

Assessment of the TB Pharmaceutical Management System in Namibia: February 13–March 4, 2011

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May 2011



This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Ministry of Health and Social Services and Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

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Owunna, C., R. Chana Chapchet, C. Ntege, and N. Nashilongo. 2011. *Assessment of the TB Pharmaceutical Management System in Namibia*. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
CCRC	Central Clinical Review Council
CMS	Central Medical Store
DSP	Directorate of Special Programmes
FEFO	first expiry, first out
HIV	human immunodeficiency virus
IDPIG	<i>International Drug Price Indicator Guide</i>
MDR	multidrug resistant
MOHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
Nemlist	Namibia Essential Medicines List
NMPC	National Medicines Policy Coordination
NMRC	National Medicine Regulatory Council
NTCP	National Tuberculosis Control Program
NTLP	National Tuberculosis and Leprosy Program
PC&I	Pharmaceutical Control and Inspection
PhSs	Division of Pharmaceutical Services
PMTB	pharmaceutical management for tuberculosis
QSL	Quality Surveillance Laboratory
RMS	Regional Medical Stores
RMT	regional management team
SHPA	senior health program administrators
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems [program]
STG	standard treatment guideline
TB	tuberculosis
TB CAP	Tuberculosis Control Assistance Program
TIPC	Therapeutic Information and Pharmacovigilance Center
USAID	US Agency for International Development
WHO	World Health Organization
XDR	extensively drug-resistant

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EXECUTIVE SUMMARY

Namibia adopted the DOTS strategy in 1993 and it was implemented at the lowest level of the health care system through DOTS centers. The storage conditions of anti-tuberculosis (TB) medicines at DOTS centers have been a concern because of the high ambient temperatures in Namibia, particularly during the summer months. The Ministry of Health and Social Services (MoHSS) decided that a full-scale pharmaceutical system assessment should be done to focus on first- and second-line TB medicines to identify any gaps in the system to ensure that patients receive quality, safe, and efficacious medicines, and hence improved treatment outcomes.

The objectives of the assessment were—

- To build local capacity on the tools used to conduct pharmaceutical management assessment of anti-TB medicines
- To assess the processes of anti-TB medicines management in terms of national TB treatment policy and guidelines, medicine selection and registration, medicines quantification and procurement, quality control and assurance, storage and distribution, rational medicine use, and management support
- To make recommendations to enhance the management of anti-TB medicines in Namibia

Findings on policy and guidelines showed that almost all health facilities visited during the assessment had a copy of the most current version of national TB treatment guidelines except for a few DOTS sites. Regarding the treatment of DR-TB, it appears that there has been slow adoption of the latest guidelines, as many clients are still being managed according to the previous version of the guidelines. It also revealed that there has been some communication gap between the National Tuberculosis and Leprosy Program (NTLP) and the Central Medical Store (CMS) in relation to planning for the implementation of new guidelines.

Findings also showed that not all TB medicines on the TB tracer medicine list are selected according to international recommendations. For example, when the WHO Model List of Essential Medicines (16th edition, updated March 2010) was compared with the tracer list of anti-TB medicines in Namibia, it was found that 10 of the 13 (76.92%) medicines listed in the tracer list were in the WHO Model List. When compared with the list of medicines on the Global Drug Facility (GDF) catalogue list, 84.62% (11 out of 13) of the first-line TB medicines were included in the GDF list. For second-line treatment, 70% of the TB medicines in the trace list were included in both the WHO Model List and the GDF catalogue list. The discrepancy was in the group five medicines (amoxicillin/clavulanate 875/125 mg, clarithromycin 500 mg, and clofazimine 100 mg).

Quantification of first- and second-line TB medicines for procurement is done by CMS using the consumption method that considers only the quantity of medicines issued. The minimum and maximum stock levels are used to determine order quantities. Average minimum stock level kept at the CMS for all medicines is five months whereas the maximum stock level is nine months.

Findings showed that quantification of second-line TB medicines using the consumption method promotes overstocking and increases risk of expiry particularly for second-line TB medicines. The CMS procurement prices for TB medicines (first- and second-line) was compared to international buyer prices reported by other countries in the *International Drug Price Indicator Guide* (IDPIG) published annually by MSH. The IDPIG provides median prices for essential medicines derived from actual prices paid by governments or agencies through competitive bidding. Findings showed that Namibia is effectively procuring 56% of the TB medicines at prices below the median prices reported in IDPIG. The rest of the medicines (44%) are being procured above the median international comparison price.

Activities at the quality surveillance laboratory (QSL) were assessed and findings revealed that, although the laboratory is well staffed with trained personal, it operates sub-optimally because of several challenges including lack of some primary reference standards, lack of sufficient storage space for some chemicals (inflammables), insufficient quantities and types of some laboratory equipment, and lack of capacity to carry out microbiology tests. Results of the quality assurance test on anti-TB medicines revealed that of the 32 samples sent to the Centre for the Quality Assurance of Medicines (CENQAM) for testing, only one sample of rifampicin 450 mg from the intermediate hospital Oshakati failed quality control tests. Further investigation will be undertaken to determine the reason for the failure.

Physical structure and store practices analysis at central, regional, district, and facility levels showed that, in general, most storage facilities were clean and pest free; medicines were stored on shelves away from direct light and moisture and well arranged according to the CMS catalogue numbers. However, there were a few stores with leaking roofs, non-functional air conditioners (or none at all), cracked floors, and insufficient storage space. Some facilities were not updating their inventory records on a regular basis. Stock-out of anti-TB medicines was rare, but when it occurred, patients did not miss their medicines because they were available at DOTS facilities. For first-line medicines, in 72% (range, min – 0%; max – 100%) of health facilities, their physical stock count for a set of tracer TB medicines matched their inventory record count.

Patients with TB displayed good knowledge of the medication they were taking and the consequences of missing or not completing treatment, a factor that promotes adherence.

Stakeholders interviewed at health facilities and pharmacies reported the need for training of staff to improve their knowledge and skills. They also reported the problem of high staff-turnover and weak staff-retention strategies from the national level.

The following are key recommendations from the assessment.

General

- There appears to be suboptimal communication between the CMS under PhSs and the NTLP. This may have severe consequences for anti-TB medicine stock levels and functioning of NTLP generally. NTLP and CMS should improve communication about program activities that affect TB medicines. The PhSs pharmacist coordinator for the NTLP is the intermediary person responsible for interacting with CMS to both obtain and provide relevant information that can affect stock levels on a regular basis.
- It is recommended that CMS and NTLP develop a plan to implement the new TB guidelines. If this is done, stock outs and wastage of anti-TB pharmaceuticals will be minimized. A plan for quantification training and rational use should also be put in place to support reduction of TB medicine stock-out and wastage.

Medicine selection and registration

Considering the need for good quality anti-TB medicines, it is recommended that all medicines that are used in Namibia for the treatment of TB infection be registered with the medicines regulatory council and that those currently on compassionate registration be reevaluated and registered if they meet the appropriate criteria.

Medicine quantification and procurement

When making purchases, it is recommended that Namibia regularly refer to international medicines references and use a standardized approach that considers actual patient numbers in addition to consumption data. In addition, training on quantification should be conducted for staff at all levels, including DOTS promoters.

Quality control and assurance

Communication between CMS and QSL should be increased so that QSL knows when batches of medicines requiring testing have arrived and when to collect them for testing. QSL's testing capacity should also be improved. CMS should also enforce the tender contract clause requiring suppliers to deliver each product with batch certificates.

Storage and distribution

Inventory management at all levels of the TB medicine supply chain should be strengthened through training facilitated by regional pharmacists.

Rational use

To improve adherence to anti-TB medicines, patients' counseling must be reinforced at every clinic visit. The Central Clinical Review Committee (CCRC) should work to ensure its guidelines are followed and TB guidelines or job aids should be available at all levels of care.

INTRODUCTION

Background

Namibia established a national control program for tuberculosis (TB) in 1991 and adopted the World Health Organization's (WHO) DOTS strategy in 1993. The country reached nationwide coverage of the DOTS strategy by 1995. DOT is part of the DOTS strategy that addresses patient adherence to TB medicines. DOTS was implemented at the lowest level of the health care system through DOTS centers located in communities to improve access to TB treatment. DOTS supporters are in charge of these centers, and they are responsible for managing and administering first- and second-line anti-TB medicines to patients. Traditional DOTS centers in Namibia are made of steel and rib-trough sheeting with no air conditioners or fans. TB medicines administered to patients are stored at these centers for several days to more than a week. The storage conditions at DOTS centers have been a concern because of the high ambient temperatures in Namibia, particular during the summer months. This led to concerns over the quality of TB medicines administered to patients at that level which may be compromised because of these storage conditions.

The Ministry of Health and Social Services (MoHSS) decided that a full-scale pharmaceutical system assessment should be done to focus on first- and second-line TB medicines to identify gaps in the system that need to be addressed to ensure that patients receive quality, safe, and efficacious medicines to improve treatment outcomes. MoHSS requested that the Strengthening Pharmaceutical Systems (SPS) program, a United States Agency for International Development (USAID)-funded program support them in conducting a countrywide, rapid TB pharmaceutical management system assessment and support the sample collection and quality control testing of TB medicines. The terms of reference provided by MoHSS were as follows—

- To orient the TB program managers and the Directorate of Special Programmes' (DSP) pharmacists on the assessment of the pharmaceutical system and the tools to be used
- To oversee the process involved in assessing the pharmaceutical management system
- To design a sampling plan to assess the quality of the TB medicines dispensed at the DOTS sites
- To provide feedback to MoHSS on the activities undertaken and make appropriate recommendations

A team comprising National TB and Leprosy Program, DSP Pharmaceutical Services (PhSs), and SPS staff conducted the rapid assessment by using the Pharmaceutical Management for Tuberculosis Assessment (PMTB) indicator-based tool developed and field tested by the Rational Pharmaceutical Management Plus program, the predecessor to SPS, both funded by the US Agency for International Development (USAID). The rapid assessment and sampling were conducted February 13 to March 4, 2011, at 20 sites at central, regional, district, and peripheral levels in seven regions of the country. This report presents the findings from this activity.

