Malawi: Assessment of the Logistics and Supply Chain Management of Anti-TB Medicines

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ABBREVIATIONS AND ACRONYMS

CHAM	Christian Health Association of Malawi
CMS	Central Medical Store
DMLO	drug management logistics officer
DOTS	directly observed treatment short course
DTO	district TB officer
EHP	essential health package
FDC	fixed-dose combination
FEFO	first expiry, first out
GDF	Global Drug Facility
GoM	Government of Malawi
HIV	human immunodeficiency virus
HSA	health surveillance assistants
LMIS	logistics and management information system
LSCM	logistics and supply chain management
MDR-TB	multidrug-resistant TB
MoH	Ministry of Health
NDQCL	National Drug Quality Control Laboratory
NTP	National Tuberculosis Program
PMPB	Pharmacy, Medicines, and Poison Board
QECH	Queen Elizabeth Central Hospital
RMS	regional medical store
SOP	standard operating procedure
SSC	senior stores clerk
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organisation
ZTO	zonal TB officer

EXECUTIVE SUMMARY

Malawi is a landlocked country in Southern Africa. It is bounded in the west by Zambia, in the east, south, and southwest by Mozambique, and in the north by Tanzania. In Malawi, health care is provided by both the public and private sectors; the public sector services are free of charge while user fees are charged in the private sector. Treatment of tuberculosis (TB) is within the scope of the public sector and it is integrated as an essential health package (EHP) following the sector-wide approach.

TB, a disease of public health significance in Malawi, is controlled centrally by the National Tuberculosis Program (NTP) in a tiered system. NTP provides technical support to lower levels in the program. In 2005, the case notification rate was 27,610 cases; this dropped to 24,356 in 2009. In 2004, of the total of 27,000 cases diagnosed with TB, 34% were smear positive cases; the urban districts of Mzuzu, Blantyre, Lilongwe, and Zomba accounted for 47% of the total cases in 2004. By 2009, Malawi exceeded the World Health Organization's (WHO) treatment success rate target of 85% by achieving a success rate of 88%.

To strengthen the NTP, a review of its activities as a forerunner to this report was conducted to inform the next NTP strategic plan. The review highlighted some challenges with drug management including inadequate storage space for sufficient buffer stock at the national level, inadequate storage space, poor stock management, and inadequately maintained stock records at the facility level.

This report presents the finding of assessment of the logistics and supply chain management (LSCM) of anti-TB medicines in Malawi. The purpose was to produce, in collaboration with the NTP logistician and NTP senior management, a comprehensive field report that identifies strengths and weaknesses and provide recommendations to the NTP program manager. The review utilized the methodology for pharmaceutical management assessment for TB developed by the USAID-funded Rational Pharmaceutical Management Plus (RPM Plus) program in 2005. The review concentrated on qualitative assessment at all levels of TB management.

Various strengths and weaknesses were identified in the LSCM of anti-TB medicines, and recommendations were made on the basis of key issues that negatively impacted service delivery such as those listed below.

Drug Regulation and Quality Assurance

- NTP should always request the results of quality assurance tests carried out on all anti-TB medicines. The NTP should follow up with the National Drug Quality Control Laboratory (NDQCL) and the Pharmacy, Medicines, and Poisons Board (PMPB) to ensure that it is regularly updated on the quality of all products that enter the country.

- Standard operating procedures (SOPs) for post-marketing surveillance of anti-TB medicines should be developed by the PMPB in collaboration with the NTP and circulated to the health facilities so that the quality of anti-TB medicines in circulation would be actively monitored.

Product Quantification and Procurement

- For long-term planning and sustainability, the Government of Malawi (GoM) must continue to budget for anti-TB medicines; however, it must also search for alternative funding sources (bilateral and multilateral organizations) in addition to that supplied by the Global Drug Facility (GDF). Budgeting should be based on a procurement planned for at least two years with an appropriately organized supply plan, developed and revised regularly, based on the in-country need.

- Considering the current drive to strengthen the Central Medical Store (CMS), NTP should integrate its procurement process into the CMS procurement machinery while NTP continues with quantification, providing accurate data for purchase to the CMS.

- It is in the long-term interest of NTP and partners to ensure that the capacity of the drug management logistics officers (DMLOs) is strengthened. The DMLOs have to be trained on all aspects of forecasting and quantification, beginning with basic principles. They may then become trainers for the other staff in the pipeline. It is worth mentioning that the current human resource development plan of the NTP does not specifically mention the pharmaceutical cadres in any training plan. Alternatively, and as part of its service integration plan at the district and health-center levels, NTP should work closely with the pharmaceutical services directorate to integrate pharmacy technicians in the district TB management team.

- The DMLOs should follow established maximum and minimum stock levels as indicated on the NTP drug management guideline. Accurate consumption data already exists in all the facilities. Patient data could be used to supplement the estimation of need when necessary. The maximum and minimum stock levels should be used at health facilities to make orders from regional stores.

Warehousing and Storage

- NTP should support training of store managers and staff on good storage practices.

- NTP should advocate for an assessment of national storage capacity of anti-TB medicines to help identify health facilities needing store refurbishment or reconstruction.

Transport and Distribution

- NTP should ensure that transportation of anti-TB medicines is done at the same time with other EHP commodities. This is in line with service integration promoted by NTP at

service delivery points. It will save staff time, eliminate costs borne by the system due to separate transport arrangements, create an opportunity to monitor timely ordering by the district TB officers (DTOs) and health surveillance assistants (HSAs), and allow the regional medical stores and DTOs time to conduct other activities.

Inventory Control and Logistics Management Information Systems

- NTP should advocate for integration of its information system into the current logistics management information system (LMIS) for the EHP and seek opportunities for its staff to be trained on the LMIS.

- The anti-TB medicines guidelines should be integrated into the national TB guidelines. The number of months of stock for maximum and minimum stock levels is very clear.

- Pharmacy technicians in district hospitals should be engaged to support inventory management practices at the district and health center levels because they store anti-TB medicines alongside other essential medicines and health commodities.

Dispensing and Rational Use

- NTP should identify one preferred way of dispensing anti-TB medicines to patients and scale it up to all districts and zones. One way of doing this is to tie current treatment successes and completion rates to zonal dispensing practices. The dispensing practices of zones that achieve high treatment success and completion rates should be upheld and scaled up.

- For the next round of trainings for the directly observed treatment short course (DOTS)/TB, NTP should stress the importance of taking and documenting patients' weight and providing treatment according to weight.

- NTP should also provide weighing scales for facilities that need them.

Management Support

- Regular support supervisory visits by the DMLOs should be implemented; reports should highlight problems and list recommendations and actions taken to resolve the problems.

- After each support supervisory visit, the service delivery levels should improve. Therefore, DMLOs should, in collaboration with partners, develop an indicator-based tool to monitor progress for the anti-TB medicines logistics system.

- NTP should expand the use of job aids in health facilities and all service delivery points and also use them as training materials.

INTRODUCTION

Country Profile

Malawi is a landlocked country in Southern Africa. It is bounded on the west by Zambia; on the east, south, and southwest by Mozambique; and on the north by Tanzania.

Figure 1. Administrative map of Malawi

Malawi is divided into the northern, central, and the southern regions. These regions are subdivided into 28 districts, which are further subdivided into traditional authorities. The population of Malawi is 13.1 million; 15.3% reside in urban areas. Between 1998 and 2008, the

population grew by 4.2 million people. This high population growth was attributed to a high fertility rate and a low contraceptive prevalence rate. As of 2009, Malawi's GDP per capita was USD 290. Malawi is predominantly an agricultural nation; the agricultural sector accounts for 35% of GDP; 93% of export earnings; and 80% of employment. Sources of public sector revenue include taxes on personal income and company profits, trade taxes, and grants from donors. As of FY 2008–09, the public sector health budget allocation was 10.2%.

Overview of Malawi Health Care System

The Malawi health care system is made up of both the public and private sectors. The public sector includes all government health institutions. The private sector consists of for-profit and faith-based organizations such as the Christian Health Association of Malawi (CHAM). Services provided by the public sector are free of charge while the private sector charges user fees. The health system is divided into the central administration and tertiary-, secondary-, and primary-level institutions. The Ministry of Health (MoH) belongs to the central unit together with the Reproductive Health Unit, the Health Education Unit, the Research Unit, the Community Health Services Unit, the NTP, the HIV/AIDS Department, and the Central Medical Store (CMS). The central units provide leadership and coordinate the development, review, and enforcement of health policies for the government. To facilitate service delivery and ensure efficient policy implementation and monitoring, MoH established five health zones with zonal officers who are responsible for providing technical support to district health management teams.

At the tertiary level, health care is delivered by central hospitals that provide specialist referral services to their respective zones. Central hospitals include the Queen Elizabeth (QECH) in Blantyre, Zomba in Zomba, Kamuzu in Lilongwe, and Mzuzu in Mzimba. In addition to referral services, they also provide the essential health package (EHP) services.

The secondary-level health service providers are the district and CHAM hospitals. These hospitals provide general services, primary health care services, and supervision to lower units. In addition, they provide training and support to community-based health programs and are managed by a district health management team which in turn receives support from the zonal health supervisory officers.

Health care provision at the primary level is undertaken by health surveillance assistants (HSAs), community-based distributing agents, community health nurses, and other volunteers within community and institutional settings, such as community initiatives, health posts, dispensaries, maternities, health centers, and community and rural hospitals. Here, promotive and preventive services, including HIV testing and counseling as well as community case management of acute respiratory tract infections, are given. HSAs are also involved in providing medicines to patients with TB.

Tuberculosis in Malawi

TB is a disease of public health significance in Malawi (MoH, 2007). In 2005, the number of cases notified was 27,610; this dropped to 24,356 in 2009. In 2004, of the total of 27,000 cases

diagnosed with TB, 34% were smear positives; Mzuzu, Blantyre, Lilongwe, and Zomba urban districts accounted for 47% of the total. In 2009, Malawi exceeded the WHO treatment success rate target of 85% by achieving an 88% success rate. In the same year, death rates decreased to approximately 7%. The TB default rate has decreased from 4% in 2006 to 2% in 2009/2010.

National Tuberculosis Program

The National Tuberculosis Program (NTP) was launched in 1964 and currently has 100% directly observed treatment short course (DOTS) coverage. The aim of the NTP is to reduce the burden of ill health due to TB until the disease is no longer a public health problem. Previously a vertically operated program, the NTP is currently integrated into the general health services. TB treatment is a component of the EHP of MoH through its sector-wide approach to public health. Structurally, the NTP has several units with different complimentary roles.

