO and the GFATM have supported the health worker training in the remaining 12 districts to implement collaborative activities.

The TB/HIV collaborative activities that were planned for implementation at the district level by the end of 2006 include—

- Developing joint TB/HIV implementation plans
- Establishing a system for HIV surveillance of TB patients
- Establishing a system for TB surveillance of people living with HIV/AIDS

## **Purpose of the Study**

RPM Plus Program designed a study to investigate commodity management in support of TB/HIV collaboration as described by WHO's *Guidelines for Implementing Collaborative TB and HIV Programme Activities*. This assessment focused on two levels—establishing the mechanisms for collaboration, which includes planning and information management for monitoring and evaluation; and clinical interventions, which includes HIV testing and counseling for TB patients, IPT, CPT, and treatment adherence.

This study report describes the implementation of TB/HIV collaborative activities in Tanzania and how pharmaceutical management has been addressed in policies, working documents, and in practice. The study addressed the following questions—

- To what extent has pharmaceutical management been addressed in the national TB/HIV policy?
- What strategy has been proposed or implemented to manage (1) commodities used by both programs, and (2) commodities required for new interventions? What are the conditions that influenced this decision?

- To what extent have TB and HIV programs adapted common procedures, such as for adherence promotion and information management?
- Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities in order to increase effectiveness and efficiency?
- What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed?

## **Study Methodology**

As part of an RPM Plus pharmaceutical management capacity building initiative activity in five East African tertiary institutions, two postgraduate candidates from the Department of Pharmacy at Makerere University, Kampala, conducted this assessment. The investigators were supervised directly by a professor from the Department of Pharmacy, and remotely by two MSH/RPM Plus staff members.

The study involved a review of relevant policy guidelines and reports on TB, HIV/AIDS, and TB/HIV collaboration and interviews (Annex 5. Appendix A.). The investigators used an interview guide developed by RPM Plus to collect data from key stakeholders at the national, program, and health facility levels. Stakeholders included the representatives of the TB and HIV/AIDS programs (MoH and Uganda AIDS Commission), National Medical Stores, Joint Medical Stores, Joint Clinical Research Centre (centers of excellence in HIV/AIDS care and research) and selected health facilities offering clinical services to HIV and TB patients (Joint Clinical Research Centre, Kampala; Makerere University Hospital; and TASO's Mulago health facility) (Annex 5. Appendix B.). Unfortunately, potential stakeholders from sexually transmitted infections/HIV programs could not be reached because of their busy schedules.

Areas addressed in the assessment included—

- TB/HIV national policies and guidelines, areas of collaboration, and roll-out plans
- Policies and plans on pharmaceutical management in support of TB/HIV collaboration
- Pharmaceutical management structures of the TB and HIV/AIDS programs and for the coordination of TB/HIV services, including information management and human resources
- Procedures used by the programs to select, quantify, procure, distribute, store, dispense, and finance pharmaceuticals and commodities
- Adherence monitoring and adherence promotion activities
- Perceptions of stakeholders on the opportunities and challenges of TB/HIV collaboration

A limitation of the assessment is that the concept of implementing collaborative TB/HIV activities has only recently been considered by the Ugandan government. Consequently, data and information on TB/HIV collaborative activities in Uganda are limited. In addition, some facilities selected for the assessment needed additional approval of the survey protocol, which could not be obtained in the time available. As a result, data collection was restricted to consenting institutions.

## **Assessment Results**

### ***Establishing Mechanisms for Collaboration***

#### *Policies and Guidelines for TB/HIV Collaboration*

Uganda's TB/HIV coordinating committee developed and finalized the national policy guideline for collaborative activities and launched their program in May 2006. The policy guideline was adapted from the WHO interim policy document of 2004 and lessons learned from the ProTEST research initiative, which assessed interventions to help interrupt the sequence of events by which HIV infection fuels the TB epidemic.