Country Overview

Namibia covers 824,000 km² with a population of approximately 2.1 million. The population growth rate is about 2.5% per annum and is slowly declining. Although relatively sparsely populated, 60% of the people live in six northern regions of the country where the population density is much higher than the average density would suggest. Two-thirds of the people live in rural areas. Apart from the northern regions that benefit from perennial rivers, the rest of the country has an arid climate that permits cattle ranching—if it is cautiously managed—but little rain-fed agriculture. Namibia is blessed with a wealth of mineral resources comprising diamonds, uranium, copper, zinc, and gold. The cold Benguela current on Namibia’s Atlantic shore contains rich, albeit varying, quantities of marine resources.

Namibia’s developmental aspirations are explicitly formulated in the national long-term plan “Vision 2030”. All development policy decisions are guided by “Vision 2030” and are implemented through national development plans. Education, much neglected in colonial times, has turned into a cornerstone of development policy with about 25% of the budget allocated to education. Namibia shares many developmental challenges with the partner countries of the Eastern and Southern African regions. These include poverty of large strata of the population, natural disasters such as floods and drought, and the HIV epidemic.

Namibia pursues sound macroeconomic policies and has a past record of stable economic growth rates. The foreign public debt stock of 5.4% of GDP is relatively low by international comparison. According to the UN classification, Namibia is a middle-income country with per capita GDP of approximately USD 3,000 (NAD 18,000). This classification is, however, simplistic and misleading because income and wealth are very unevenly distributed in Namibia. A sizable proportion (28%) of the population is poor and about 4% are severely poor. At the same time, a segment of the society is very wealthy even by international standards. The consumption of the richest 10% of households is more than 20 times higher than that of the poorest 10%.

Health Care System in Namibia

The two main components of the Namibia health system are the public health service (including faith-based) and a private sector. The public health system is integrated centrally with four levels of care—national, regional, district, and community levels. Through MoHSS, the government provides public health services (including some faith-based health facilities), and private health services are offered by private practitioners, hospitals, and clinics as well as by traditional healers. MoHSS’s authority is further decentralized into 13 regional health directorates and 35 health districts.

The MoHSS Strategic Plan 2009–2013 highlights TB as a health priority, emphasizing the importance of focusing on reducing and eventually eliminating the disease along with HIV and malaria. The strategic plan further emphasizes the importance of improving service provision, reviewing and improving human resource management, defining and implementing an

infrastructure development and management strategy, addressing governance issues, and redressing financial deficit and management issues.

The main strategic outcomes and activities for the second medium-term strategic plan for TB and leprosy 2010–2015 include—

- Expanded and enhanced high-quality TB DOTS and leprosy services
- Increased access to high-quality TB/HIV treatment and care interventions
- Improved and scaled-up programmatic management of drug-resistant TB
- Strengthened general health systems that effectively support TB and leprosy services
- Strengthened partnerships for TB control and leprosy eradication
- Empowered communities of people with TB and leprosy

Structure of the Ministry of Health and Social Services

MoHSS consists of the offices of the Minister and Deputy Minister, the offices of the Permanent Secretary and Deputy Permanent Secretary, and three departments—Policy Development and Resource Management, Regional Health and Social Welfare Services, and Health and Social Welfare Policy. Health and Social Welfare Policy is further divided into the Directorates of Primary Health Care, Social Welfare Services, Special Programs, and Tertiary Health Care and Clinical Support Services.

The Directorate of Special Programs (DSP) is further divided into the Divisions of Resource Management; Health Sector Responses; and Expanded National AIDS Response Coordination. The national TB program is under the office of the Deputy Director, Division of Health Sector Responses. The Division of Pharmaceutical Services (PhSs) is under the Directorate of Tertiary Health Care and Clinical Support Services.

There are 13 regional health offices and regional directorates and directors. The regional management teams manage health and social services within each region. The District Coordinating Committee is responsible for overall health planning, coordination, management, and implementation in each of the 35 districts including TB activities in both the public and private sectors.

Health Facility Distribution

The public health system has a network of health facilities comprising approximately 1,150 outreach points, 267 clinics, 44 health centers, 30 district hospitals, 3 intermediate hospitals, and 1 national referral hospital, as well as various social welfare service points. Each district has health centers and clinics that provide public health services. About 60% of the total population of Namibia resides in the Northern regions (Oshana, Kavango, Oshikoto, Ohangwena, Caprivi, and Omusati) and as a result, there are more health facilities in these regions than in the Southern and Central regions.

Table 1. Health Facilities in Namibia (2009 Data)

Region	Number of hospitals	Number of health centers	Number of clinics	Total population
Ohangwena	3	2	28	265,992
Omusati	4	6	41	245,788
Oshikoto	3	3	16	184,175
Oshana	2	5	11	178,665
Caprivi	1	4	25	88,084
Kavango	4	7	46	265,373
Erongo	6	2	15	113,573
Kunene	3	3	22	76,598
Otjozondjupa	6	3	20	163,475
Hardap	2	3	11	71,995
Karas	3	3	13	73,135
Khomas	5	2	7	336,617
Omaheke	1	1	12	79,959
National	43	44	267	2,143,411

Source: Ministry of Health and Social Services: Second Medium term Strategic Plan for Tuberculosis and Leprosy (2010- 2015).

National Tuberculosis and Leprosy Program

The National Tuberculosis Control (NTCP) program in Namibia was established in 1991. The program changed its name in 2009 to the National TB and Leprosy (NTLP) program. The current mandate of the program is to control TB, leprosy, and TB/HIV in the country. Its activities include policy analysis, review, and formulation; strategic and annual planning; resource mobilization; program coordination; social mobilization and advocacy; capacity building; linkages with programs and stakeholders; monitoring and evaluation (M&E); surveillance; and research. The tasks of medicines selection, ordering, and distribution are under the direction of the division: pharmaceutical services. However, the DSP has a pharmacists' coordinator whose duties include ensuring that commodities procured by the Central Medical Store (CMS) meet the CDC's and Global Fund's quality assurance requirements and that there is sound communication between the DSP and PhSs in programming, reprogramming, and implementing new policies and guidelines.

To better manage patients with drug-resistant TB (DR-TB) and extensively drug-resistant TB (XDR-TB), a Central Clinical Review Committee (CCRC) was established. This committee performs many tasks including the review and enrollment of all multidrug-resistant TB (MDR-TB) patients on appropriate regimens and the provision of guidance on the medical management of all MDR patients, especially those with HIV and/or other concomitant diseases. Management of these patients is particularly demanding, especially regarding decisions to change, stop, or temporarily suspend treatment because of side effects, failure, or lack of adherence. The committee also monitors the pharmaceutical supply chain. The CCRC consists of the NTLP chief medical officer, DR-TB coordinator, the Tuberculosis Control Assistance Program director, PhSs pharmacist coordinator, senior medical officer for HIV, doctors from select hospitals, occasionally laboratory personnel, and clinical mentors.

At the service level, TB and leprosy program activities are fully integrated. There is one national TB referral hospital in the capital city of Windhoek (Kataura Intermediate Hospital) and three regional referral hospitals. In each region, a senior health program administrator (SHPA) is appointed to TB and leprosy activities and this person is referred to as the regional TB and leprosy coordinator. The District Coordinating Committee is responsible for overall health planning, coordination, management, and implementation in each district, including TB activities for the public and private sectors.

The TB DOTS centers which are found at the community level fall under the outreach points. DOTS centers are only available in some regions, such as Erongo, where the burden of TB is high and access to treatment is low. In these centers, DOTS providers administer oral TB medicines and water to patients daily and watch while they swallow their medicine.

Division of Pharmaceutical Services

PhSs is divided into three sub-divisions—National Medicine Policy Coordination (NMPC), Pharmaceutical Control and Inspection (PC&I), and CMS.

The NMPC coordinates the implementation of the national medicine policy and the national pharmaceutical master plan. It is responsible for ensuring appropriate medicine selection in the country through the development and review of standard treatment guidelines and by updating the Namibia Essential Medicines List (Nemlist); they promote appropriate medicines prescribing, dispensing, and use by health care workers and patients through therapeutic committees; and they manage human resource development in pharmaceutical services across MoHSS. NMPC monitors pharmaceutical service delivery through the indicator- based pharmacy management information system.

PC&I has four sections with different responsibilities.

The Inspection and Licensing section is responsible for compliance and enforcement of the Medicines and Related Substances Control Act, 2003 (Act 13 of 2003). It ensures all manufacturers in and outside the country who apply for registration of their products in Namibia and those with registered products in Namibia follow the current Good Manufacturing Practices. It is also responsible for licensing and registration of manufacturing premises including regulations and guidelines enforcement and disposal of waste medicines. Namibia does not locally manufacture TB medicines.

The Medicine Registration section is responsible for ensuring that all medicines used in the country are registered as required by law. Registration is required for each pharmaceutical formulation as well as subsequent versions of the same products that may differ in strength or dosage forms.