Central Unit

This unit reports to the secretary for health. It is headed by the TB program manager who is supported by two deputy program managers and officers responsible for research; advocacy, communication, and social mobilization training; TB/HIV; drug logistics; multidrug-resistant TB (MDR-TB); central reference laboratory; and data management. The functions of the NTP include advocacy, partnership and collaboration, service integration, policy formulation, development of guidelines, monitoring and evaluation, and mentorship. The central level also includes a national TB advisor position manned by a senior physician providing guidance to the NTP.

Zonal Level

At the zonal level, zonal TB officers (ZTOs) head TB activities and report to the TB program manager through zonal health supervisors (ZHSs). Their functions include—

- Coordinating TB control activities by working closely with district health staff
- Supervising and training district health staff responsible for TB control activities
- Compiling and analyzing TB data for the zone
- Ordering, distributing, and monitoring supplies

District Level

At the district level, activities are managed at three levels—the district TB officer (DTO), who heads a district TB management team; the peripheral level (health centers and health posts); and community-level TB activities. The activities include health education, diagnosis, treatment, and patient care services. It is at this level that service integration takes place. The district TB management team is made up of the DTO, the assistant DTO, focal TB clinical officer, focal TB nurse, a laboratory technician, and a pharmacy technician.

The functions of the DTO include—

- Implementing NTP activities
- Supervising health workers in case findings and chemotherapy
- Updating the TB register
- Compiling quarterly reports on notified cases and treatment outcomes
- Training peripheral health workers in collaboration with the district health officer, ZTO, and information, education, and communication officer
- Ordering supplies, drugs, laboratory reagents, and slides

Peripheral Level (Health Center and Health Post)

The peripheral unit performs the following functions—

- Sending TB suspects or their specimens to microscopy centers for investigation
- Providing treatment services including DOT
- Tracing defaulters and irregular attendees
- Keeping patients records and submitting sputum results to the DTO
- Conducting health promotions and education for patients and the community

Community

Community members assist in case findings and proving DOT.

Background to the Assessment

In February 2011, a team of experts and resource personnel reviewed NTP activities to inform its next strategic plan; the first independent review was conducted in 2005. In terms of anti-TB drug management, the review identified the following challenges—

- Inadequate national storage capacity for sufficient buffer stock
- Inadequate storage space and conditions for TB drugs in most facilities visited
- Poor stock management at the facility level including inadequately maintained stock cards
- Near-to-expiration drugs (February/March 2011) in many facilities
- Inadequate pharmacy supervision at the district level
- Transport logistics

By June 2011, in addition to the above challenges, it was noted that—

- At the district level, there were stock outs of some first-line drugs, particularly for pediatric formulations and adult fixed-dose combinations (FDCs), for example, rifampicin/isoniazid/ethambutol

- There were delays with Global Drug Facility (GDF) procurements beyond projected delivery dates
- Stock outs were not being communicated to the NTP

Furthermore, the recent moves to decentralize anti-TB drug management implies an impending need to increase availability of the medicines in the decentralized sites, requiring personnel that are trained in the overall management of these medicines.

Purpose and Objectives

The purpose of the assessment was to produce, in collaboration with the NTP logistician and NTP senior management, a comprehensive field report that identifies anti-TB medicines logistics and supply chain strengths and weaknesses and provides recommendations to the NTP program manager. The objectives were—

- Conduct a situational analysis and internal audit of the current logistics and supply chain management (LSCM) system at all levels, including CMS, the NTP Central Unit, the zonal and district TB offices, district health officer pharmacies, and health facilities.
- Produce a comprehensive field report for the NTP identifying LSCM system strengths and weaknesses and providing recommendations to the NTP program manager.
- With stakeholders, explore ways to leverage proposed reforms to LSCM systems for malaria and HIV to strengthen TB LSCM system.
- With NTP, produce a LSCM action plan to enumerate concrete steps to overcome LSCM bottlenecks and streamline the system to ensure an uninterrupted supply of quality TB drugs and commodities.

METHODOLOGY

The pharmaceutical management of TB indicator-based assessment tool was used to conduct the rapid assessment. One of the strengths of the tool is its ability to capture both quantitative and qualitative information. However, because of time and logistics constraints, the tool was adapted to capture only qualitative information in the pharmaceutical management cycle. The pharmaceutical management cycle is based on the pharmaceutical management framework developed by Management Sciences for Health with support from USAID.

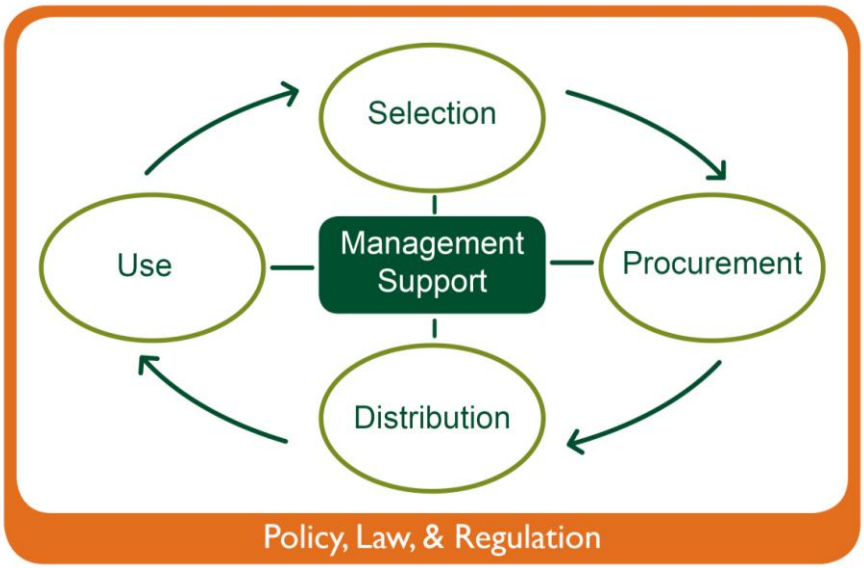


Figure 2. Pharmaceutical management framework

Source: Center for Pharmaceutical Management. 2011. *Center for Pharmaceutical Management: Technical Frameworks, Approaches, and Results.* Arlington, VA: Management Sciences for Health.

The key elements of the pharmaceutical management framework include—

- **Selection:** choosing high-quality TB medicines in appropriate dosage forms and strengths
- **Procurement:** quantifying TB medicine needs, selecting an appropriate procurement method, managing tenders, establishing contract terms, assuring drug quality, and monitoring adherence to contract terms
- **Distribution:** meeting customs requirements, stock control, stores management, and delivery to drug storerooms and TB facilities
- **Use:** appropriate diagnosing, prescribing, and dispensing by the provider and proper consumption by the patient

- **Management support:** involves organization and management, financing, information flow, and human resource management

Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to fight TB by ensuring continuous access to quality, safe, and effective TB medicines. In this assessment, the main pharmaceutical sector areas investigated were medicines policies and guidelines, medicine selection, warehousing and storage, distribution and transport systems, inventory management, quality assurance, and rational use.

Preparatory Phase

The logistics for this assessment were coordinated by the NTP with support from USAID Malawi and SPS Arlington. The NTP drug management logistics officers (DMLOs) were responsible for planning meetings with stakeholders. Because of communication challenges from NTP Malawi, it was not possible to discuss the assessment tools with stakeholders prior to the assessment. Because it was difficult to get information from the NTP that would have shaped the assessment tools to the Malawi context, an online literature search on Malawi's health policy, TB situation, and economy was conducted to formulate some of the assessment questions. In addition, the NTP provided some technical documents during the assessment.

Sampling Plan and Sample Size

A purposive sample of NTP, regional, and district pharmacy stores; central and district hospitals; and clinics and health centers that focus on TB medicines management were selected. The sampling was based on—

- Burden of TB disease
- Facility distribution
- Ease of accessibility
- Overall challenges presented by facility

Overall, 21 sites made up of hospitals, health centers, and storage facilities were selected from 4 of the 5 zones in Malawi, accounting for two-thirds of the population. Also included were 3 of the country's 4 urban cities that accounted for 41% of all new smear-positive TB cases in 2009. The 21 sites were 13 health centers, 3 district hospitals, 2 central hospitals, 2 regional medical stores (RMSs), and the CMS. Others included the Pharmacy Medicines and Poison Board (PMPB), the National Drug Quality Control Laboratory (NDQCL), and the NTP.

Tracer Drug List

The DMLOs provided a list of anti-TB medicines that were used for susceptible as well as MDR-TB cases. The tracer list as shown in Table 1 consisted of 17 different medicines of separate dose preparations as well as FDCs.

Table 1. Malawi Tracer Drug List for LSCM Assessment

First line	Medicine symbol	Strength	Dosage form
Rifampicin/isoniazid	RH	150 mg/75 mg	Tablet
Rifampicin/isoniazid/pyrizinamide	RHZ	60 mg/30 mg/150 mg	Tablet
Rifampicin/isonaizid	RH	60 mg/30 mg	Tablet
Rifampicin/isoniazid/pyrazinamide/ethambutol	RHZE	150 mg/75 mg/400 mg/275 mg	Tablet
Ethambutol	E	100 mg	Tablet
Isoniazid	H	100 mg	Tablet
Rifampicin	R	150 mg	Capsule
Ethambutol	E	400 mg	Tablet
Rifampicin/isoniazid/ethambutol	RHE	150 mg/75 mg/275 mg	Tablet
Streptomycin	S	1 g	Vial
Second line			
Cycloserine	Cs	250 mg	Tablet
Ethionamide	Eth	250 mg	Tablet
Kanamycin	Km	1 gm	Vial
Levofloxacin	Lfx	250 mg	Tablet
Capreomycin injection	Cm	1 gm	Vial
Pyrazinamide	Z	400 mg	Tablet

Data Collection

Various forms with semi-structured questions were used to collect data (annex D). Table 2 is a list of the forms used and the source of data collection. A list of the facilities visited is shown in annex B. Samples of the various data collection instruments are found in annex A.

Table 2. Data Collection Forms

No.	Data collection forms	Information collected from
1	TB Interview Guide at Health Facility	Health facilities
2	Regional/district medical store interview guide	Stores in district hospitals and RMS
3	Medical records review data form (intensive phase)	TB treatment sites in hospitals and health centers
4	Medical records review data form (continuation phase)	TB treatment sites in hospitals and health centers
5	Storage condition for TB medicine form	Stores in district hospitals, RMS, CMS, and some health centers
6	CMS interview guide (distribution units)	CMS
7	NDQCL interview guide	NDQCL
8	NTP interview guide	NTP

Several meetings which were ongoing at the time of this assessment necessitated the revision of the previously planned schedule for data collection (the revised schedule is shown in table 3).