In 2006, the TB/HIV coordinating committee also developed an orientation manual for health workers on implementing TB/HIV collaborative activities at district level. This training document was designed to build technical knowledge and skills essential for implementing TB/HIV collaborative activities in health care delivery. The document was developed after the International Union Against Tuberculosis and Lung Disease and the Global TB Drug Facility conducted a biannual review of the TB program in August 2005, which revealed that most health workers lacked knowledge on TB/HIV collaborative activities, resulting in poor implementation.

The coordinating committee also developed a communication strategy for TB/HIV collaboration that was jointly produced by the TB and HIV programs as well as other stakeholders and partners. The communication strategy will guide key players at national, district, subdistrict, and community levels on the main activities associated with TB/HIV collaboration.

#### *Planning for TB/HIV Collaboration*

The national plan for implementing collaborative activities indicates that TB patients should be referred for HIV voluntary counseling and testing (VCT) within the health facility or to another health facility and that HIV/AIDS patients should be referred for TB screening and treatment the same way, depending on how services are delivered in the area. The MoH has introduced referral forms to track referral of patients to VCT and TB services. Although routine referrals have not yet been formally evaluated at the 12 new pilot districts, the NTLP suspects that facilities are not routinely referring patients, because referrals records are very poor, especially from HIV clinics.

In Uganda, TB services are provided down to health center III level (which includes national referral hospitals, regional referral hospitals, district hospitals, health center IV—subdistrict, and health center III—subcounty), while HIV services are only provided to health center IV level, with limited coverage at health center III facilities.

TB/HIV collaborative services are integrated at health centers that provide both TB and HIV services; the same health workers usually provide treatment and dispense medicines to both TB and HIV patients. However in hospitals and at health centers that provide only TB services, patients are supposedly referred to another facility to receive HIV services. ARV medicines are dispensed either from the hospital pharmacy or from the HIV clinics.

Patients receive TB medicines free of charge, but they do not always receive free ARV medicines. The government-funded stock of ARVs is provided free to patients, but this stock is limited and few new patients are accepted into treatment with government ARVs; therefore, patients sometimes have to pay subsidized fees for ARVs that are provided through a non-government source. The government tries to ensure that patients started on ARVs continue to receive their medications. However, patients who start ART with NGO subsidies have to pay before accessing a subsequent dose. If the patient is unable to pay, then he or she will not receive medication unless the facility has a government stock of ARVs. Often, the patients who cannot afford to pay are switched to the government program, but if there is not enough stock available to add new patients, interruptions in ART may occur. Patients are counseled to start ART only if they can afford to pay for it when government stock is not available.

### ***Managing TB/HIV Pharmaceuticals***

The TB program is responsible for the quantifying TB-related commodities. Every quarter, district program offices estimate the required quantities using the number of TB cases reported the previous quarter. The National AIDS Control Programme (NACP) handles the quantification of HIV commodities using the number of HIV patients that are eligible for ART; however, the quantities actually procured depend on available resources which are very limited. Currently, CPT is provided mainly through the HIV clinics and outpatient departments in health facilities. Stakeholder interviews at health facilities indicated that quantification of co-trimoxazole for CPT is based on available budget as opposed to estimated patient need.

Essential medicines in Uganda are currently procured by the NMS, Joint Medical Stores, private pharmacies, and a few other organizations. NMS is an autonomous government agency that procures, stores, and distributes medicines to government facilities under a centrally managed financing mechanism. NMS is responsible for storing and distributing TB medicines to public health facilities, while procurement of TB medicines in the last few years has been done by the NTLP through Global TB Drug Facility grants. In addition, TB medicines were previously procured through the World Bank's multi-country HIV/AIDS program initiative. In general, the TB program rarely experiences stock-outs of TB medicines; however, stock-outs did occur when the disbursement of GFATM grant money was interrupted in August 2005. WHO mobilized funds for an emergency procurement to fill the gap.