The Quality Surveillance Laboratory (QSL) is responsible for, among other things, analyzing medicines for the CMS to ascertain the level of quality and efficacy of medicines for batch release, analyzing samples for registration and inspection, carrying out post-marketing

surveillance activities and ad hoc testing, and carrying out proficiency testing with WHO and other regional bodies.

The Therapeutic Information and Pharmacovigilance Center (TIPC) was launched in May 2008 to ensure that health care professionals and the public get unbiased information on medicines. The centre provides medicine information reactively—in response to therapeutics enquiries from health care workers on a daily basis—and proactively by using various media including quarterly publications, web sites, and dear health care professional letters. The centre has also provided comparative cost-effectiveness review information to hospitals to update their medicine lists. TIPC monitors the safety of medicines on the Namibian market through a voluntary reporting system. It is responsible for the detection, assessment, and prevention of adverse medicine reactions and medication errors. It also conducts active medicine safety surveillance of select medicines for public health programs to provide evidence-based information for risk minimization. Such medicine safety information also is shared with the WHO international drug monitoring program in which Namibia is a full member.

CMS is responsible for procurement, storage, and distribution of more than 600 medicines listed in the Nemlist, including TB medicines. It has the same responsibilities for more than 800 medical supply items in the country. Items are distributed to two regional medical stores, one in Oshakati in the Northwest and the other in Rundu in the Northeast. CMS also provides medicines and supplies directly to over 40 health facilities—mostly hospitals, but they also directly supply health centers and clinics in the Windhoek area. The CMS implements its activities through the departments of procurement and tenders, distribution, and administration and support services.

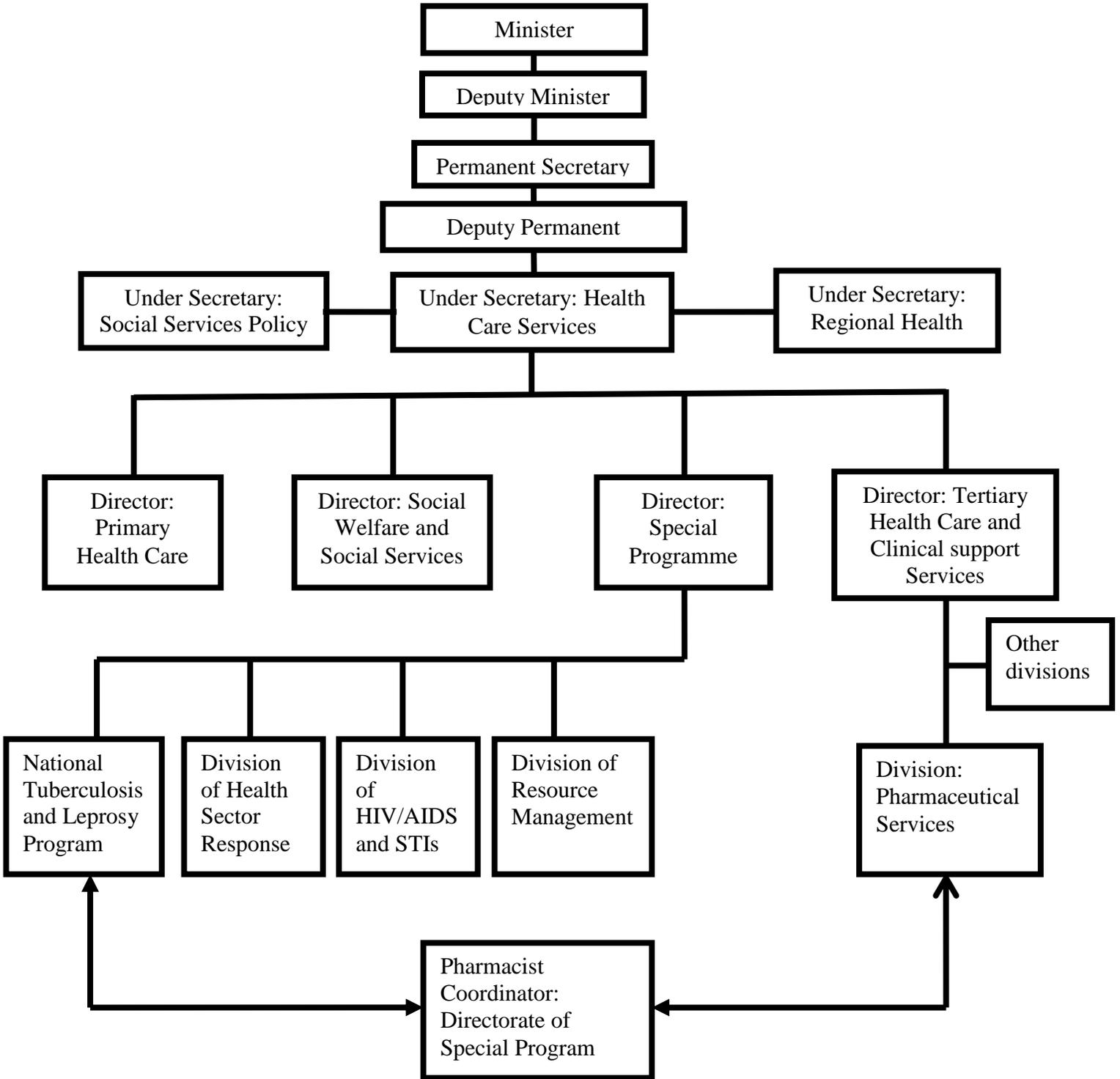


Figure 1. Organizational Chart of the Ministry of Health and Social Services

Tuberculosis Situation in Namibia

Namibia has a high case-notification rate compared to other TB countries in the world. According to 2009 WHO TB data, the case-notification rate is 634/100,000 population, equivalent to 13,332 cases of TB. This represents about a 3% decrease in numbers from 2008 data (13,737). The distribution of TB burden varies across Namibia's 13 regions with the highest burdens (according to 2009 NTLP data) in Khomas, Kavango, and Erongo regions in that order.

The treatment success rate for new smear-positive cases has increased over the years from 64% in 1997 to 82% in 2008¹. However, the country is yet to attain the global target of 85%. The case detection rate reported for 2009 is 76% which is above the global target of 70%. The TB default rates have also decreased significantly from 21% in 1997 to 4% in 2008 according to the 2009 NTLP annual report.

In Namibia, 301 TB cases were confirmed as MDR and almost all (292) of the patients were started on treatment according to the data from WHO (2009).

TB is the leading cause of death in people living with HIV/AIDS. The WHO 2009 data reported that 58% of TB patients who were tested for HIV were positive. Of the 13,332 TB patients reported in 2009, 9649 (74%) had a known HIV status either through provider-initiated testing and counseling (when TB was suspected) or testing prior to attending TB care, which is a significant increase from 67% in 2008. The percentages of HIV-positive TB patients who were started on Co-trimoxazole prophylaxis therapy and antiretrovirals are 78% and 35%, respectively, which is still not up to the desired 100% according to the TB global targets for 2015.

The 2006 TB treatment guidelines were revised in 2010. Even though the revised version is not yet published and implemented, health workers are being trained on the basis of the new guidelines. The use of 2RHZE/4RHE for new patients is recommended in this new guideline to comply with the new WHO recommendation for settings where isoniazid resistance among new TB cases is high and isoniazid susceptibility testing is not done.

A program to specifically treat patients with MDR-TB started in 2008, and treatment with second-line TB medicines started in 2009. As of February 2011, over 500 MDR-TB patients and 17 XDR-TB patients have been identified and placed on treatment. The national TB reference laboratory's capacity for drug susceptibility testing is only for first-line medicines except for pyrazinamide. For suspected XDR-TB patients who have completed MDR-TB treatment without getting cured, samples are sent to a laboratory in South Africa for drug susceptibility testing of other medicines that Namibia cannot test.

In 2004, the WHO interim policy on TB/HIV collaborative activities recommended several interventions to reduce the burden of TB and HIV. Namibia has a TB/HIV guideline in place as part of the antiretroviral treatment guidelines. The guideline recommends testing of all TB

¹https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=NA&outtype=html

suspects for HIV. Although this is done regularly, a few patients still fall through the cracks. Isoniazid preventive therapy has been implemented since 2006 in Namibia, and in 2009, 17,737 HIV patients were provided this therapy (WHO 2009). Other WHO recommendations for TB/HIV collaborative activities such as co-trimoxazole preventive therapy for HIV-positive TB patients, screening of HIV patients for TB, and starting TB patients on antiretroviral treatment have also been implemented.

AIM OF THE ASSESSMENT

The aim of the assessment was to provide managers of the NTLP in Namibia with valuable information in relation to pharmaceutical management practices that will enhance treatment outcomes by identifying challenges and proposing actionable recommendations that will optimize the process of selection, procurement, distribution, and use of anti-TB medicines.

Objectives

- To build the capacity of the Namibia team on the tools used to conduct a pharmaceutical management assessment of anti-TB medicines
- To assess the processes of
 - National TB treatment policy and guidelines
 - Medicine selection and registration
 - Medicines quantification and procurement
 - Quality control and assurance
 - Storage and distribution
 - Rational medicine use
 - Management's support of anti-TB medicines
- To make recommendations to enhance the management of anti-TB medicines in Namibia

Assessment Methodology

The PMTB indicator-based tool was used to conduct the rapid assessment and to identify strengths and weaknesses in the TB pharmaceutical sector. The PMTB methodology consists of the quantitative (data collection forms) and qualitative (key informant interviews and literature search) methods for data collection. The main pharmaceutical sector areas investigated include medicines policies and guidelines, medicine selection, storage, distribution and inventory management, quality assurance, and rational use.