Table 3. Data Collection Schedule

Day 1	In-brief of key stakeholders, final assessment planning, part of the key stakeholder interviews at central level
Day 2	Data collection continued at central level; in-brief of USAID/review of documents
Day 3	Data collection continued at central level/review of documents
Day 4	Data collection at Salima district/review of documents
Day 5	Data collection at Ntcheu district/review of documents
Day 6	Document review
Day 7	Travel to southern region
Day 8	Visit Facilities in Blantyre
Day 9	Visit facilities in Chiradzulu and Thyolo and travel to Zomba
Day 10	Visit facilities in Zomba and Machinga and travel to Lilongwe
Day 11	Visit facilities NDQCL and PMPB and prepare for out-briefing
Day 12	Out-brief USAID and NTP

FINDINGS

The findings presented in this report were obtained using semi-structured interviews conducted with key staff of the TB program from the policy to implementation levels. The list of staff interviewed is shown in annex A. Other data collection methods included review of patient medication charts and observations. These findings are presented in the following thematic areas—

- Policy and product selection
- Drug regulation and quality assurance
- Product quantification and procurement
- Warehousing and storage
- Transportation and distribution
- Inventory control and logistics management information systems (LMISs)
- Dispensing and rational use
- Management support
- TB/HIV collaboration

Policy and Product Selection

In Malawi, the government's policy restricts the procurement and distribution of anti-TB medicines to the public sector. The government launched NTP in 1964, and in 1984, it fully implemented the DOTS strategy to provide 100% DOTS coverage.

Availability of Guidelines

A list of essential anti-TB medicines have been selected and are in use in Malawi. This list is in accordance with the World Health Organization's Essential Medicines List for treatment of susceptible TB and MDR-TB. The list is also in line with the list of medicines that are available from GDF.

Malawi has standard treatment guidelines that incorporate the Malawi Essential Medicines List, 4th edition, 2009. In addition, the NTP has a TB treatment manual (6th edition, 2007) that lists the names of medicines for each type of TB case for adult and pediatric patients and the appropriate strengths and dosage forms. It also specifies what medicines are available as FDCs and separate dose products. The manual does not include medicines used for the treatment of MDR-TB; Malawi uses a standardized approach to treat MDR-TB patients with capreomycin, cycloserine, ethionamide, pyrazinamide, and levofloxacin. A policy document to guide the management of MDR-TB (edited in 2010) is available in electronic form; the form is printed and used in treatment once an MDR case is notified and confirmed in the community by a health facility. In Malawi, MDR-TB is managed at the community level.

Table 4. Types of Anti-TB Medicines for Adults and Children Listed in the Malawi NTP Manual, 6th Edition, 2007

Injectable product: streptomycin 1 g					
Adults			**Pediatrics**		
FDCs	**Name of medication**	**Strength (mg)**	**FDCs**	**Name of medication**	**Strength (mg)**
RHZE	Rifampicin	150	RHZ	Rifampicin	60
	Isoniazid	75		Isoniazid	30
	Pyrazinamide	400		Pyrazinamide	150
	Ethambutol	275	RH	Rifampicin	60
RHE	Rifampicin	150		Isoniazid	30
	Isoniazid	75	**Separate dose preparations (adult and pediatric)**		
	Ethambutol	275	Z	Pyrazinamide	400
RH	Rifampicin	150	E	Ethambutol	400 and 100
	Isoniazid	75	H	Isoniazid	100

The NTP has an anti-TB medicines management guideline that was developed from the national pharmaceutical management policy. This guideline details the pharmaceutical management procedures of anti-TB medicines, but is not included in the national TB manual. The national tuberculosis manual is currently being revised.

The number of cases on each anti-TB medicines regimen, according to the 2010 annual report (NTP, June 2011), are as shown in table 5.

Table 5. Distribution of TB Patients by their Therapeutic Regimens, 2010

Treatment category	Regimen type	Number of patients
New smear-positive pulmonary TB patients	2RHZE/4RH	7,240
Smear-positive pulmonary TB (relapse)	2RHZES/1RHZE/5RHE	750
Smear-negative pulmonary	2RHZE/4RH	8,245
Smear-negative extra pulmonary TB	2RHZE/4RH	4,857
Treatment after default	2RHZES/1RHZE/5RHE	323
Treatment failure	2RHZES/1RHZE/5RHE	67
Recurrent TB	2RHZES/1RHZE/5RHE	1,054

Compliance to Manuals and Guidelines

Stakeholder interviews revealed that to ensure compliance to the guidelines by prescribers and dispensers, ZTOs and DTOs regularly conduct supportive supervisory visits. However, of the 19

health facilities assessed where TB patients were treated, the TB manual was available in only 16 (84.2%) facilities. In the three (15.8%) facilities without the manual, two reported that the manual was available, but not accessible, and the one facility said that the manual was not available at all. In one facility where the manual was available but not accessible, it was reported that the nurse in-charge had probably locked it up. In the second health center, the HSA had taken the manual home. Job aids for prescribers and dispensers were available only in some health centers, especially those in the south west zone. However, there were variations in the design of the job aids.

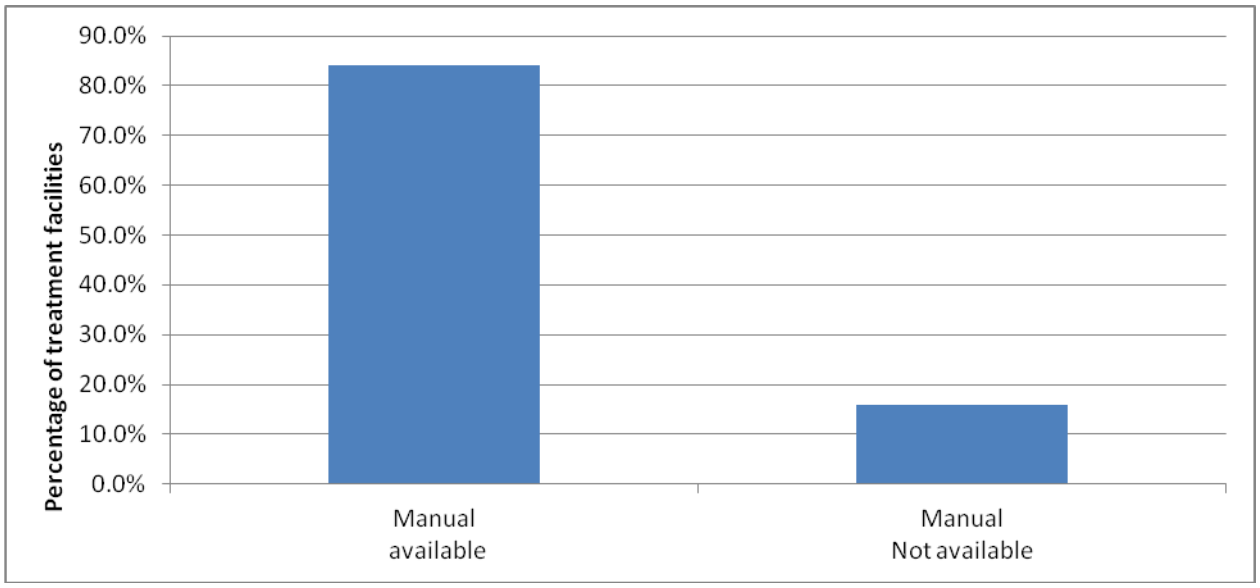


Figure 3. Availability of recent TB treatment manual in health facilities

Regulation and Quality Assurance

The national drug regulatory authority of Malawi is the PMPB. In principle, all anti-TB medicines (first and second lines) used in Malawi are expected to be quality-certified by PMPB before they can be used. At the helm of the PMPB is the Medicines Registration Committee, which oversees the medicines registration process through its secretariat. The secretariat liaises with the PMPB, the company requesting product registration, and the NDQCL. Any pharmaceutical company that intends to register anti-TB medicines for use in Malawi sends its request to PMPB, who then sends samples to NDQCL. If any sample does not meet quality standards, the registration process is halted. However, if the product has been registered and a batch is found to have quality problems, NDQCL sends the same sample to a WHO certified laboratory in South Africa for confirmation. The NDQCL has requested WHO accreditation, which is pending as of the assessment.

To minimize quality issues, it was reported that NTP has selected only WHO prequalified pharmaceutical manufacturers and obtained products from GDF. The main suppliers of anti-TB medicines with registered products are Lupin Ltd., Svizera Europe BV, Sandoz (Pty) Ltd.,

Macleods Pharmaceuticals Ltd., South African Druggist (Malawi) Ltd., Aspen Pharmacare Intl., and Cipla Ltd. As of the assessment, all these companies together had registered 37 anti-TB medicines.

Table 6. Number of Registered Anti-TB Medicines in Malawi on the WHO Prequalification List

First line	Symbol	Dosage form	Total registered	Total included in WHO pre-qualification list
Ethambutol 100 mg	E	Tablets	1	0
Ethambutol 400 mg	E	Tablets	2	3
Ethambutol HCl 400 mg + isoniazid 150 mg	EH	Tablets	2	2
Ethambutol 275 mg + rifampicin 150 mg + isoniazid 75 mg + pyrazinamide 400 mg	RHZE	Tablets	3	4
Isoniazid 100 mg	H	Tablets	2	2
Isoniazid 300 mg	H	Tablets	2	2
Pyrazinamide 400 mg BP	Z	Tablets	1	3
Pyrazinamide 500 mg	Z	Tablets	4	1
Rifampicin 150 mg + isoniazid 75 mg	RH	Tablets	2	3
Rifampicin 300 mg	R	Tablets	1	0
Rifampicin 60 mg + isoniazid 30 mg + pyrazinamide 150 mg	RHZ	Tablets	2	1
Rifampicin 60 mg + isoniazid 30 mg	RH	Tablets	2	2
Rifampicin 150 mg + isoniazid 75 mg	RH	Tablets	2	3
Streptomycin 1 g	S	Vials	3	0
Second line				
Cycloserine 250 mg	Cs	Capsules	2	2
Ethionamide 250 mg	Eth	Tablets	3	2
Ofloxacin 200 mg	Oflx	Tablets	1	1
Ofloxacin 500 mg	Oflx	Tablets	1	1
Prothionamide 250 mg	Prth	Tablets	1	0
Total			37	32

Table 6 shows that ofloxacin and prothionamide are registered in the country as second-line anti-TB medicines, although they are not in the standard list; however, levofloxacin 250 mg and kanamycin 1 g vials are in the standard list, but are not yet registered. The PMPB did not provide any reason for these unregistered products.

Lupin had four of its FDC anti-TB medicines for adult and pediatric patients rejected in 2010 while two were pending registration, all because of quality problems.

When a manufacturing laboratory registers a pharmaceutical product of a particular active ingredient and strength and wishes to register the same active ingredient in a different strength, the manufacturer must complete the registration process all over again; every year, pharmaceutical products must be re-registered for them to circulate in the market. Stakeholder interviews indicated that there was no official hard copy manual to guide the re-registration process, but MALADIS, a computer software package, is used for drug registration. This program captures details of the product to be registered, such as applicant name, certificate from regulatory authority of country of origin, evidence of registration in other countries, certificate of analysis, and Good Manufacturing Practice and clinical trials reports.