The NACP procures HIV-related medicines and supplies, which are stored and distributed to public facilities by the NMS. ARV procurement for the private sector is carried out by private pharmacies, the Joint Clinical Research Centre, and Medical Access Uganda Limited, a private nonprofit company, with approval from the National Drug Authority. Additionally, the Joint Medical Stores, a nonprofit organization, procures and stores ARV medicines for the Catholic Relief Services.

Currently, the HIV and TB programs manage the logistics for ARVs and TB medicines separately; TB medicines are delivered to district health facilities on a quarterly basis, while ARVs are distributed to about 164 facilities every four weeks.

## **Managing Information for Monitoring and Evaluation**

The NTLP collects routine data on TB treatment and outcomes through quarterly reports from health facilities and districts. The quarterly reports include data on new TB cases, relapses, sputum conversions, and treatment successes, and now have been revised to include a section on TB/HIV collaborative services, including HIV testing and status, if the patient is on CPT and/or ART, and date started. According to the TB program manual, district TB and leprosy supervisors should schedule monthly supervisory visits to health units in their districts to monitor information management.

ART monitoring is done centrally by the NACP and includes clinical data and logistics and supply information. The NACP has not yet revised its reporting forms to include TB/HIV collaborative activities because its current data collection forms are new and still need to be validated. Also, because the ART program is still actively scaling up and collecting important information, the NACP is reluctant to interrupt data collection by changing forms at this time.

Two of the health facilities (Joint Clinical Research Centre and TASO, Mulago) use computerized systems for data collection and reporting at the HIV/AIDS clinics. Clinical information is kept in patient files and also is summarized in pre-ART and ART registers, which include information on CPT provision.

Uganda's national policy guidelines for TB/HIV collaborative activities clearly outline ten indicators that will be used for monitoring and evaluating the country's TB/HIV activities. For TB/HIV collaborative activities, the NACP is responsible for collecting and monitoring TB- and HIV-related indicators for VCT clients and patients attending HIV clinics; however, reporting forms have not yet been updated to fully capture this information. The NTLP is responsible for collecting TB- and HIV-related indicators for TB patients registered in TB clinics (Table 1). To increase collaboration, the policy guidelines recommend that the two programs establish mechanisms for sharing information.

**Table 1. Indicators to Track TB/HIV Collaborative Activities in Uganda**

1.	Proportion of TB patients who are HIV-positive
2.	Proportion of VCT clients who have been screened for TB symptoms
3.	Proportion of people living with HIV/AIDS attending HIV treatment and care services who have been screened for TB symptoms
4.	Proportion of people living with HIV/AIDS attending HIV treatment and care services who have been newly diagnosed with TB
5.	Proportion of newly diagnosed HIV-positive clients who are given treatment for latent TB infection
6.	Proportion of registered TB patients who have been tested for HIV
7.	Proportion of registered TB patients tested for HIV who are positive
8.	Proportion of HIV-positive TB patients who receive at least a one-month dose of co-trimoxazole preventive therapy during their TB treatment
9.	Proportion of HIV-positive registered TB patients who are given ART during TB treatment
10.	Presence of joint TB/HIV information, education, and communication materials in TB and HIV services

TB clinics report to the district TB coordinators, who then report to the NTLP. Presently, up to 70 percent of all districts providing TB/HIV care are reporting some of the data to central level

NTLP. The NTLP uses this data to guide decision making and identify areas that need improvement. Information reported from the facilities includes the—

- Number of TB patients offered HIV counseling
- Number of TB patients tested for HIV
- Number of TB patients who are HIV-positive

TB program recording and reporting forms have been revised to include information on CPT treatment. The TB treatment cards indicate if a patient is on CPT and the date treatment started. Quarterly reports sent to NTLP indicate information on the number of health facilities providing CPT for TB co-infected patients.

According to the indicators developed for monitoring collaborative activities, the indicator “proportion of HIV-positive TB patients who receive at least a one month dose of CPT during TB treatment” will be monitored through the TB program. At the end of TB treatment, when collating patients’ treatment outcomes, health facilities will report the number of TB patients on ART and CPT through the district TB coordinator to the NTLP .