Preparatory Phase

The DSP team in collaboration with the SPS team coordinated the logistics for this assessment. The team met with stakeholders to discuss the tool, process, and expected outcomes from the assessment. Prior to the actual assessment, background information was collected through literature search and documents provided by the program to enhance understanding of the general health system structure and flow of TB pharmaceuticals at all levels. This information was used to develop qualitative questions that were administered at the different levels of the system.

Sampling Plan and Sample Size

The sampling plan of 32 sites for data collection included hospitals, health centers, clinics, DOTS centers, and storage facilities. The country was divided into four areas and facilities were chosen based on—

- Burden of TB disease
- Facility distribution
- Facility workload
- Climate variations (for TB medicine quality control sampling)
- Overall challenges presented by facilities

The sites visited included 5 district hospitals, 6 health centers, 9 clinics, 6 DOTS centers, 2 intermediate hospitals (one of which was a pilot site), 1 central medical store (CMS), 2 regional medical stores (RMSs) and 1 hospital pharmacy located in 7 regions—Khomas, Karas, Erongo, Oshana, Kavango, Otjozondjupa, and Omaheke. A complete list of data collection sites is provided in annex 1.

Data were also collected from the DSP, NTLP, PC&I, QSL, and the procurement unit of the CMS.

Medical Record Review Sample

Data for medical record reviews were randomly selected from the facilities' TB unit register or treatment cards for patients treated within the previous 12 months. The following criteria were pertinent to selection of records for review—

- New smear-positive patients with pulmonary TB
- Patients for whom weight band and age information are available for the two treatment phases
- Patients with other types of TB disease were not selected

Tracer Medicine List

The tracer medicine list was compiled in collaboration with the DSP pharmacist to reflect the essential TB medicines and supplies necessary for first- and second-line treatment and consists of the 24 items listed in table 2.

Table 2. Namibia Tracer Medicine List for PMTB Assessment

First line	Medicine symbol	Strength	Dosage form
Rifampicin/isoniazid	RH	150 mg/75 mg	Tablet
Rifampicin/isoniazid/pyrazinamide	RHZ	60 mg/30 mg/150 mg	Tablet
Rifampicin/isoniazid tablet	RH	60 mg/30 mg	Tablet
Rifampicin/isoniazid/pyrazinamide ethambutol	RHZE	150 mg/75 mg/400 mg/275 mg	Tablet
Ethambutol	E	400 mg	Tablet
Ethambutol	E	100 mg	Tablet
Isoniazid	H	100 mg	Tablet
Isoniazid	H	300 mg	Tablet
Pyrazinamide	Z	400 mg	Tablet
Rifampicin	R	150 mg	Capsule
Rifampicin	R	450 mg	Capsule
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 g	Vial
Levofloxacin	Lfx	250 mg	Tablet
p-Aminosalicylate	PAS	4 g	Powder sachet
Amoxicillin/clavulanate	Amx/Clv	1 g (875/125 mg)	Tablet
Capreomycin injection	Cm	1 g	Vial
Clofazimine	Cfz	100 mg	Tablet
Amikacin injection	Am	500 mg	Vial
Cefoxitin injection		1 g	Vial
Clarithromycin	Clr	500 mg	Tablet

Data Collection

To build the capacity of the Namibia team on the tools used to conduct the pharmaceutical management assessment of anti-TB medicines, eight data collectors participated in a one-day training which involved—

- Explaining the purpose of the survey
- Familiarizing data collectors with survey questionnaires and data collection techniques
- Introducing data collectors to the data collection forms and instructions

During the training, the data collectors were distributed into groups of twos and each team reviewed the forms for data collection for clarity of language and understanding. Role plays were conducted by data collection teams to typify an interview encounter and appropriate corrections were made. The tools were then adapted to suit the country situation. One member of each pair in a team was appointed team leader. The team leaders' responsibilities included ensuring completeness of data forms before leaving health facilities, ensuring that correct information was collected, cleaning and computation of data, and general logistics.

Data forms were used by data collectors to gather information from TB health facilities, medical stores, and several departments under MoHSS. The data collection forms and where they were used are listed in table 3. Sample data collection forms used can be found in annex 5.

Table 3. Data Collection Forms Summary

Codes	Data Collection Forms	Information collected from
A-0	TB Interview Guide at Health Facility	Health facilities
A-00	Regional/district medical store interview guide	Stores in district hospitals and RMSs
A-1	Stock out data form	Stores in district hospitals, RMSs, CMS, health centers, and some clinics
A-2	Inventory data form	
A-3a	Medical records review data form (intensive phase)	TB treatment sites in hospitals, health centers, clinics and DOTS centers
A-3b	Medical records review data form (continuation phase)	
A-5	Exit poll interview form	Health facilities where TB patients receive treatment
A-6	Storage condition for TB medicine form	Stores in district hospitals, RMSs, CMS, and some health centers
A-7	Quality assurance sampling form	DOTS centers, some clinics, health centers, and district hospitals
Central Level Forms		
A-8	CMS interview guide (procurement and distribution units)	CMS
A-9	PC&I interview guide	PC&I
A-10	QSL interview guide	QSL
A-11	NTCP interview guide	NTCP
A-12	Minimum quality standards forms	QSL
A-13	International Price comparison form	CMS procurement unit

The assessment was carried out over a period of three weeks (table 4).

Table 4. Assessment Activities Schedule

Week 1	In-brief of key stakeholders, final assessment planning, some key stakeholder interviews at the central level, training data collectors, and piloting data collection forms
Week 2	All teams traveled to six regions to collect data from health facilities and medical stores
Week 3	Key stakeholder interviews from the rest of central level sites, data cleaning, preliminary data analysis and debrief of stakeholders

The quantitative data collected was checked for accuracy and completeness prior to entry into Microsoft Excel for analysis. The qualitative data were collated and summarized.

Sample Collection for QA Testing

The assessment included post-marketing surveillance for TB medicines component which was conducted in close collaboration with the QSL. TB medicine batch samples were collected from the 7 regions visited for quality testing. The sampling plan required that medicines be collected from the lowest level (DOTS sites) and, when sufficient quantities were not available, sampling was done from the next lowest level. First- and second-line anti-TB medicines were sampled in three dosage forms—tablets, granules and powder for injection. For the granules, only one sample was collected (para-aminosalicylic acid) whereas the rest were tablets. Medicines collected were intact in the original manufacturers' packaging. Storage and transportation conditions were controlled throughout the period. The sample identification system was based upon an agreed coding method that included the sample's active pharmaceutical ingredient (API), strength, source, and batch number. Samples were collected at the various levels of the distribution chain (see below). Each team collected a minimum of 12 samples of a predetermined formulation. A total of 32 batches of anti-TB medicines selected randomly from samples collected during field visits were sent to the Centre for the Quality Assurance of Medicines (CENQAM), a WHO accredited quality control testing laboratory of the School of Pharmacy, North West University, Potchefstroom, South Africa, for testing. Results from this exercise will be presented and discussed in another report because the quality control tests had not been completed at the time this report was written.

Quality indicators assessed at the laboratory were the content of the active ingredient (assay) and the dissolution rate (for tablets only), which were compared to standard specifications for these products in the relevant pharmacopoeia (the United States Pharmacopoeia [USP] and the International Pharmacopoeia).

FINDINGS AND DISCUSSIONS

National TB Treatment Policy and Guidelines

The national TB treatment policy guides implementation of TB activities in the country. It provides a standardized and harmonized approach for treatment of first- and second-line TB patients at all levels. The current national treatment guidelines for first-line TB treatment were created in 2006. This guideline was revised in 2010 but has not yet been signed and launched for use. Health worker trainings have already commenced in preparation for launch of the revised guidelines. The new guidelines involve a few changes in TB treatment regimens according to new recommendations by WHO.

In May 2008, for second-line treatment, a circular that supersedes the previous DR-TB treatment guidelines was disseminated through the office of the Permanent Secretary of MOHSS to all TB health facilities. This circular provided new instructions for treatment of DR-TB patients in the country. The Central Clinical Review Council (CCRC) was established to monitor DR-TB treatment and control regimen switches and adjustments to promote rational prescribing and use by patients. For TB/HIV co-infection, guidelines for implementing collaborative treatment and care are included as a section in the antiretroviral treatment guidelines last revised in 2010.

Availability of Guidelines

Almost all health facilities visited during the assessment had a copy of the most current version of the national TB treatment guidelines except for a few DOTS sites. The TB treatment guidelines were accessible to all health staff for reference and use at the health facilities where they were present. The goal of the indicator “Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present” is to measure the level of access to recent treatment information on effective TB control and management by health workers. Findings show that national treatment guidelines are well disseminated and, most importantly, that health workers have access to these guidelines to support their day-to-day activities.

In all the clinics, health centers and district hospitals assessed guidelines were available and accessible but only available in 67% of the DOTS sites assessed.