Medicines imported into Malawi for use in the public sector are sampled by CMS and sent for testing at NDQCL. Results of the quality test are sent to CMS for decision. If the analysis was requested by PMPB as part of the registration process or as part of the routine in-country post marketing surveillance process, the result will be sent to PMPB. As part of the registration process, if NDQCL raises quality issues with a product and alerts PMPB, the manufacturer or product importer will be alerted. Depending on the nature of the quality problem identified, the product might be de-registered, a Good Manufacturing Practices re-inspection is requested, or a warehouse inspection is arranged.

When defective products in circulation are to be recalled, CMS identifies where supplies were sent and PMPB issues an order for CMS to recall the products. The quantities recalled/seized are then verified by PMPB inspectors. Stakeholder interviews revealed that there is no standardized system for reporting bad-quality medicines in circulation within the health system. In the six months prior to the interview, it was revealed that four reports of products with doubtful quality were received from the facilities by the PMPB. However, no feedback had yet been issued by PMPB. In the 24 months preceding this assessment, it was reported that a manufacturer submitted applications to register seven anti-TB medicines, of which four failed. The Medicines Committee decided to suspend the registration of the other three products until a Good Manufacturing Practices inspection of the manufacturing facility was conducted.

It was reported that when imported anti-TB medicines were received at CMS, they were quarantined and sampled for quality assurance testing. Stakeholder interviews revealed that until the medicines met the standard of quality specified they were not released for consumption. Document review revealed that this was not often the case. Of the 28 batches of anti-TB medicines sampled for testing over the 12 months preceding this assessment, only 9 batches were tested. However, all 28 batches were eventually released for use.

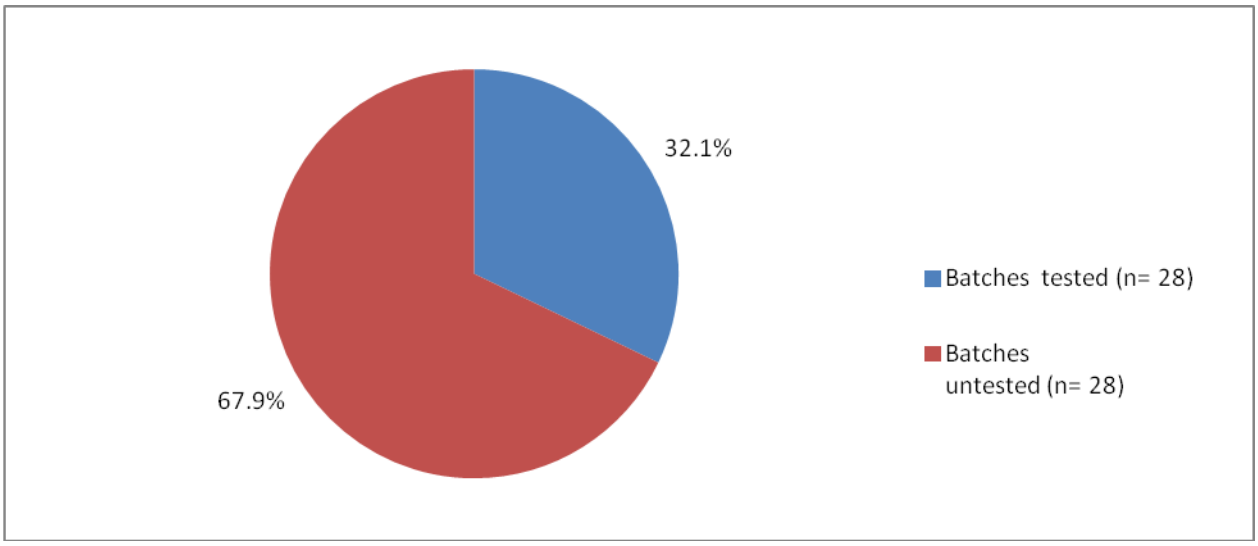


Figure 4. Distribution of batches (n = 28) of anti-TB medicines sampled for quality assurance test in Malawi between October 2010 and September 2011

Routine tests reportedly conducted by the NDQCL include identification, assay, disintegration, dissolution, and uniformity of dosage form. NDQCL reports that all these tests are mandatory. However, document review and stakeholder interviews revealed that NDQCL had been able to perform only uniformity of weight, assay, and identification tests for anti-TB medicines because of a lack of standard reference materials. It was also revealed that monographs like the International Pharmacopeia, British Pharmacopeia, and US Pharmacopeia are available, but their use depended on staff capacity. Not all staff are adequately trained to use all the instruments in place. The laboratory reported that it needed more reference standards and more equipment such as infrared spectrometers.

Forecasting/Quantification and Procurement

The quantity of anti-TB medicines needed in the country is calculated at the national level. At the service delivery points, DTOs estimate the need for each facility. In principle, all anti-TB medicines are procured through the GDF through a grant agreement with the Government of Malawi (GoM).

Stakeholder interviews revealed that forecasting and quantification of anti-TB medicines was done by a team of three at the NTP level in collaboration with GDF. NTP provided the number of cases to be treated for the quantification period. The team of three persons consisted of the two DMLOs and the project management unit officer (PMUO), who is responsible for all financial transactions and sits in management meetings in the MoH on behalf of NTP. Stakeholder interviews revealed that quantification of first-line anti-TB medicines was based on a procurement period of six months and a lead period of four months. Although stakeholder interviews revealed that buffer stock was not factored into the national-level quantification process, a review of a grant application form showed that a buffer stock of 10% of the actual

need was added to the final calculation. Quantification at the national level was done by using the forms provided by GDF and was based on the morbidity method (i.e., the number of patients needing treatment for the quantification period). The total quantity of each medicine was then calculated as tablet/capsule units or as vials. A 10% additional quantity was included in the calculation to act as buffer stock. Procurement was done through GDF which supplied the medicines as a grant.

It was revealed that once GDF agreed with NTP on the quantities of products to be procured, a three-way communication between NTP, GDF, and CMS was initiated. When GDF was about to supply, CMS was informed of the quantity of anti-TB medicines to be shipped so that CMS could allocate storage space. When CMS confirmed availability of space, GDF then shipped the quantity agreed on. When GDF was unable to supply, the NTP requested CMS to procure the products from WHO prequalified suppliers. For medicines used to treat MDR-TB, it was reported that GDF did a quantification and procurement based on the number of notified cases for the previous order period. However, products were shipped in small quantities as requested by NTP because of the short shelf-lives of the products.

After quantification and procurement, the products are air-freighted to Lilongwe. It was reported that port clearance was undertaken by the GoM through a private enterprise called Allied Freight and that the Ministry of Finance provided a waiver for the clearing charges (custom duties). It was also reported that it took between two and four days for medicines to be cleared from the port of entry (Kamunzu International Airport) and that procedures for receiving and checking medicines (physical inspection, drug specifications, and quantities) were adequate. Storage conditions at the port of entry were periodically evaluated by the PMPB.

Interviews with stakeholders revealed that the GoM secured a grant agreement with GDF to supply needed anti-TB medicines for a period of three fiscal years. This agreement began in 2007/08, and GDF shipped medicines for 2007/2008 and 2008/2009 fiscal years. The products were usually received in September of each fiscal year. In 2009/2010, GDF did not supply the requested quantity as a result of misunderstandings between GDF and GoM that stemmed from the operations of GoM's cash budget and the funding of the third year grant. Although GoM had hoped that the Global Fund was to continue with supplies for the third year, the Global Fund had expected GoM to take over the procurement process. This resulted in stock-outs and the need for emergency orders, which were financed by GoM. Because of the breach in supplies from GDF, GoM included a budget for anti-TB medicines for 2011/2012 fiscal year.

After negotiations, GDF resumed supplies and the first consignment for the financial year 2010/2011 was received in April 2011. Although GDF resumed supply, it could not provide NTP with ethambutol 100 mg due to manufacturers' lack of raw materials (NTP was informed accordingly, which in turn informed the responsible department in MoH). While the GoM was in negotiation with GDF, NTP requested CMS to place an emergency order for the needed anti-TB medicines including ethambutol 100 mg to preempt stock outs. CMS floated a tender. Although it was an open national tender, it was restricted to WHO prequalified suppliers of anti-TB medicines registered with the PMPB (the same manufacturers supplying GDF). At the time of the assessment, CMS was still searching for ethambutol 100 mg from WHO prequalified manufacturers who could not supply GDF. CMS is not an integral part of the anti-TB medicines

procurement process and thus, it plays a passive and reactive role. This challenges any market intelligence analysis CMS could make. It was observed during stakeholder interviews that communication between NTP and CMS was not sufficient.

Ordering of Anti-TB Medicines by Health Facilities

At the district level, ordering anti-TB medicines is done every three months in principle, and the DTOs are responsible for estimating the quantities of medicines to order. These estimates are then sent to the zonal officers who cross-check the calculations for accuracy. To facilitate the calculation, a worksheet developed by the NTP is used at the district level. To determine quantities of each regimen, the worksheet must be filled with the number of patients, treatment phase, and stock on hand. A separate section of the sheet requires that a reserve quantity be estimated. After reviewing and comparing several forms, it was noted that the reserved quantity was equal to the same quantity of the particular anti-TB medicines needed for the number of patients on treatment. The quantity to order was determined by adding the reserve quantity to the number of medicines needed (based on the number of patients on treatment) and subtracting the stock on hand. Although this method provided sufficient quantities of anti-TB medicines to be kept for the next three months, a review of the forms showed that some DTOs had some calculation challenges that resulted in over ordering and stock outs. For instance, in Machinga District Hospital, RHE and streptomycin 1 g were over ordered while in Salima District Hospital, the calculation for RHZE showed that the quantity to order was zero, which was not the case.

It was also observed that, although all the districts visited had trained pharmacy technicians, it was not their duty to estimate anti-TB medicines needs; they were restricted by policy. The pharmacy technicians were, however, responsible for the quantification of all other essential medicines found in the pharmacy.

Generally, none of the DTOs and the HSAs interviewed had attended any training specifically on estimating the quantity of anti-TB medicines needed. However, a comprehensive training on TB management, including a component on pharmaceutical management, was conducted in 2007. The day and a half training session was organized mainly for DTOs.

Warehousing and Storage

Warehousing and storage deal with the movement of goods from the airport to the storage facilities including the service delivery points.

When anti-TB medicines are air-freighted into the country, they are stored in the airport's general storage facility for a maximum of four days. From the airport, medicines are received at CMS where they are quarantined until, in principle, they pass quality assurance tests; at that point, CMS and NTP are notified. NTP then provides CMS with the distribution plan to the RMSs.