### ***Implementing Interventions***

In addition to the TB and HIV program commodities that are used for diagnosing and treating TB and HIV infections, HIV test kits for TB patients, isoniazid for IPT, and co-trimoxazole for CPT will be needed to effectively implement TB/HIV collaborative activities at the facilities.

#### *HIV Testing in TB Patients*

Opt-out, provider-initiated HIV diagnostic counseling and testing (DCT) is the policy in Uganda for patients enrolled at TB clinics. Health providers in the 12 districts supported by WHO and NTLP through the GFATM have been trained to implement opt-out DCT. The other TB/HIV collaborative health facilities still refer TB patients to VCT services, but this is not done routinely. Reportedly, patients are lost during referrals between health facilities because they are not followed-up properly. Diagnostic treatment units are found at all health center level IV facilities; they provide DCT but may not necessarily offer ART.

Although TB health workers have been trained to provide DCT, referral is sometimes affected by stock-outs of HIV test kits at VCT centers. Generally, adequate stocks of HIV test kits were available at the national level, but facility-level stock-outs have been attributed to the failure of health workers to request HIV test kits in time. However, the NMS was also out of stock on HIV test kits in January and February 2006. The HIV program is responsible for the procurement and distribution of HIV test kits. The TB program is not involved in the quantification of test kits.

#### *Isoniazid Preventive Therapy*

IPT for HIV-positive patients is not yet the policy in Uganda, so, this service is unavailable in public health facilities. The Uganda policy does recommend isoniazid prophylaxis for children under the age of five years who live in the same household with newly discovered smear-positive

tuberculosis patients. IPT is also recommended for breastfeeding infants at high risk of infection from a mother with pulmonary TB. Unlike HIV-positive patients, these two groups do not require tuberculin testing to exclude active TB.

Stakeholders had a number of concerns regarding the provision of IPT for HIV-positive patients. Some argued that the majority of HIV patients might be eligible for isoniazid prophylaxis and that subsequent widespread use may lead to increased drug resistance. Diagnosis of latent tuberculosis in HIV-positive patients remains a challenge because the commonly used tuberculin skin test is less sensitive in patients with HIV/AIDS. Additional challenges include cold chain management for tuberculin skin tests, training in proper intradermal injection, and test reading. Furthermore, diagnosis of active TB mostly relies on confirming a positive sputum smear, but about half of TB patients may be smear-negative, and some might receive isoniazid prophylaxis even though they have active TB.

Because of the challenges to implement IPT, this service is not routinely offered and detailed guidelines for isoniazid prophylaxis are not yet available. Currently, facilities that have the capacity to provide IPT are encouraged to do so, but institutions that want to offer IPT must meet stringent eligibility criteria, including having a treatment default rate of less than or equal to five percent for TB patients. This has been very difficult to achieve because patients are not regularly followed up in these facilities. Table 2 below lists the other eligibility criteria for IPT.

**Table 2. Eligibility criteria for institutions or organizations to provide isoniazid preventive therapy**

<b>A. Human resource</b>
A.1 Medical Officer
A.2 Laboratory Assistant
A.3 Trained counselor
A.4 Pharmacy Technician
A.5 Adherence supporters
<b>B. Infrastructure</b>
B.1 Functional laboratory
B.2 X-ray or access to X-ray services
B.3 Counseling room/space
B.4 Consultation room
<b>C. Equipment and logistics</b>
C.1 Facilities for TB microscopy
C.2 Facilities for tuberculin skin testing
C.3 Cold chain system
C.4 Facilities for HIV testing
C.5 Sustainable supply of anti-TB drugs including isoniazid
C.6 Sustainable supply of HIV test kits
<b>D. Other key performance issues</b>
D.1 TB default rate of NOT greater than 5 percent

Source: MoH. TB/HIV Draft Policy, 2005

Facilities visited as part of the assessment were not generally giving IPT to infants and children living in the same household with a sputum smear-positive pulmonary tuberculosis patient, even though this intervention has been in practice for many years. Like most other health facilities, the assessment facilities did not offer IPT to HIV-positive patients, which may explain why isoniazid had expired in the store.