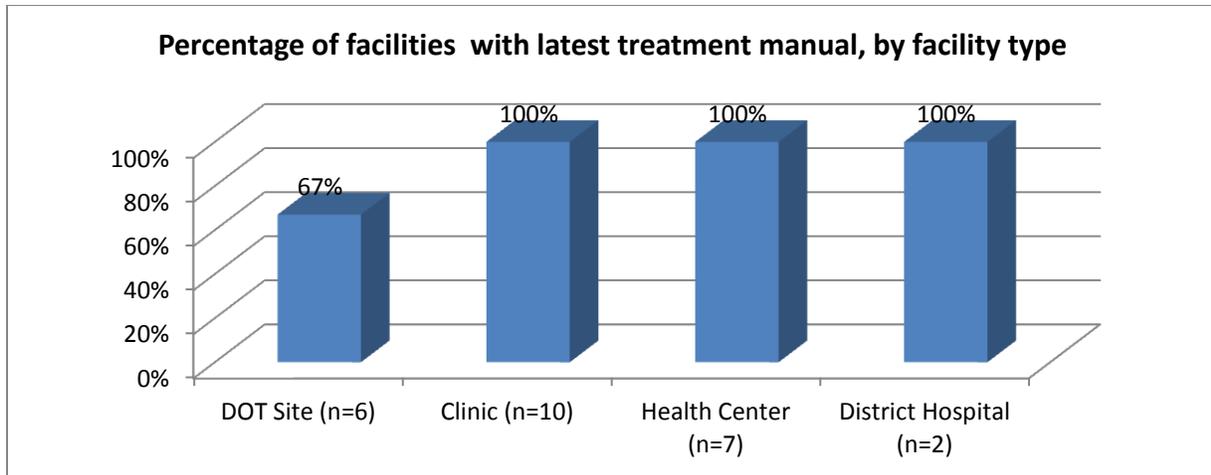


Figure 2. Distribution of latest TB treatment manual by facility

Introduction of New TB Treatment Guidelines

The CMS was not aware of any timeline to launch new treatment guidelines and has not developed any phase-in, phase-out plans for the new medicines recommended in the guidelines and the old ones that will no longer be used. If this plan is not implemented prior to roll-out of new TB treatment, there will be a high quantity of TB medicines wastage in the supply pipeline. It is critical to have this plan in place before implementation and roll-out of new treatment guidelines.

Compliance to Guidelines and Policies

Even though the DR-TB treatment circular has been disseminated since 2008, assessment findings showed that not all health facilities were following these guidelines. The May 2008 circular stated clearly that Amikacin injection should be replaced with Kanamycin injection because of the following reasons—

- Anecdotal experience indicates that Kanamycin is probably less toxic than Amikacin
- Kanamycin is less expensive
- Kanamycin resistance does not necessarily confer resistance to Amikacin

Also, ciprofloxacin tablets should be replaced with levofloxacin because it has twice the potency of ciprofloxacin. When regional reports sent to the pharmacist responsible for TB, HIV, and malaria under the DSP (September 2010 data) were reviewed, it was observed that some of the regions still had patients on these medicines.

Table 5. Number of Patients Still on Medicines that Should Be Discontinued

Medicine	Number of patients	Region
Amikacin injection	4	Caprivi, Hardap, and Omusati
Ciprofloxacin	22	Caprivi, Khomas, Omusati, and Oshana-Namaland with 19 patients

Key stakeholder interviews also revealed that regimen switches and adjustments were done without consultation with the CCRC. It was not possible to determine the total number of facilities where this practice occurred because not all data collectors probed for this information.

TB Medicine Selection and Registration Compliance with International Recommendations

Appropriate selection of safe and effective TB medicines that are affordable for the country is essential to improve treatment outcomes. WHO recommends regimens for first- and second-line TB treatments for countries to adopt based on their individual situations. Namibia has taken the necessary steps to ensure that appropriate medicines have been selected for TB and DR-TB treatment in the country.

The medicine registration section under the PC&I sub-division of PhSs is responsible for ensuring that all medicines are registered by the Namibian Medicines Regulatory Council according to the laws and policies of the country. In Namibia, all medicines that are distributed and consumed in the country are required to be registered. And all medicines included in the Nemlist should be registered. Medicine registration is the first step towards ensuring safety and efficacy of medicines procured and consumed in the country.

The registration process requires that an application be submitted for every new pharmaceutical product for use in the country. Several technical documents are mandated for submission during the application process—

- Certificate from regulatory authority of country of origin
- Evidence of registration in other countries
- Certificate of analysis
- Clinical trial reports
- Certificate of good manufacturing practice.
- API manufacturing site details

A WHO-type certificate of product moving in international commerce is not a requirement for applicants to submit. If the application meets all stated criteria, it is granted full registration in the country. Once a product is registered, it does not require re-registration as long as the annual fee is paid to maintain the registration in the country. No other documents are required from the applicant once a product is registered unless specific quality issues occur with the product. For products that are not registered and are imported into the country, “compassionate clearance” is required before the products can be allowed into the country. A compassionate clearance is

granted when a hospital or program requires certain medicine(s) that are not on the Nemlist or are not registered in the country for treatment of a group of patients.

Namibia does not routinely test all medicines submitted for registration; priority is given to testing of procured medicines for consumption in the country. The only time products are tested for registration is when they are suspected of poor quality. An information system, PharmaDex, is used to manage all registered medicines in the country. The system tracks dossiers and submissions and issues registration certificates among other functions. All negative product quality reports are sent to PC&I to take action which may include recall of the product. Standard operating procedures (SOPs) are available for reporting product quality complaints. More SOPs are currently under development to guide PC&I practices including an SOP to guide product recall at facilities.

The most current WHO Model List of Essential Medicines (16th edition, updated March 2010) was reviewed and compared with the list of TB medicines used in Namibia. Findings showed that 76.92% (10 out of 13) of first-line TB medicines used in Namibia were included on the model list. When compared with the list of medicines on the Global Drug Facility (GDF) catalogue list, it was found that 84.62% (11 out of 13) of the first-line TB medicines were included on this list. The discrepancies are rifampicin 60 mg/isoniazid 30 mg/pyrazinamide 150 mg and rifampicin 60 mg/isoniazid 30 mg tablets which were not included on the WHO model list but were included on the GDF catalogue and rifampicin 150 mg which is on the WHO model list but was not included on the GDF catalogue list. The rifampicin 450 mg strength was not included in either the WHO model list or the GDF catalogue list. WHO does not recommend the use of rifampicin as a single medicine for treatment of TB because of the risk of drug resistance.

For second-line TB medicines, although a total of 11 medicines were on the tracer list used for the assessment, only 10 medicines were considered because the remaining medicine (cefoxitin injection 1 g) was no longer in use in the country. For second-line treatment, 70% of the TB medicines used in the country were included in both the WHO model list and the GDF catalogue list. The discrepancy was from the group five medicines (amoxicillin/clavulanate 875/125 mg, clarithromycin 500 mg, and clofazimine 100 mg). WHO recommends that group 5 medicines should not be used for routine DR-TB treatment because their contribution to efficacy of multidrug regimens is still not clear. They are reserved for cases where it is difficult to design adequate regimens from the medicines in groups 1–4 such as for patients with XDR-TB and only to be used in consultation with an expert in treatment of DR-TB.

Table 6. Percentage of TB Medicines Used in Namibia on WHO and GDF Model Lists

Regimen	WHO model list (%)	GDF catalogue list (%)
First line	77	85
Second line	70	70

Although Namibia qualifies to use group five medicines because they have XDR-TB cases (about 17 reported at time of visit); it appears unlikely that these medicines are being used rationally according to WHO recommendations. When the DR-TB report sent from each region

to the DSP pharmacist (September 2010 data) was reviewed, it was observed that a total of 36 patients are on amoxicillin/clavulanate, 22 patients on clofazimine, and 15 patients on clarithromycin.

Registration of TB Medicines

Results showed that out of a total of 24 medicines on the tracer list, 87.5% of TB medicines used in the country are registered. Rifampicin 150 mg capsules, rifampicin 150 mg/isoniazid 75 mg/ethambutol 275 mg tablet, and PAS are currently not registered in the country. The review considered the exact medicine strength and dosage forms used in the country. Other strengths of rifampicin and rifampicin/isoniazid/ethambutol tablets not currently used in the country are registered; PAS has been allowed under “compassionate clearance” since 2008.

Table 7. Number of Registered Medicines in Namibia Prequalified by WHO

First line	Medicine symbol	Dosage form	Total number registered	Total number included on WHO pre-qualification list
Rifampicin/isoniazid 150 mg/75 mg	RH	Tablet	2	2
Rifampicin/isoniazid/pyrazinamide 60 mg/30 mg/150 mg	RHZ	Tablet	1	0
Rifampicin/isoniazid tablet 60 mg/30 mg	RH	Tablet	1	0
Rifampicin/isoniazid/pyrazinamide/ethambutol 150 mg/75 mg/400 mg/275 mg	RHZE	Tablet	3	2
Ethambutol 400 mg	E	Tablet	3	1
Isoniazid 100 mg	H	Tablet	2	1
Isoniazid 300 mg	H	Tablet	2	1
Pyrazinamide 400 mg	Z	Tablet	1	1
Rifampicin/isoniazid/ethambutol 150 mg/75 mg/275 mg	RHE	Tablet	0	0
Second line				
Cycloserine 250 mg	Cs	Tablet	1	1
Ethionamide 250 mg	Eth	Tablet	2	1
p-Aminosalicylate 4 g	PAS	Powder sachet	0	0
Amikacin injection 500 mg	Am	Vial	1	0
Total			19	10

The list of registered TB medicines in the country was compared with the list of WHO prequalified medicines. The review considered exact medicine strength and dosage form used in the country. For example, all tablets of the same strength were considered irrespective of the tablet delivery rate. Only 13 medicines from the tracer list were compared with the WHO prequalification list because the other medicines used in the country do not have WHO

prequalified manufacturers. Results showed that out of a total of 19 medicines registered in the country (the same medicines name, strengths, and dosage forms were registered more than once but each time by a different manufacturer), 53% of them are WHO prequalified manufacturers and for second-line medicines alone, only 40% were prequalified.

This review did not go further to determine if the CMS procures from the registered prequalified suppliers in the country. However, it is worthy to note that CMS maintains two suppliers for most TB medicines and awards a contract to both suppliers to supply TB medicines. The main suppliers were Macleods pharmaceuticals whose products are on the WHO prequalified list and Svizera pharmaceuticals who does not have any prequalified product on the WHO list.