In the medicines receiving section of CMS, a huge warehouse is used to briefly store anti-TB medicines for a maximum period of one month. The warehouse is made of translucent plastic

roofing sheets about 20 meters wide, 40 meters long, and almost 20 meters high at its peak. The building provides free air circulation, but there is no temperature control system. At the time of the visit, the warehouse did not have any anti-TB medicine in stock. Pallets were available, but no pallet racking system. The warehouse was clean, free from humidity, and had loading docks. It has a separate section for quarantining and adequate security measures with security guards at the main entrance and burglar bars at the doors. The few products found were zoned in their therapeutic categories. One forklift was visible. At the CMS receipt section, SOPs for receiving and dispatching products were available and regularly used by the pharmacist in-charge.

Two RMSs, central (cRMS) and southern (sRMS), were also assessed.

Stakeholder interviews revealed that cRMS served the central, west, and east zones, for a total of 154 health institutions (1 central hospital, 9 district hospitals, 137 health centers, and 7 CHAM hospitals). The cRMS was easily accessible with 16 full-time staff, 80 percent of whom were workhands. It was revealed that the workhands lacked basic knowledge on store management procedures. The cRMS building was too small and overcrowded for its volume of operation and had one dock used for on- and off-loading. Available office spaces were onsite, tiny, and overcrowded and were used by the senior stores clerk (SSC) and the pharmacy technician. The store had visible security with security guards at the main entrance and burglar bars in the main storage area. To enhance security, the office of the SSC was located such that he could, at any time, see the transactions in the stores. The SSC kept the keys to the main entrance of the storage area. One of the walls of the cRMS was cracked and tilted. Fans for ventilation were not working, there was no air conditioner for temperature control, and the windows were permanently closed. The cRMS had specific areas for cold chain storage with updated temperature charts. Dangerous products and injections were stored separately. Separate areas for receiving and delivery of products as well as for storing expired products were seen.

Stakeholder interviews revealed that because the store was overcrowded, pests, such as rats and cockroaches, were present. Although essential medicines were not stored in any systematic way, anti-TB medicines were grouped together and stored on pallets. The store had a hand pallet truck, with no pallet/storage rack. From the way that the store was arranged, it was obvious that proper inventory management procedures were seldom followed. This observation was confirmed by stakeholder interviews which also revealed that no SOP for store management was available.

The sRMS was easily accessible and had 76 staff, 11 of whom were full time. The staff consisted of pharmacists, pharmacy technicians, and workhands. The products were zoned and stored according to temperature condition and "sensitivity". There were cold chain and dangerous products storage areas. Antibiotics were considered highly sensitive or transactional as reported and had their own storage space. Within zones, it was reported that products were stored alphabetically, but on physical examination, we found this was not the case. There were no separate areas for storing bulk and loose products. The floor was chipped off in some areas due to the movement of storage equipment. Although air conditioners for temperature control were available, they were not working. A separate area for expired products existed. The store had a general purpose SOP for receiving and storing all medicines.

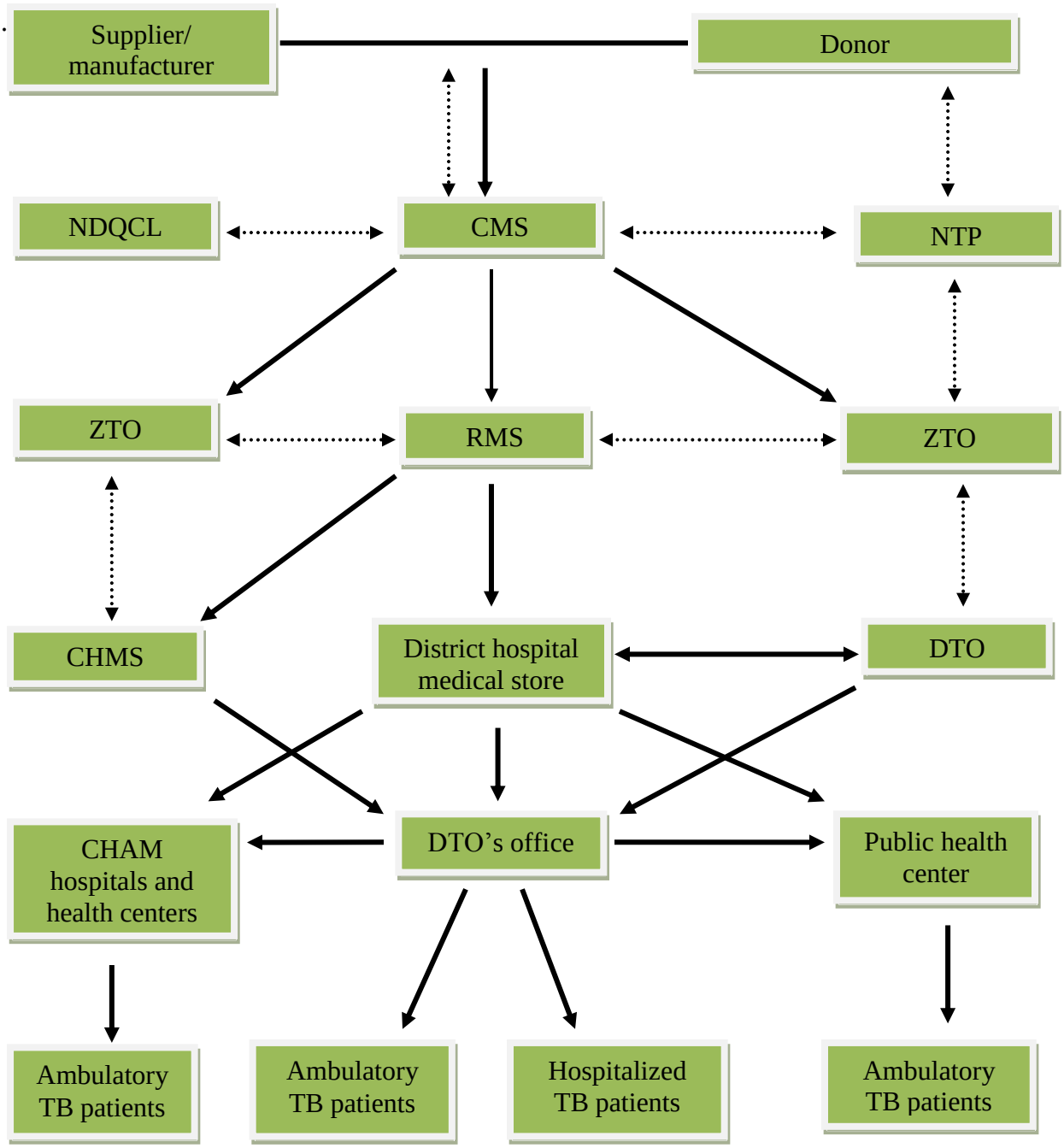
The Chiradzulu District Hospital store had sufficient space in the pharmacy for storage of medicines. However, the space was not properly managed. Medicines where not kept in a systematic manner, with cartons on the floor and on shelves. Apart from Chiradzulu, all the central and district hospital stores visited were small and overcrowded. Refrigerators and lockable cupboards for storage of cold chain items and dangerous goods were available. Some stores were humid. In Salima District Hospital, products were kept at a height almost touching the ceiling. No SOP was available in any of the stores for receiving and storing medicines and for general store management, though some pharmacy technicians reported they were familiar with the procedure. Anti-TB medicines were kept in a separate section in the stores. All the stores did not have sufficient pallets and shelves; in some, cartons were kept on the floor. Medicines were not arranged in any specific pattern, and from observation, some of the stores were not frequently cleaned. In QECH and cRMS, pests were reported and pesticides were reportedly being used.

At the health-center level, HSAs often kept expired medicines and medicines returned to the pharmacy (because the patient died) together with usable stock. Some health centers, which became treatment registration sites because of decentralization, kept their medicines in the pharmacy and also maintained a small stock at the HSA's office. In one health center, the HSA kept anti-TB medicines in his office and from the same office, sold drinks, dresses, and foodstuffs to the patients and public as a private enterprise.

Transportation and Distribution

The distribution of anti-TB medicines throughout the supply pipeline followed the push and the pull systems. Anti-TB medicines from the transit store of the CMS are allocated (pushed) to the three regional stores and from the three regional stores, district hospitals pull down their needs to the districts by placing orders through their zonal officers.

The NTP is notified when anti-TB medicines pass quality assurance tests and are ready for shipment to the regional stores. NTP writes to the controller of CMS, allocating medicines to the various RMSs. A review of one such mail from NTP revealed that anti-TB medicines were allocated 56% to the southern, 37% to the central, and 7% to the northern regions. Medicines for MDR-TB remained in the CMS and were sent to districts on instructions from the NTP when the district reported a new case. Figure 5 illustrates the flow of communication and anti-TB medicines in the supply pipeline.



Solid arrows indicate direction of medicine supply; dotted arrows indicate medicine order and supply information flow.

Figure 5. Anti-TB medicines supply pipeline and information flow

Orders are placed by using a requisition issue and receipt voucher (RIRV) from the ZTOs to the RMSs. The policy warrants that orders from the DTOs are verified by the ZTOs. They compare number of patients on treatment, stock on hand, and quantities of medicines requested. Once the ZTOs confirm the accuracy of the calculations, the order is sent to the RMSs, which pack and

ship to the districts the quantities requested by the ZTOs. At the districts, a district/health center drug committee is responsible for receiving, cross-checking, confirming, and signing the RIRV.

In each central and district hospital, the DTO keeps a certain amount of stock for each anti-TB medicine. Some of the medicines are dispensed to patients during the intensive phase of treatment and upon their discharge from the hospitals. Upon discharge, some DTOs dispense to the patients all the medicines required for the rest of the intensive and continuation phases; other DTOs provide to the patients enough medicines for two weeks and require patients to report to the health facility closest to home to get additional medicines every two weeks. The DTOs receive medication orders from the health centers. After cross-checking and confirming need, they place orders with the district hospital stores. It is the DTOs responsibility to ship the medicines to the health centers.

Transportation is provided by the supplier—CMS transports to RMS, RMS to districts, and districts to health centers. However, it was reported that there have been instances when the health centers went to the district levels and the district levels went to the regional stores to collect anti-TB medicines. Several factors were reportedly responsible for this and included stock outs at higher levels, lateness in submitting orders by lower levels, lack of fuel for motor-bikes, insufficient quantities of medicines received by patients upon discharge from the hospital, smaller than ordered quantities of medicines received by the ordering facility, and increases in the number of tablets per dose as a result of patients gaining weight during treatment. Instances were reported in which staff at health centers and CHAM hospitals paid the cost of transportation out-of-pocket to collect medicines from the district because "they did not want to leave the patient without medication."