### *Co-trimoxazole Preventive Therapy*

Providing CPT to eligible HIV-positive and TB/HIV co-infected patients is the policy in Uganda, and the MoH developed a national policy guideline for co-trimoxazole prophylaxis for people with HIV/AIDS in 2005. In the national guidelines, CPT is indicated for all HIV-positive people with WHO clinical stage 2, 3, and 4; any HIV-positive patient with CD4 < 200 cells/mm<sup>3</sup>; and any HIV-positive patient with active TB. Currently, CPT is provided through HIV clinics, TB clinics, and the general outpatient department.

The national guidelines recommend that HIV-positive patients without access to ART be given lifelong CPT. However, if ART is available, CPT can be stopped when the patient's CD4 count has increased to 200 cells/mm<sup>3</sup> or more for at least six months. Because CD4 machines are not generally available at lower levels of care, patients tend to remain on CPT for a long time.

Procurement of co-trimoxazole used for CPT and to treat other infections is done through the essential medicines program with funding from the MoH. Each health district and facility has

allocated budget for procuring essential medicines, including co-trimoxazole. No additional budget has been provided to implement CPT at health facilities. Visits to health facilities identified a lack of needs assessment for co-trimoxazole for CPT. Forecasting of requirements is based on available budget as opposed to the actual needs of the patients. Consequently, stock-outs have occurred in some health facilities.

At health facilities, eligible patients receive CPT through the general outpatient department dispensing window. In some hospitals with high case loads, the HIV clinic may requisition co-trimoxazole for CPT from the general pharmacy and dispense it directly. Although the MoH policy is to provide co-trimoxazole free of charge, patients have to buy their medicine from retail drug outlets when there are stock-outs at the health facility. The co-trimoxazole procured by the districts is used for CPT as well as for acute care. Because CPT is given for a longer period, patients that require acute treatment with co-trimoxazole are usually given preference over patients that need prophylaxis. This results in frequent treatment interruptions due to stock-outs for patients on CPT who cannot afford to purchase co-trimoxazole out-of-pocket.

Some NGOs providing CPT buy their own stock of co-trimoxazole, which is usually not provided free of charge to the patients, unlike in public health facilities where CPT is free, though stock is limited. At the time of the study, one of the health facilities visited (TASO) was receiving co-trimoxazole for CPT through a donor, while another facility (Joint Clinical Research Centre) had started negotiations with another donor to be able to provide a more reliable supply of co-trimoxazole for CPT. The NACP included procurement of co-trimoxazole for CPT in a Global Fund proposal, which at the time of the assessment had been submitted but not yet approved.

Most private pharmacies authorized to dispense Class B medicines (like co-trimoxazole) are mostly located in urban and peri-urban settings. Although clinics and retail medicine shops are widely distributed throughout communities around the country, in theory, they are not authorized to supply antimicrobials to patients.

### ***Monitoring and Promoting Treatment Adherence***

The TB program monitors patient adherence during the intensive phase (first two months) through directly observed treatment at the facility or in a community-based program. Usually patients start on facility-based treatment for the first two weeks while the health workers organize the community volunteers. Community-based TB care with directly observed treatment is practiced in all districts. A public health worker (referred to as a subcounty health worker) links the formal health system to communities in their respective subcounties. Subcounty health workers conduct community mobilization, train and supervise community volunteers, and replenish the volunteers' stock of TB medicines every two weeks. The community-based treatment supporters are responsible for keeping the patients' TB medicines, observing the patients take their medicines daily, updating their treatment cards, observing if they experience any problems with treatment, and reminding the patients about sputum smear tests at two, five, and eight months of treatment.