TB Medicines included on the Nemlist

All (100%) first- and second-line TB medicines used in the country are included in the most current version of the Nemlist (fourth edition). Although PAS 4 g power has not been registered in the country, it was also included in the Nemlist.

Quantification and Procurement

Procurement responsibility for TB medicines is under the CMS. The Government of Namibia with the aid of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) provides all the funding needed for procurement of first- and second-line TB medicines in the country. Open international competitive tenders are floated every two years and orders are placed periodically over the two-year period. An electronic system is used to guide the tender process and all tenders entered into this system are automatically ranked according to specified criteria, for example, price of the product. Selected suppliers are then evaluated by the tender committee who also rank suppliers by their own specified criteria which include product quality requirements and past performance of suppliers. The tender committee is responsible for deciding which supplier(s) will win. Multiple suppliers can win the tender for the same product. During the supplier selection process, quality control testing of the product sample is only done when the evaluation committee determines the need for it.

The tender contract issued to suppliers requires that product delivery occur 6 to 8 weeks after placing the order. The contract allows for 2 partial deliveries within the 8-week window although some suppliers exceed this time period. The penalty for late delivery is a 0.5% charge every week the delivery is late up to a maximum of 10% charge after which the contract can be cancelled or the buy-out (purchase from another supplier) clause in the contract is implemented where the supplier becomes responsible for the difference in cost for procuring a portion of the product from a different supplier.

The procurement unit has two electronic systems for managing tenders and order; the first system is the tender management system, which is used just to manage tenders, and the other is called SYSPRO, which is a stock management system that tracks purchases. SYSPRO tracks dates orders were sent and received, order due dates, quantities ordered and received, among other parameters. The SYSPRO system used at CMS has a separate section for quantification

and forecasting of medicines. Quantification is done by the distribution pharmacist and orders are placed based on minimum and maximum stock levels taking into consideration average consumption rate, delivery lead-time, expiry dates, and maximum level of stock. Quantification is done monthly but orders are placed over a longer period depending on the medicines. Several procurement management reports are generated as required such as product evaluation reports, product ranking reports, and supplier responsiveness reports (suppliers that provided all documentation required in the tender application). No system currently exists for supplier monitoring; however, the USAID-supported Supply Chain Management System (SCMS) project is currently working with the procurement unit to develop a tool for supplier performance monitoring.

Quantification of Medicines

Quantification of first- and second-line TB medicines for procurement was done by CMS with no input from the NTLP program. The CMS orders TB medicines once their maximum stock levels are depleted and before the minimum stock levels are reached. Gaps were identified in communication between the CMS and the NTLP regarding planned changes to program activities that will affect medicines use. Also, the NTLP does not receive any unsolicited information about the stock status of TB medicines particularly in situations such as the imminent expiration of large quantities of TB medicine stock.

TB medicine quantification is done using the consumption method that considers issues data. The minimum and maximum stock levels are used to determine order quantities. Average minimum stock level kept at the CMS for all medicines is five months and the maximum stock level is nine months. Orders are placed every six to eight weeks once the maximum stock level is depleted. The number of patients on treatment is used for quantification only when a medicine is new. Subsequent orders are placed using the minimum and maximum stock levels.

The most common problems reported by the procurement staff during stakeholder interviews include—

- Delayed deliveries
- Delivery of orders without proper documentation
- Poor outer box packaging and inadequate labeling
- Supply of short shelf-life products

Even though the tender contract requires that orders should have a shelf-life of at least 2 years or 80% for products with a maximum shelf-life of 30 months, short dated products were still received sometimes from suppliers. And because the CMS may have depleted their current stock of the product, they were forced to accept some of the short-dated medicines to prevent stock-out situations. The tender contract also specifies that products be delivered directly to CMS so the CMS is not responsible for clearing the medicines upon arrival in the country. However, grant/donation medicines are cleared by the CMS. The CMS obtains a VAT exemption certificate for every shipment received.

On the average, it takes the procurement unit about 6 months to prepare tender documents, about 2-3 days for tender adjudication, and about a day to award the contract to the supplier. All medicines procured are on the Nemlist. However, programs can justify procurement of products not on the Nemlist by going through a process to obtain a compassionate clearance. Supplier payments are made within 30 days after delivery of orders.

The main challenges the procurement staff would like to see addressed include—

- Inadequate staff levels
- No in-depth training conducted for staff on procurement activities in the last few years to improve their knowledge and skills
- Support to monitor supplier performance and improve supplier responsiveness to CMS; the USAID-supported SCMS project is supporting the CMS to develop an information system to track supplier performance

TB Medicines Pricing in Namibia

The CMS procurement prices for TB medicines were compared with the *International Drug Price Indicator Guide* (IDPIG) which contains a spectrum of prices from pharmaceutical suppliers, international development organizations, and government agencies. The guide provides a good price comparison for countries to see if they are getting the best prices available. The “buyer” price in the guide was used for comparison because the CMS prices collected are Carriage and insurance paid to (CIP) prices (means that the seller pays for carriage and insurance to the named destination point, but risk passes when the goods are handed over to the first carrier. In most cases, the median price was used for the comparison, but if no median price was available, a single supplier or buyer price was used. For some of the products, buyer prices were not available so the supplier price adjusted upward by 15% was used to accommodate for freight/shipping and handling charges. The IDPIG guide recommends adding 10 to 15% when supplier prices are used to adjust for shipping costs. The CMS prices used were from the last procurement period within the last 12 months (2010) whereas the IDPIG used were from 2010. For a few products, the CMS buy-out prices were used for the comparison. Buy-out transactions take place when the contracted supplier cannot deliver the medicines within the agreed timeframe and the CMS is experiencing shortages or stocks out requiring the CMS to procure from another supplier most often at a higher cost; however, the difference in cost is paid back by the original contracted supplier.

Table 8 shows that Namibia is effectively procuring 56% of the TB medicines below the international buyer or supplier prices compared as shown in table 8 below. All the negative numbers indicate that the country is procuring medicines below the compared international price. The rest of the medicines (44%) are procured above the median international comparison price particularly pyrazinamide 400 mg which is procured at 92% above median international price and rifampicin/isoniazid/ethambutol 150 mg/75 mg/275 mg tablet which is procured at 91% above median international prices (note that supplier prices adjusted by 15% was used for comparison of both medicines).

Table 8. Comparison of CMS Procurement Prices versus International Prices

Medicine name, strength, and dosage form	CMS comparison unit price (USD)	Price difference: CMS minus IDPIG unit price (USD)	Percent difference: CMS vs. IDPIG unit price	Comments
Rifampicin/isoniazid 150 mg/75 mg tablet	0.0378	-0.0106	(28)	
Rifampicin/isoniazid/pyrazinamide 60 mg/30 mg/150 mg tablet	0.0217	N/A	N/A	No comparison price available
Rifampicin/isoniazid tablet 60 mg/30 mg tablet	0.0171	N/A	N/A	No comparison price available
Rifampicin/isoniazid/pyrazinamide/ethambutol 150 mg/75 mg/400 mg/275 mg tablet	0.0779	0.0050	6	
Ethambutol 400 mg tablet	0.0329	-0.0070	(21)	
Ethambutol 100 mg tablet	0.0153	N/A	N/A	No comparison price available
Isoniazid 100 mg tablet	0.0048	-0.0110	(230)	
Isoniazid 300mg Tablet	0.0181	-0.0107	(60)	
*Pyrazinamide 400 mg tablet	0.0257	0.00204	92	Adjusted supplier price used
Rifampicin 150 mg capsule	0.0235	-0.0418	(178)	
Rifampicin 450 mg capsule	0.0652	N/A	N/A	No comparison price available
*Rifampicin/isoniazid/ethambutol 150 mg/75 mg/275 mg tablet	0.0607	0.00546	91	Adjusted supplier price used
Streptomycin 1 g vial	0.2094	-1.1436	(546)	
Cycloserine 250 mg tablet	1.0695	-0.0897	(8)	CMS buy-out price used; single buyer price used
Ethionamide 250 mg tablet	0.1047	-0.0552	(53)	
*Kanamycin 1 g vial	0.3910	0.046365	88	CMS buy-out price used; adjusted supplier price used
Levofloxacin 250 mg tablet	0.0355	N/A	N/A	No comparison price available
p-Aminosalicylate 4 g powder sachet	0.2027	N/A	N/A	No comparison price available
Amoxicillin/clavulanate 1 g (875/125 mg) tablet	0.5450	N/A	N/A	No comparison price available
Capreomycin injection 1 g vial	2.1500	-12.7126	(591)	CMS buy-out price used; single buyer price used
Clofazimine 100 mg tablet	3.9429	N/A	N/A	No comparison price available
Amikacin injection 500 mg vial	1.1420	0.8170	72	CMS buy-out price used
Cefoxitin injection 1 g vial	4.3700	1.3202	30	CMS buy-out price used; single buyer price used
Clarithromycin 500 mg tablet	0.4386	0.1267	29	

*No buyer prices were available; 15% was added to supplier prices to adjust for freight/shipping and handling charges for comparison.

TB Medicine Specifications

During the field visits, the team observed that some of the TB medicines on the tracer list at the facilities were from two different manufacturers. Stakeholder interviews at health facilities reported that patients sometimes get confused when they are given medicines from one manufacturer one week and from a different manufacturer the second week; so health workers had to spend more time convincing them they are the same medicine. CMS reported that the same specifications are used for procurement from both suppliers.