At the health-center level, two systems of managing patient medications were practiced. Anti-TB medicines were kept either on a named patient basis or in bulk for a group of patients. In one of the distribution method, patients discharged from the hospital were given all their medications for the rest of the intensive and the continuation phases. They took the medications to the health centers closest to their homes to store them and returned to the health center every month for refills. In this case, the health centers kept medicines on a named patient basis and did not keep stock cards. In other health centers like Senga Bay, medicines were stocked in bulk, but without stock cards. However, the medicines were kept just for the number of patients on treatment and were ordered every month from the DTO.

Inventory Control and Logistics Management Information System

When anti-TB medicines are received in the RMSs, they are registered on stock cards. When the products were to be supplied, it was reported that they were released on the basis of first expiry, first out (FEFO). However, because of the small size of the cRMS, it was reported by some SSCs that FEFO was hardly practiced. From observation, it was found in most stores visited that only one batch of each of the different anti-TB medicines was available. This helped reduce the risk of medicines expiring due to ignoring FEFO. Batch numbers were tracked, but not by all stores.

Stakeholder interviews at all levels of the pipeline revealed that the number of months of stock taken to be maximum and minimum levels were not maintained, and in some instances, same-tier facilities gave different numbers of months of stock for minimum and maximum levels. CMS reported that they did not have a maximum or minimum stock level because the anti-TB medicines they received were dispatched to the RMSs within a week. The RMSs also reported that they neither had defined maximum and minimum stock levels, nor a defined period for stock replenishment. Buffer stock was not considered at the CMS and RMSs levels. Although DTOs reported that they factored in buffer stock quantity when quantifying anti-TB medicines, it was observed that buffer-stock level was not maintained. Review of stock cards revealed that in facilities where buffer stock was said to be kept, the buffer stock quantity was not equivalent to the number of months of stock claimed to correspond to buffer stock. In one regional store, it was reported that physical counting of stock took place monthly whereas in another, it was every three months.

At the district hospital pharmacies, the maximum stock level was reported to be three months, but the minimum stock level was zero months of stock; replenishment of stock took place when the last product was issued from the store. In addition, buffer stock was either not kept at some levels, or where it was kept, it did not reflect a systematic calculation, even though stakeholders reported that buffer stock was factored in their calculations of quantities to order.

Stock outs occurred frequently at all levels of the supply chain, but stakeholders reported that often it did not result in patients not having medicines because medicines were transferred between health facilities. At the time of the assessment, ethambutol 100 mg was out of stock in some facilities; stock replenishment of RHE, which was previously out of stock, had occurred. Stock outs for the following products were experienced during the past 12 months at all levels for various lengths of time.

- Rifampicin 150 mg/isoniazid 75 mg tablets
- Rifampicin 60 mg/isoniazid 30 mg/pyrazinamid 150 mg
- Rifampicin 60 mg/isoniazid 30 mg
- Ethambutol 100 mg

Apart from QECH, all the other health facilities assessed had not had ethambutol 100 mg for a period of up to six months. Figure 5 compares the rate of stock of anti-TB medicines in three zonal district hospitals in Malawi (Salima District Hospital in central east zone, Ntcheu District Hospital in central west zone, and QECH in south west zone). The three district hospitals were chosen for comparison because of the different ways medicines were distributed from them to the health centers, each posing its own risk of patients running out of medicines when stock outs occur.

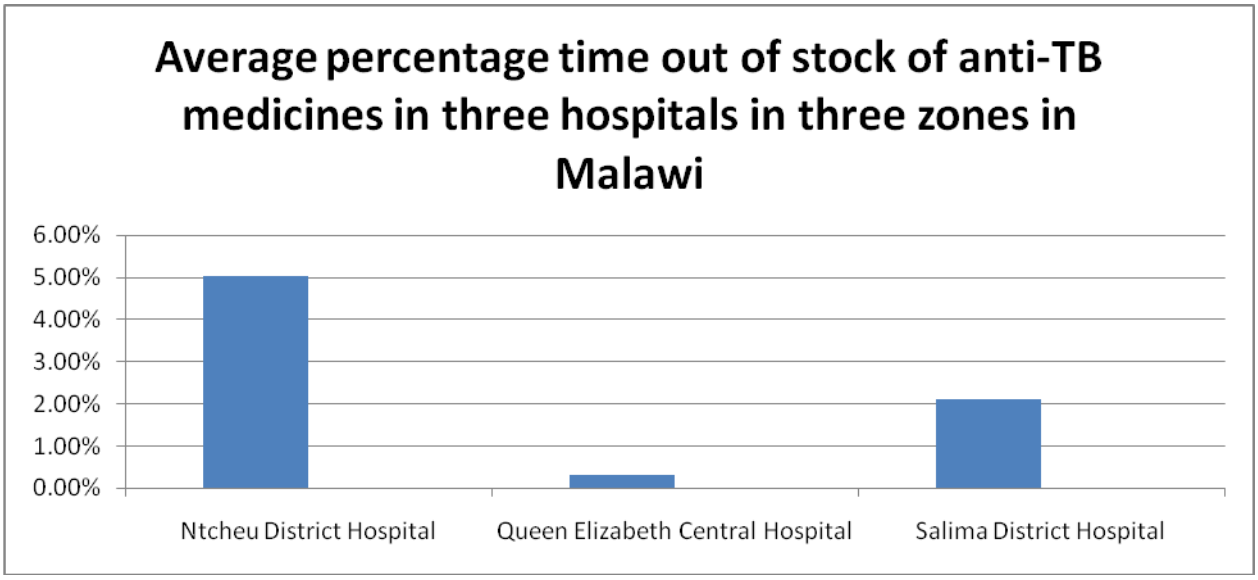


Figure 6. Time out-of-stock of anti-TB medicines in three different district hospitals in three zones in Malawi

Medicines were out of stock 5.04% of the time at Ntcheu District Hospital; 2.11% of the time at Salima District Hospital; and 0.3% at QECH. The long stock out of ethambutol 100 mg in Salima and Ntcheu accounted for the high stock out rate for both hospitals.

Stock outs were reported to be caused by delays in delivery, quantities delivered not in conformity with quantities ordered, transportation not available, forecasting errors, and insufficient and unqualified staff.

To reduce the incidence of stock outs in facilities, The DMLOs at NTP coordinated interfacility transfer of stock through the RMSs. At the lower levels, the district and health center management coordinated medicines transfers. When interfacility transfers occurred, the requesting facility used the interfacility drug requisition (IDR) form, which is sent to the lending facility's management for approval. It was reported that the anti-TB medicines borrowed were never refunded.

Expired anti-TB medicines were also found in some facilities; in one facility, an expired ethambutol 100 mg was found within usable stock. In that facility, the DTO reported that he was aware that the medicine was expired, but the pharmacy technician said he was not aware; this is an indication of the passive role that pharmaceutical personnel play in the LSCM of anti-TB medicines in most facilities. It was reported that short-dated products were frequently supplied from the RMSs to the district and health centers. The other reasons reported for expired medicines included untrained staff and errors in forecasting. The following products were found to have expired in different health facilities in the past 12 months preceding this assessment—

- Rifampicin 150 mg/isoniazid 75 mg
- Rifampicin 150 mg/isoniazid 75 mg/ethambutol 400 mg/pyrazinamide 275 mg
- Ethambutol 100 mg

A computerized LMIS, the supply chain manager, developed by USAID JSI/DELIVER project, was used to track inventory of all essential medicines kept in the medical stores of the regions and districts. However, anti-TB medicines were not included in this system and were managed by stock cards kept on the shelves close to the medicines. In the district hospital pharmacies, six different drug monitoring documents were used for inventory management—the RH daily monitoring book, anti-TB drug balance record book, anti-TB drug order book, DTO shadow file, ZTO shadow file, and drug requisition record book. These documents were used to monitor drug movements from the RMSs to the health centers. A sample of the booklets was cross-checked in Machinga and Chiradzulu Hospitals and the hospitals were found to have accurate transactional records. In QECH, though the booklet was correct, the stock in the DTO's office was not part of the stock in the booklet. The DTO kept a separate record of the stock.

It was observed that information from the drug monitoring books was not collated and reported to inform decision making. For instance, there was no consolidated-district or zonal-level report that indicated quantities of anti-TB medicines and commodities received, consumed, and balance for any particular period. Stakeholder interviews revealed that although the medicines' transaction reports were supposed to be received at the central level at least every quarter, this was never done. From the documents reviewed, medicine transaction reports were not part of the reports requested from ZTOs and DTOs.

Dispensing and Use

The treatment policy stipulates that patients with TB be admitted in district hospitals for two weeks after which they are discharged with medications. The central-hospital level does not admit any patient. It was observed that dispensing of anti-TB medicines followed two different approaches.

In some health facilities in some zones (Ntcheu District in the central west zone), upon discharge from the hospital, patients were supplied with all their needed medications for the rest of the intensive and continuation phases. The patients then took the medicines to the health center where s/he would be receiving treatment. At the health center, the medicines were stored on behalf of the patient. Based on scheduled appointments, the patients went to pick up medicines every two weeks or every month.

In other zonal health facilities, the patients reported to the nearest health center where s/he would be getting medicine refills. From these health centers, patients got their medicines every month (Senga Bay Baptist Hospital in Salima district in the central east zone). The medicines were supplied to the health centers in boxes, not on a named patient basis. The HSAs in the health centers determined the quantities of medicines needed for the number of patients they had. For a patient or guardian to collect the next routinely refilled medication, the patient's adherence behavior to the previously supplied medications was assessed. An adherence monitoring form was filled out by the patient or guardian and was evaluated by the HSAs. A review of some of the forms showed 100% adherence. However, this was a self-reported adherence rate by the patient or guardian. Stakeholder interviews revealed very low defaulter rates of 0% up to 2% in some facilities visited, corroborating the effectiveness of the self-report.

A total of 112 charts of patients on intensive and continuation phases of treatment were reviewed. It was observed that all patients in the intensive phase received the correct dosage of anti-TB medicines for their weights. However, it was also observed that in transitioning from the initial phase to the continuation phase, weights of patients were not frequently recorded to make dosage adjustments due to weight gain during the intensive phase; 50% of patients in the continuation phase did not have their weight taken before they were moved over to and throughout the continuation phase. Some of the reasons the HSAs gave were lack of weighing scales, scales shared with other departments, not aware that patients were to be weighed frequently, and not aware of the consequences of not weighing patients.

In the south western zone, it was found that job aids were available to aid prescription of anti-TB medicines. However, in the health centers of the central east and central west zones, no job aids were found.