The HIV program offers ARV treatment only to patients who agree to comply with post-eligibility counseling. ARVs are given to the patient monthly, with additional counseling provided during visits for medicine refills. Patient adherence is assessed in relation to clinical, immunological, and virological improvement. Pill counts and regular attendance of scheduled appointments are often monitored to indicate adherence or compliance to treatment.

A home-based care approach has been adopted for keeping people living with AIDS in the community, which helps relieve the already overstrained health facilities. However, a community survey conducted in Kiboga and Pallisa districts showed that a community-based directly observed treatment approach for monitoring adherence in TB patients may not work for ART because patients' HIV status would be disclosed to the community.

The implementation guidelines for TB/HIV collaborative activities at district level do not recommend any adherence monitoring techniques for CPT. In one of the health facilities visited (TASO), a home-based treatment approach was used to promote adherence to ARVs, TB medicines, co-trimoxazole and other medicines for opportunistic infections.

## **Lessons Learned**

### ***Establishing Mechanisms for Collaboration***

- The Uganda experience has shown that a national approach involving a broad range of stakeholders is required for sound planning and implementation of TB/HIV collaborative activities. A first step is to establish a national committee for TB/HIV coordination that is responsible for developing a national policy and guidelines for collaborative activities; however, detailed work planning may better be done in smaller working groups.
- To effectively implement TB/HIV collaborative activities at all levels of the health care system, health workers, patients, and communities need to be educated about the interventions. Uganda developed a communication strategy to raise awareness about TB/HIV and activities.
- Health worker training alone does not lead to expected results; a feasible plan and resources should in place to supervise, monitor, and evaluate implementation activities.
- Quantification of commodities based on available budget rather than estimated need leads to stock-outs and the ineffective implementation of activities.
- A good information system can support both program monitoring and pharmaceutical management of commodities required for the collaboration. Data collection and reporting forms need to be adapted accordingly.
- Data derived from collaborative activity reports may help estimate requirements at national level; however in Uganda, recording and reporting of program data were often found to be incomplete.

### ***Implementing Interventions***

Collaborative services are more difficult for patients to access when they are not provided at the same facility or in the same department. Stakeholder interviews indicated that collaborative

services are easier to implement in facilities that offer comprehensive care because patients are sometimes lost during referrals if not properly followed up.

### *Providing HIV Testing and Counseling*

- Even when HIV test kits are available at regional or national stores, health facilities may have stock-outs because of delayed requisition of new stock. Regular supervision may improve such pharmaceutical management practices.

### *Introducing Isoniazid Preventive Therapy*

- IPT cannot be implemented effectively when health workers do not have the means to exclude active TB. A reliable detection technique and the associated supplies and services must be accessible, such as radiological services and x-ray films, tuberculin skin tests, and a cold-chain system.

### *Introducing Co-trimoxazole Preventive Therapy*

- Using a decentralized district budget alone to purchase co-trimoxazole is insufficient to assure continuous CPT for HIV-positive and TB/HIV co-infected patients.
- Treatment interruptions are inevitable when patients must purchase co-trimoxazole from private suppliers. In Uganda, most private retail outlets that are approved to sell co-trimoxazole are located in urban and peri-urban areas, leaving rural areas undersupplied. In addition, the cost of medicines in private outlets is relatively high. Despite co-trimoxazole being a comparatively low-cost medicine, the cost for one month of treatment is considerable for people with low income.
- Access to CPT in rural areas is further limited when it is only provided at health center IV level.

### **Monitoring and Promoting Treatment Adherence**

- Based on the experience at an NGO facility (TASO), a home-based treatment approach can improve CPT adherence.
- Home-based treatment including ART, TB treatment, and CPT provides relief for over-stretched health services
- Community-based directly observed treatment for patients on ART presents an opportunity for improving access and adherence to treatment, but maintaining patient confidentiality is a challenge. It is not possible to simply copy the approach used by the TB program for community-based treatment, because patients' HIV status will be revealed to the community.