Quality Assurance and Control

Namibia has selected the right medicines according to WHO recommendations and procured the correct medicines but if the medicines are of poor quality, the treatment goals will still not be achieved. As a minimum requirement, all TB medicines used in the country should be registered. Through registration, the NMRC is able to find out if the supplier or manufacturer meets the minimum quality standard requirements for registration in the country. During procurement, detailed specifications are requested from the supplier to help ensure that high-quality TB medicines are bought and received in the country. After procured medicines are received, the quality of the products should be verified both by physical inspection of each shipment and laboratory testing of selected products. Once it is confirmed that the medicines are of good quality, this quality should be maintained throughout the supply chain by ensuring appropriate storage, transportation, dispensing, and use by patients. Post-marketing surveillance should also be conducted to identify and report problem products and initiate product recalls.

The section of PC&I responsible for carrying out medicine quality control tests is the QSL. The main activity performed by the QSL currently is to analyze each batch of medicine procured by CMS to ascertain its level of quality and efficacy. The laboratory is striving to get accreditation for ISO/IEC 17025 standards through the South African National Accreditation System. Current reforms are underway to prepare the laboratory for this certification. The laboratory practices are guided by SOPs which are currently under revision in preparation for the certification. The following tests are performed by the laboratory—

- Identification
- Friability
- Dissolution
- Uniformity of weight
- pH
- Uniformity of content
- Assay and loss on drying

The laboratory does not have microbiology capability and no bioequivalence testing capability for rifampicin containing TB medicines. The identification and assay tests are mandatory tests carried out for all medicines at QSL; the dissolution test is also carried out if the manufacturer is new to the country. British Pharmacopeia and United States Pharmacopeia monographs are used as testing standards. The equipment for testing at the laboratory is not sufficient but some new equipment is expected such as HPLC and UV and IR spectrometers, with assistance from the Global Fund.

Quality Surveillance Laboratory

Findings from key stakeholder interviews at the QSL revealed that, although the laboratory is well staffed with trained personal, they are still not able to carry out their regular functions effectively because of several challenges that need to be addressed. Some of the challenges highlighted include—

- Insufficient physical space and the need for restructuring the laboratory layout to meet specified criteria for ISO 17025 accreditation.
- Inflammables are stored inside the laboratory; this safety hazard has to be addressed as part of the requirements for the ISO17025 accreditation.
- Absence of required primary chemical reference standards for testing some of the TB medicines such as cycloserine. Currently, only secondary standards are used which are not as reliable as the primary standards.
- Laboratory is currently unable to test ethambutol and ethambutol-containing TB medicines because of the length of time required to test these products with the only functional testing equipment (Karl Fisher) at the laboratory. New equipment is expected through the Global Fund.
- No capacity to test any of the TB injectables such as streptomycin and kanamycin because the laboratory does not have microbiology capability.
- Levofloxacin is not tested in this laboratory because there is no method available to carry out the quality control tests.
- Need to strengthen post-marketing surveillance activities of the QSL.

Quality Assurance of TB Medicines

According to the CMS, samples from all batches of TB medicines that are received are sent to the QSL for testing. Upon review of data collected from CMS and testing request orders sent from CMS to QSL, it was found that out of the total of 69 TB medicine batches procured in the last 12 months, only 26% (17) of the batches were sent for testing at QSL (excluding injections). Out of the 17 batches sent to QSL for testing, only 47% (8 batches) were tested at the time of the visit. All the medicines tested passed the quality control test. As a standard procedure, when batches fail quality control tests, they are sent to a collaborating laboratory in South Africa for confirmation. It was reported that no sample sent to that laboratory has failed quality control testing.

The team was informed at CMS that all medicines received were accompanied with a batch certificate and in cases where it was not sent, the CMS requested it from the supplier, and that all batch certificates received are sent with the testing request orders to QSL. When the team reviewed all quality test request orders and accompanying documents sent to QSL in the last 12 months preceding the visit, it was found that none of TB medicines sent for testing (17 batches) had an accompanying batch certificate.

Quality control tests were carried out on sampled anti-TB medicines. A total of 58 samples were collected from the seven regions visited during the assessment. A total of 32 batches were randomly selected using an agreed sampling protocol and were sent to CENQAM in South Africa for testing. Only one sample (rifampicin 450 mg from the intermediate hospital at

Oshakati) failed quality control tests. The sample showed an average dissolution of 48% that failed to meet the NLT 75% acceptance criteria. The same sample also didn't have the address of the manufacturer, country of manufacture, and manufacturing date indicated. The sample however passed the assay test with a value of 104.6%.

During the testing exercise, both batches of ethambutol that were sampled showed failures at USP S1 level in the dissolution tests when tested using the International Pharmacopoeia method for dissolution. These samples, however, passed when they were subjected to the USP method.

Storage and Distribution

The CMS is responsible for storage and distribution of TB medicines at the central level. It supplies medicines to two regional stores and over 40 hospitals (district, referral, and intermediate) in the country. The store receives first-line TB medicines every month and second-line medicines every 9–12 months. All batches of TB medicines received at the store are supposed to be sampled using a sampling SOP and sent to the QSL for testing. Medicine batches are not quarantined pending quality testing results from QSL; they are distributed to health facilities for use and are recalled if the test result is unfavorable. When orders are received at the CMS, they are checked for completeness, accuracy, and validity; visual inspections are conducted and random samples taken for testing. The CMS tracks batches of all orders received and issued but does not track orders once issued. Invoices, delivery notes, and packing lists do not include any batch numbers making it difficult for health facilities to determine what batches they were sent. They have to open each box to get the batch number.

Although TB medicines orders are placed when the maximum stock levels (9 months) are depleted before getting to the minimum stock level (5 months), TB medicines have been out of stock in the past because of reasons such as delays in supplier delivery. Physical counts are done once a year around March; partial cycle counts for specific medicines are supposed to be done every 6 weeks, but because of limited store staff, the cycle counts are rarely done.

There is occasional loss of all medicines due to theft. However, loss of TB medicines due to theft is rare. The security guards at the store are not properly trained to screen people that come in and out of the CMS. The security company is provided by the Government and the CMS does not have any control over their performance.

For scheduled orders, the CMS delivers orders to the facilities where it supplies medicines by using its own vehicles. Facilities have to pick up their orders for unscheduled/emergency requests. CMS deliveries to the facilities are done every 6 weeks although deliveries are sometimes delayed because of limited number of vehicles and drivers at the CMS. The vehicles are maintained and managed by a unit in the CMS that can track the movement of the delivery trucks once they leave the store.

Communications between health facilities and the CMS is done via telephone, fax, and email.

Health facilities and stores do not provide any separate report on their stock levels to the CMS; they are only required to report their stock on hand routinely in their order forms, but this is not always done by all facilities. The CMS, on the other hand, does not consider stock level outside CMS during quantification of medicines needs. The SYSPRO system is also used at the Regional Medical Stores (RMS); it maintains all inventory management records and distribution data for the products in the store. The delivery notes, packing lists, and other records used in the store are generated from the electronic system. Some of the information monitored by the SYSPRO system includes quantities issued and received, average monthly consumption, minimum and maximum stock levels, and expiry dates. Inventory records at the CMS are kept for up to 10 years. Many reports are provided through the electronic system only upon request by programs or the pharmacist coordinator of DSP. The system however does not routinely monitor the distribution costs and performance of the distribution system.

Store Management

Almost all stores visited at the central, regional, district, and facility levels were clean and pest free. Medicines were stored on shelves, away from direct light and moisture. In most of the sites visited, medicines were arranged according to the CMS catalogue. In most stores, air conditioners were functional. The DOTs centers visited in Erongo region did not have any fans or air conditioners.

The CMS key stakeholder interviews reported that the store roof is leaking and there is very limited space for storage of medicines in the warehouse requiring use of storage areas outside the premises which presents a challenge for the staff managing the stores. However, the team was informed that plans are underway by the Government to find a new location for the CMS with sufficient space to store all medicines.

TB medicine storage conditions were not optimal in some of the stores visited; for example, at Eluwa clinic, TB medicines were stored in direct sunlight by the windows and there was no air conditioner; at Rundu RMS, floors were chipped creating dust in the storeroom and on medicines; and at Otjiwarongo district hospital, storage space was insufficient and the roof was sacked. The team was informed that cats entered the store through the broken ceiling. Also, TB medicines were stored in different locations at the facility.

The team also observed that Capreomycin injection 1 g was supplied by two different manufacturers. The Macleod pharmaceutical formulation does not require refrigeration whereas the Svizera laboratory formulation requires refrigeration (store at temperature not exceeding 15 °C). At one of the facilities visited, the Svizera formulation was not refrigerated. Further investigation revealed that a circular was sent to all the regions about storage of this medicine, but apparently, this has not been implemented at all health facilities.

Inventory Management Practices

Inventory records were regularly updated and up-to-date in all stores visited except at Oshanini health center where stock cards have not been updated since February 2010. The physical count conducted at the CMS showed that only 29.6% of record count (SYSPRO stock status on day of visit) of the set of tracer TB medicines corresponded to physical counts.

For first-line medicines, data collected from 19 health facilities showed that an average of 72% (range, min 0%; max 100%) of health facilities had their physical stock count for a set of tracer TB medicines corresponding to their inventory record count.