The defaulter rate was extremely low in all the health facilities visited. In areas where treatment defaults were reported, some of the patients were temporary or seasonal workers such as fishermen and plantation workers. They followed their business; seasonal workers got their medicines and did not return to continue treatment, especially when the season ended.

Patients on treatment did not frequently complain of side effects of their medicines. However, in some of the service delivery points, it was reported that when side effects occurred, they were treated at the health-center level. Information on side effects of medicines, such as type, nature, and possible cause, was not routinely collected; some facilities collected this information, most did not. In QECH, this information was not collected on a standardized form, but the DTOs tried to design a paper-based information collection system.

Management Support

Human Resources

The NTP has two pharmacy technicians–the DMLOs–responsible for national level coordination of the pharmaceutical logistics activities of anti-TB medicines. At the zonal, district, and health center levels, no pharmaceutical personnel were included in the TB management team. However, in the district hospitals, anti-TB medicines were kept at the main pharmacies which were strictly under the control of pharmacy technicians. The latter worked in collaboration with DTOs. Two DMLOs makes a very small team to implement and strengthen anti-TB medicines supply chain management activities.

Financing

From stakeholder reports, in previous years, the GoM did not have a budget for the procurement of anti-TB medicines until problems occurred with getting supplies from GDF. Because certain factors were not considered during quantification, it remains doubtful that the government would budget sufficiently for anti-TB medicines procurement. A holistic budget will include other factors such as transportation, capacity building, supportive supervisory activities, quantification

review meetings, and buffer stock, which was not included in national-level quantification calculations.

Communication

Communication was reported to be consistent and cross-cutting at all levels. Health center staff reportedly communicated well with DTOs and ZTOs, and DMLOs communicated frequently with ZTOs. Communication was by email, fax, and phone, including cell phones. In addition to other reasons for communicating, staff resolved other challenges due to medicines management especially stock outs. However, communication of medicine inventory management practices was a challenge at all levels.

Monitoring and Evaluation

The DMLOs revealed that, because of budget constraints and time, they concentrated on estimating medicines requirements and coordinating the distribution and redistribution of medicines to and between health facilities. Though mandated to supervise pharmaceutical functions at all levels, in the past 12 months, they had been able to execute this function only once. It was also noted in the report of their supervisory visit that issues related to anti-TB medicines were superficially handled.

The ZTOs are responsible for overseeing the overall management of TB activities within the zones. The DTOs are responsible to the zonal officers who supervise them. It was reported that supervision from the zonal offices to the districts occurred every month in some cases whereas in others, it was every three months or longer, depending on available logistics because some health centers were "too far from the district hospital." During supervisory visits, supervisors monitored drug use management and gave advice. Zonal officers communicated directly with the DTOs who managed the anti-TB medicines. No zonal supervisory visit report was seen. However, in some health centers and hospitals, recommendations to improve medicines' management practices were found on chits of papers and not in an exercise book. Review of the chits showed that some of the recommendations did not highlight challenges observed. Supervision was every two weeks from the district level to the health-facility levels. During the supervisory visit from either the zonal offices or the district offices, a checklist was used. Review of the checklist showed that it did not capture sufficient information to support improvement of pharmaceutical management activities. However, the DMLOs had their own checklist whose scope was wider and deeper.

Capacity Building

The DMLOs reported that apart from their training as pharmaceutical personnel, they had not attended any training for the past five years that could build their capacity. It was also reported that tools and job aids which could be used for efficient service delivery were unavailable. Also, at the health-center level, it was reported that staff had not had specific trainings on anti-TB medicines management. The last anti-TB medicines management training attended by DTOs took place in 2007. Some HSAs reported that the trainings focused on microscopy alone.

TB/HIV Collaborative Pharmaceutical Activities

At the time of this assessment, there was no collaborative approach at the national level to handle pharmaceutical logistics for TB/HIV co-morbidity between the HIV/AIDS program and the NTP. A policy on isoniazid preventive therapy (IPT) was in place but not yet implemented. Another policy on the management of TB/HIV patients was in the national manual for antiretrovirals.

During the assessment, it was reported that the supply of antiretrovirals was contracted out to UNICEF which operates a supply system parallel to the CMS. Operating a parallel system poses a challenge to TB/HIV service integration. Some districts had begun piloting collaborative schemes for management of patients with this co-morbidity. In one district hospital, it was reported that patients received appointments at reception and that reception informs the TB and HIV units. This prevents each of the departments from making individual appointments, thereby reducing frequent hospital visits by the patients. The model for supply of medicines to patients was still being considered.

RECOMMENDATIONS

This section summarizes the main issues identified in each of the supply chain sections and includes recommendations.

Policy and Product Selection

Issues

- The current anti-TB manual does not include a section on medicines management and the guideline on management of TB medicines is not available in the facilities. As a result, the practice of handling and distribution of anti-TB medicines to patients is not uniform across the system.

Recommendations

- The medicines guidelines that have been developed by the NTP from the national medicines policy should either be incorporated in the new national TB manual being developed or be circulated appropriately to all treatment facilities.
- MDR-TB management guidelines should also be incorporated in the new TB manual so that the national TB guideline is one composite document.

Many advantages underlie this recommendation including reduction in printing costs of multiple documents, ease of access to information, and a comprehensive source for capacity building on TB.

Drug Regulation and Quality Assurance

Issues

- It was revealed that not all batches of anti-TB medicines used in the country were tested for quality and that some product quality challenges were noticed at the facility level. The NTP revealed that they were not usually supplied with results of drug quality testing, but that they were acquired when needed. It was also reported that there was no standard format for reporting poor quality products in circulation in the country.

Recommendations

- NTP should always be sent the results of quality assurance tests carried out on all anti-TB medicines. The NTP should follow up with NDQCL and the PMPB to ensure that it is regularly updated on the quality of all products that enter the country.

- SOPs for post-marketing surveillance of anti-TB medicines should be developed by PMPB in collaboration with the NTP and circulated to the health facilities so that the quality of anti-TB medicines in circulation in the country could be actively monitored.

Product Quantification and Procurement

Issues

- The GoM has budgeted for the procurement of anti-TB medicines, but a long term procurement plan is not yet in place.
- Currently, CMS is not a significant procurement agency for anti-TB medicines; this could become a problem because the grant agreement between GoM and GDF expires soon.
- In some health facilities, DTOs' capacities to make correct estimates of needed medicines were challenged. At some facilities, the trigger to order medicines was a stock level of zero.

Recommendations

- For long-term planning and sustainability, GoM must continue to budget for anti-TB medicines and also search for alternative funding sources (bilateral and multilateral organizations) in addition to GDF. Budgeting should be based on a procurement planned for at least two years with an appropriately organized supply plan developed and revised regularly based on the in-country need.

- Considering the current drive to strengthen the CMS, NTP should integrate its procurement process with the CMS procurement machinery while NTP continues with quantification, providing accurate data for CMS' purchases.

- It is in the long-term interest of NTP and partners to ensure that the capacity of the DMLOs is strengthened. The DMLOs have to be trained on all aspects of forecasting and quantification, beginning with basic principles. They may then become trainers for the other staff in the pipeline. It is worth mentioning that the current human resource development plan of the NTP does not specifically mention any training for the pharmaceutical cadres. Alternatively, and as part of its service integration plan at the district and health-center levels, NTP should work closely with the pharmaceutical services directorate to integrate pharmacy technicians in the district TB management team to strengthen pharmaceutical management of anti-TB medicines.

- The DMLOs should follow established maximum and minimum stock levels as indicated in the NTP drug management guideline because accurate consumption data already exists in all facilities. Patient data could be used to supplement the estimation of need when necessary. The maximum and minimum stock levels should be used at health facilities to make orders from regional stores.

Warehousing and Storage

Issues

- Storage capacity is very limited at the district hospitals and some regional stores.
- Store space management is poor at the health-center level.

Recommendations

- NTP should support facility staff training of store managers on good storage practices.
- NTP should advocate for an assessment of national storage capacity of anti-TB medicines to identify health facilities needing store refurbishment or reconstruction.

Transport and Distribution

Issues

- Anti-TB medicines are transported separately from the other essential health products. At the time of the assessment, staff paid out of pocket for transportation of anti-TB medicines.

Recommendations

- NTP should ensure that transportation of anti-TB medicines is done at the same time as other EHP commodities. This is in line with service integration promoted by NTP at service delivery points. Staff time will be saved, costs borne by the system for separate transport arrangements will be eliminated, opportunities to monitor timely ordering by the DTOs and HSAs will be provided, and RMSs and DTOs will have time to conduct other activities.

Inventory Control and Logistics Management Information Systems

Issues

- Ordering and consumption are recorded in a paper-based system which is not integrated in the national LMIS. Anti-TB medicines are not yet included in the list of medicines captured in DELIVER software used for LMIS.
- There is no consolidated LMIS to report anti-TB medicine transactions.
- At the district and health-center levels, maximum, minimum, and buffer stock levels were seldom maintained; different facilities had a different understanding of the number of months of stock that make up those stock levels.

Recommendations

- NTP should advocate for its information system to be integrated into the current LMIS for EHP and seek opportunities for its staff to be trained on the LMIS.
- The anti-TB medicines guidelines should be integrated into the national TB guidelines. It is very clear as to what constitutes months of stock for maximum and minimum stock levels.

- NTP should also leverage the presence of pharmacy technicians in district hospitals to support its inventory management practices at the district and health-center levels because pharmacy technicians store anti-TB medicines alongside other essential medicines and health commodities.

Dispensing and Rational Use

Issues

- Neither the NTP national guideline for TB nor the NTP medicines management guidelines stated how medicines should be dispensed to patients after the initial two weeks of treatment. Because of this, different facilities have adopted different ways of dispensing anti-TB medicines to patients.
- Patient weights were not monitored at all times during treatment, especially when moving from the intensive to the continuation phase.

Recommendations

- NTP should identify one preferred way of dispensing anti-TB medicines to patients and scale it up to all districts and zones. One possibility is to identify zones with high treatment success and completion rates, then scale up their dispensing practices.
- NTP should ensure that during the next round of trainings for DOTS/TB the importance of weighing patients, documenting their weight, and providing treatment according to patients' weights be stressed.
- NTP should also provide weighing scales for those facilities that don't have them.

Management Support

Issues

- Currently, DMLOs rarely conduct regular support supervisory visits, and the DTOs support visits do not provide detailed coverage of drug management issues.

Recommendations

- Regular support supervisory visits by the DMLOs should be implemented with reports that highlight problems identified, recommendations made, and actions taken to resolve the problem.
- After each support supervisory visit, the goal is for service delivery levels to improve. Therefore, DMLOs should, in collaboration with partners, develop an indicator-based monitoring tool to monitor progress in the anti-TB medicines logistics system.
- NTP should make the job aids currently found in some health facilities more visible and expand their use to all service delivery points. They should also serve as on-the-job training materials.