### **Conclusions**

The government of Uganda demonstrated its commitment to decreasing the burden of TB and HIV/AIDS by establishing a TB/HIV working group charged with developing a national policy that creates a framework for collaborative activities. Since the launch of the TB/HIV national

policy in May 2006, other guidance documents have been developed that standardize the implementation of collaborative activities in the country.

Provider-initiated HIV counseling and testing for TB patients and CPT are the most widely implemented activities in Uganda. IPT for HIV-positive patients is not yet the policy, so this service is unavailable in public health facilities.

The assessment goal was to answer a series of questions regarding different pharmaceutical management issues related to TB/HIV collaboration activities—

*To what extent has pharmaceutical management been considered in the national TB/HIV policy?*

The national TB/HIV policy guidelines do not address the management of pharmaceuticals required for collaboration. Both programs operate independently while collaborating at facility level through referrals and clinical management.

*What strategy has been proposed or implemented to manage (select, quantify, procure, distribute, store, dispense and finance) (1) commodities used by both programs, and (2) commodities required for new interventions? What are the conditions that influenced this decision?*

Procurement and distribution of program commodities remain the responsibility of the separate programs. The essential medicines program provides co-trimoxazole for CPT and short-term treatment; however, treatment interruptions for CPT were reported as a result of stock-outs and the inability of patients to pay out of pocket. It appears that the current strategy was based on a historic supply of commodities.

*To what extent have TB and HIV programs adapted common procedures for pharmaceutical management, such as for treatment adherence and information management?*

Information management is an important area in the country's TB/HIV policy guidelines. Both programs are supposed to collect information on TB/HIV collaborative activities through the regular recording systems; however, the HIV program's forms have not yet been updated to include these data.

*Has program collaboration in the area of TB/HIV resulted in a restructuring of the pharmaceutical management system for program commodities in order to increase effectiveness and efficiency?*

TB/HIV collaboration has not led to a general restructuring of pharmaceutical management systems, but the HIV program is planning to build on the experiences of home-based care and community-based directly observed treatment for TB. However, limited human resource capacity and confidentiality issues are challenges.

*What advantages, opportunities, limitations, and drawbacks were experienced or anticipated as the collaboration progressed for TB/HIV collaboration and pharmaceutical management?*

Major challenges faced with the implementation of TB/HIV collaborative activities included—

- Lack of IPT implementation
- Ineffective referrals between TB and HIV services
- Inadequate support to new districts to carry out collaborative activities after training
- Unequal medicine pricing (TB medicines that are free to patients, while ARVs are not always free)
- Inadequate stocks of co-trimoxazole for CPT
- Need to modify community-based treatment model to accommodate patients on both ARVs and TB medicines

## **Appendix A. Documents Reviewed**

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## **Appendix B. Data Collectors and Key Stakeholders Interviewed**

### **Data collectors**

- Norbert Anyama
- Kibuule Dan
- Professor Richard Adoi Adome

### **Key stakeholders**

- Dr. Anna Nakanwagi-Mukwaya, National Program Officer TB/HIV, WHO Uganda
- Dr. Henry Luwaga, AIDS/HIV Integrated Model district programme, National Tuberculosis and Leprosy Program
- Mr. Bagonza David, National Medical Stores
- Mr. Anywa Thomas, National Medical Stores
- Dr. Francis Sali, Joint Clinical Research Centre
- Mr. Ociti Sunday, Joint Clinical Research Centre
- Mr. Enoch Kizito, Joint Clinical Research Centre
- Mr. Martin Oteba, Ministry of Health
- Mr. Moses Seru, Ministry of Health
- Sr. Marlis Gaul, Joint Medical Stores
- Dr. Hope Mulindwa, Makerere University Teaching Hospital
- Mr. Mutabazi Isaac, AIDS Support Programme
- Uganda AIDS Commission