ACTION PLAN

NTP should immediately carry out the following proposals that are based on the findings and recommendations of the assessment.

1. The quantification team should develop a long-term quantification plan, taking into consideration the national stock status of all the anti-TB medicines and commodities at all levels of the supply chain.

2. NTP should determine the level of stock that triggers reordering by health facilities. Without this, some district hospitals will continue to order only when pharmacy stock is depleted. This level can be determined by estimating the months of stock that corresponds to a certain number of patients as would be agreed by NTP.

3. Training of trainers' workshops should be conducted to teach the concepts and principles of managing anti-TB medicines at the primary care level. This training should include how to receive, store, order, and administer anti-TB medicines. The training materials should be adapted and used for support supervisory visits and to support on-the-job training. Also, quality improvement plans should be produced to assess the extent to which knowledge gained during training has been implemented.

4. An assessment of the capacity of the current LMIS to incorporate anti-TB medicines and commodities should be conducted.

5. The anti-TB medicines' transportation and distribution system should be redesigned to align itself with the distribution system of EHP commodities.

ANNEX A. LIST OF KEY INFORMANTS INTERVIEWED

Name	Profession	Employer
Isaac Chelewani	DMLO	
I. Zingano	Controller of CMS	CMS
D. F. C. Ngulube	SCO	cRMS
Mr. Mphatso Kawaye	Drug registration officer	PMPB
Alexander Malunguza	DTO	
Ms. Joyce Sinoya	Nurse/midwife	Salima District Hospital Pharmacy
Mr.	Pharmacy technician	Ntcheu District Hospital Pharmacy
Mr.	DTO	Ntcheu District Hospital
Mable Kadango	TB officer/TB nurse	St. Joseph Hospital (CHAM)
Bruno Banda	TB dispenser and microspopist	Namadzi Health Center
Sylvester Mumba	Environmental health officer	
Gustino Joseph	Medical assitant	Mikolongwe Health Center
Expert Kenmedi	TB focal person	
Sixto Mangani	TB officer	
Kenneth Zakeyu	Clinical officer	Lifuwu Health Center
Jameson Gomani	Senior HSA	
Calvin Lemon	Environmental health officer	
Aaron Banda	Medical sssistant in-charge	Khombedza Health Center
Samuel Chimwanza	Assistant environmental health officer	
Gervazio Kaloimm-awa	HSA	Maganga Health Center
Grant Gondwe	Clinical officer	
Edson Khombe	HSA	
Samuel Mkoma	HSA	
Paul Afiki	HSA	Baptist Medical Center Senga Bay
Simeon Nkhoma	HSA	
Ronald Ng'oma	HSA	
Vincent Cheyo	Clinician	
Chikondi Makuwa	Health center in charge	
Masannko Tsamba	Senior health surveillance officer TB	
Benson Molande	Medical assistant	Bilila Health Center
Kondwani Jimmy	Health surveillance officer	
Rose Kachinjitza	HSA	
Shadreck Mapulanga	HSA	

Kenneth Thom	Medical assistant	
Manuel Pendame	HSA TB coordinator	Lizulu Health Center
Bryn Silvungwe	Medical assistant	
Nancy Mwapasa	MA	
Mary Wiseman	Nurse	
Lucy Chilembwe	HSA	
Lucky Kabanga	Senior pharmacy technician	QECH
Sandram Chilakolako	HSA	
Mr. Loti Kayuni		RMS South
Mr. Chulu		
Mr. Kulemela D		
Mr. J. Chisahka		
Mr. B. Mwapasa		
Mary Kamiza	Deputy ZTO	Central West Zone
John Kwanjana	ZTO	
Patrick Chirwa	Deputy ZTO	Central East Zone
Noel Mphasa	ZTO	
Henry Kanyere	TB/HIV officer	National TB Program
Cornelius Kamgombe	MDR TB coordinator	
Henderson K. Mgaus	DMLO	
Kingston Mhambua	Assistant environmental health officer	Biliwiri Health Center
Ada Kasomphe	HSA	
Matsiriza Namakhwa	Senior medical assistant	
Wylie Collins	Pharmacist	QECH

ANNEX B. LIST OF HEALTH FACILITIES VISITED DURING THE ASSESSMENT

Zone	District	Facilities visited
Central east	Salima	Khombedza Health Center Maganga Health Center Senga Bay Baptist Mission Hospital Lifuwu Health Center Salima District Hospital
Central west	Ntcheu	Lizulu Health Center Biliwiri Health Center Bilira Health Center Msiyaludzu Health Center Ntcheu District Hospital
South west	Blantyre	QECH
		RMSs, South
		Zingwangwa Health Center
		Ndirande Health Center
	Chiradzulu	St. Joseph Mission Hospital
		Chiradzulu District Hospital
		Namadzi Health Center
		PIM Mission Health Center (no service)
	Thyolo	Mikolongwe Health Center
South east	Zomba	Zomba Central Hospital
	Machinga	Machinga District Hospital

ANNEX C. LIST OF DOCUMENTS CONSULTED

National Tuberculosis Control Programme Manual: 6th edition, Ministry of Health, Malawi, 2007

National Tuberculosis Control Programme: Five-Year Development Plan II 2007-2011, Ministry of Health, Malawi

Management Sciences for Health RPM Plus/USAID, Managing Pharmaceuticals and Commodities for Tuberculosis: A Guide for National Tuberculosis Programs; http://www.msh.org/Documents/upload/Guide_for_National_Tuberculosis_Programs-1.pdf

National Tuberculosis Programme, Human Resource Strategic Plan, 2010-2015, September, 2010, Ministry of Health, Malawi

TB/HIV Integrated Supervisory Checklist for Zonal TB Supervisors, Revised February, 2009

Chelewani, I. O. and H. K. Mgawi. 2010. A Report on the Supportive Visit on Drug Monitoring and Auditing in Northern Region in 4th Quarter 2010

Order form for TB drugs: New Regimens (FDC)

Carlson, C., M. Boivin, A. Chirwar et al. 2008. Malawi Health Swap Mid-Term Review Summary Report. Commissioned by the Ministry of Health, Malawi. Swiss Tropical Institute, www.swisstph.ch/fileadmin/user_upload/Pdfs/swap/swap441.pdf

ANNEX D. DATA COLLECTION INSTRUMENTS

Stock-Out Data Form

Facility name:	Data collector code:	
Facility type:	Location:	Date:

For each product, write the number of days out of stock for each month.

Commodity	Normal stock?	Feb 28 10	Mar 31 10	Apr 30 10	May 31 10	Jun 30 10	Jul 31 10	Aug 31 10	Sep 30 10	Oct 31 10	Nov 30 10	Dec 31 10	Jan 31 11	Total days out of stock
1. Rifampicin 150 mg/ isoniazid 75 mg (RH) tablet														
2. Rifampicin 60 mg/ isoniazid 30 mg/ pyrizinamide 150 mg (RHZ) tablet														
3. Rifampicin 60 mg/ isonaizid 30mg (RH) tablet														
4. Rifampicin 150 mg/ isoniazid 75 mg/ pyrazinamide 400 mg/ ethambutol 275 mg (RHZE) tablet														
5. Ethambutol 400 mg (E) tablet														
6. Ethambutol 100 mg (E) tablet														
7. Isoniazid 100 mg (H) tablet														
8. Pyrazinamide 400 mg (Z) tablet														
9. Rifampicin 150 mg/ isoniazid 75 mg/ ethambutol 275 mg (RHE) tablet														
10. Streptomycin 5 g (S) injection														
11. Cycloserine 250 mg tablets														
12. Ethionamide 250 mg tablet														

13. Kanamycin injection 1 gm														
14. Levofloxacin 250mg tablet														
15. Capreomycin injection 1 gm														
Row 1: Sum total days out of stock for all stocked commodities														
Row 2: Count total number of products checked "Y" in the normal stock column														
Row 3: Average percentage time out of stock **= (number in row 1 × 100) ÷ (365 × number in row 2)**														

Health facilities

This questionnaire is to be applied at all health facilities where TB patients are treated. The questionnaire is followed by a stock out data form, inventory data form, checklist for evaluating the storeroom, exit poll interview form, and medicine record review form

Data collector _____

Date _____

List of persons interviewed

Date of interview	Name of person interviewed	Function/designation	Tel: Email:

- Is the **most recent** TB standard treatment guideline present at this facility? Yes No

_____

_____

_____

_____

- Do health workers have access to the TB treatment guidelines?

  Prescribers: Yes No Comment:

  Dispensers: Yes No Comment:

- Are any job aids (such as posters or small pocket books with instructions about TB regimens) present at this facility to facilitate daily tasks?

  Prescribers: Yes No Comment:

  Dispensers: Yes No Comment:

- When did the last training for health workers in TB care and management take place?

  Prescribers: Yes No Comment:

  Dispensers: Yes No Comment:

- How many TB defaulters do you currently have in this facility?

_____

- What attempts have been made to trace defaulters? Any successes?

Reporting

- What reports are completed and sent regularly for TB medicines?

- What is the frequency for reporting for the reports listed?

- When was the last report sent? Comment if on time, based on schedule for reporting

Ordering TB medicines

- Who determines the quantities of TB medicines to order at this facility?

- Has the person been trained to carry out this function? If yes, when was the last training?

  Yes: When?_____

  No: Comment:_____

- What types of data are considered when determining TB medicine needs?

Question	**Check if considered**	**What parameter is used for regular orders?**
Order period		
Buffer or safety stock		
Total number of TB cases notified in a specified period		
Total number of TB medicines consumed in a specified period		
Total quantity of each medicine to order for a specified period		

Comments:

Storage and collection of TB medicines

- How does this facility get their TB medicines?

  Collect from district or facility store

  Delivered to their facility

- If collected from a store, is the transportation means/funding for transportation to collect these medicines adequate? Has transportation prevented this facility from picking up their orders on time?

_____
_____
_____
_____
_____
_____

- Complete the information that applies to the facility in this table for TB medicines

Stores	**Order frequency**	**Safety stock level maintained**	**Comments**
District hospitals			
Health centers			
Clinics			
Mobile/ community services			

- Have any quality issues been noticed or brought to your attention about TB medicines in your store? If yes, explain

_____
_____
_____
_____
_____
_____
_____

Monitoring and supervision

- How many times did a supervisor visit your facility to assess performance and practices in the last 12 months?

_____
_____
_____

- How many times did the supervisor mentor health workers at your facility to improve their performance in the last 12 months?

_____
_____
_____

- Do store managers or dispensers receive any mentoring on good storage management and inventory management during these visits?

  Yes

  No

  Comments:

- Describe three main challenges your facility is facing with TB medicine management over the past 12 months.

- What has been done to improve these challenges?

- How do you feel these challenges can be overcome?