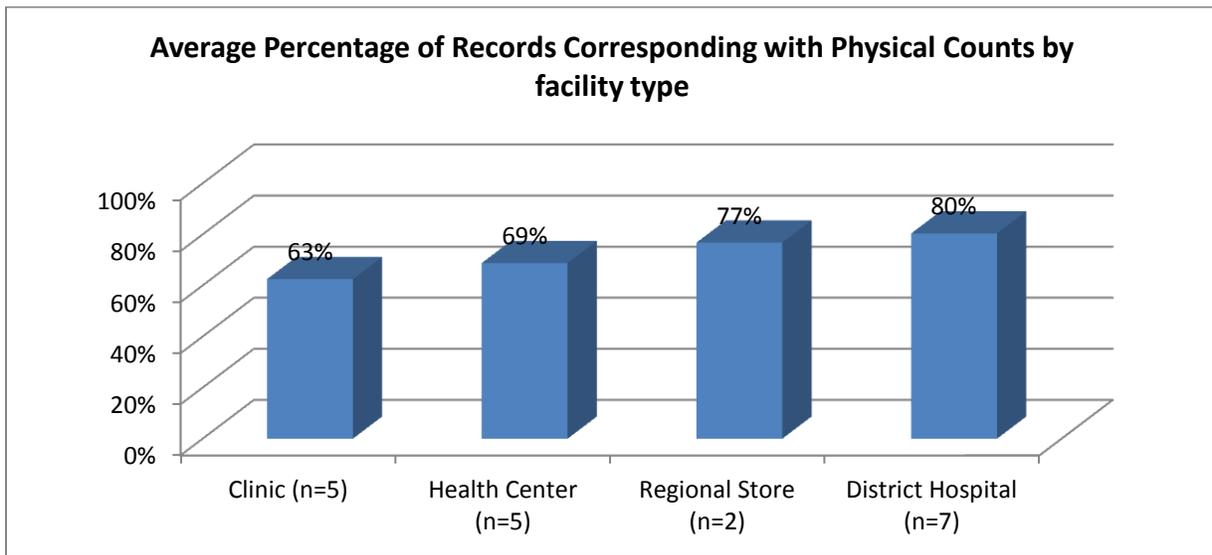


Figure 3. Distribution by facility of average percentage of inventory records that corresponded with physical counts

Clinics had the lowest percentage of physical stock count corresponding to physical count whereas district hospitals had the highest percentage of physical stock count corresponding to record count. When inventory management by regional stores was compared to district hospitals, the level of inventory management by district hospital was better than by regional store. Variations in inventory management across regions were also noticed.

According to figure 4, Khomas region maintained the highest level of inventory management followed by Erongo and Kavango. Inventory was not appropriately managed by Karas, Omaheke, and Otjozondjupa. Inappropriate inventory management will inadvertently lead to wastage and/or stock outs of TB medicines. Moreover, anti-TB medicines should be available at all times in the supply chain in order to ensure continuity in supply to the patient without which, patients may go for some days without their medicines.

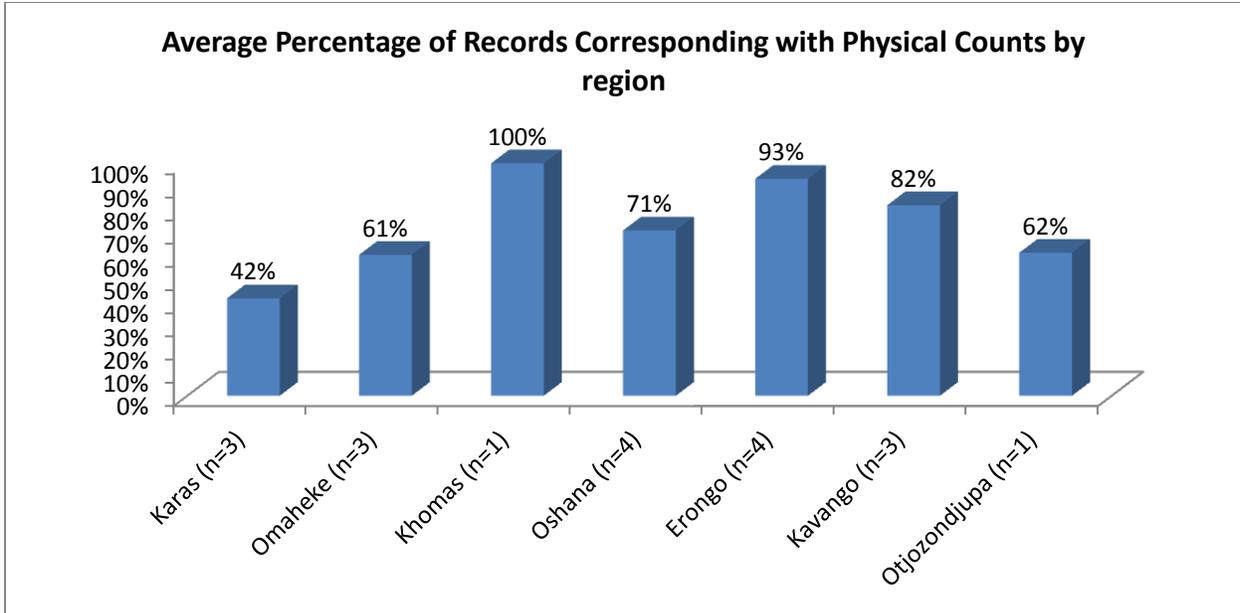


Figure 4. Distribution by region of average percentage of inventory records that corresponded with physical counts

For second-line TB medicines, an average of 96% (min 75%; max 100%) of the health facilities where data were collected had their physical count corresponding to their inventory record counts for a set of tracer medicines.

Although all facilities except the CMS reported they conduct regular physical and cycle counts throughout the fiscal year, this practice was not evident when facilities’ stock cards were reviewed. The CMS reported they are short staffed and cannot carry out regular cycle counts which they need to do for some medicines every 6 weeks according to their SOPs.

TB Medicine Ordering Practices

At all levels visited, TB medicine orders are placed using minimum and maximum stock levels. A quantification/ordering tool for first-line TB medicines was provided to the district hospital level and below by DSP, and health workers were trained to use this tool; however, in all the health facilities visited, none was using this ordering tool. Estimation of medicine needs was poorly done as it was not evident during review of stock records that the minimum and maximum stock levels were adhered to. Findings from key stakeholder interviews also showed that estimation of TB medicine needs were more poorly done at lower health care facilities; no standard method or parameter was considered when determining order quantities. Medicine order needs were largely dependent on the personal judgment of staff placing the orders.

At health facilities where DR-TB treatment is provided, second-line TB medicines orders were placed taking into consideration the number of patients on treatment. However, the CMS does not consider the number of patients on treatment when placing their orders.

TB Medicine Availability

At the CMS, inventory data for the past 12 months preceding the assessment were reviewed to find out the total number of days out of stock. Findings showed that the average percentage of time out of stock for a set of TB tracer medicines (both first and second line) during the review period was 2.9%. For the health facilities visited, the average percentage of time out of stock for the same tracer TB medicines was approximately 2% (range min 0% and max 6%). Although these stock outs occurred, it did not translate into patients going without their medicines at any of the facilities visited.

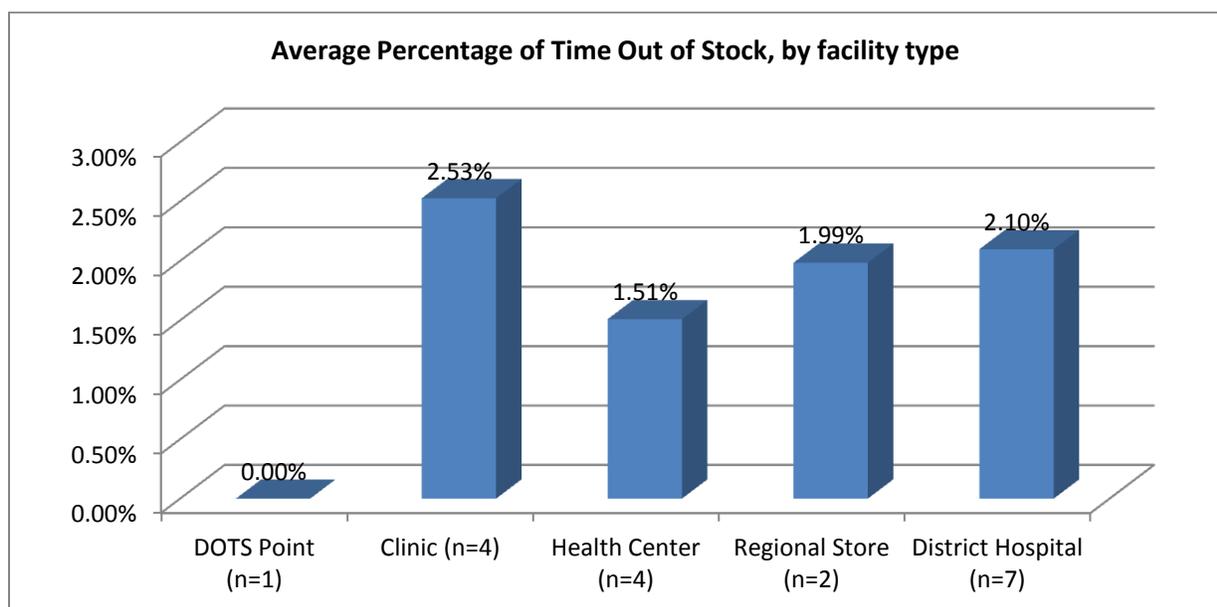


Figure 5. Time out of stock of anti-TB medicines distributed by facility type

DOTS sites never ran out of stock whereas clinics, health centers, regional stores, and district hospitals did, albeit infrequently.

The main reasons reported by key stakeholders interviewed at health facilities for the stock out included—

- Late delivery from suppliers
- Minimum and maximum stock levels not maintained
- Quantities delivered did not match quantities ordered

The average time products ran out of stock across regions was compared.

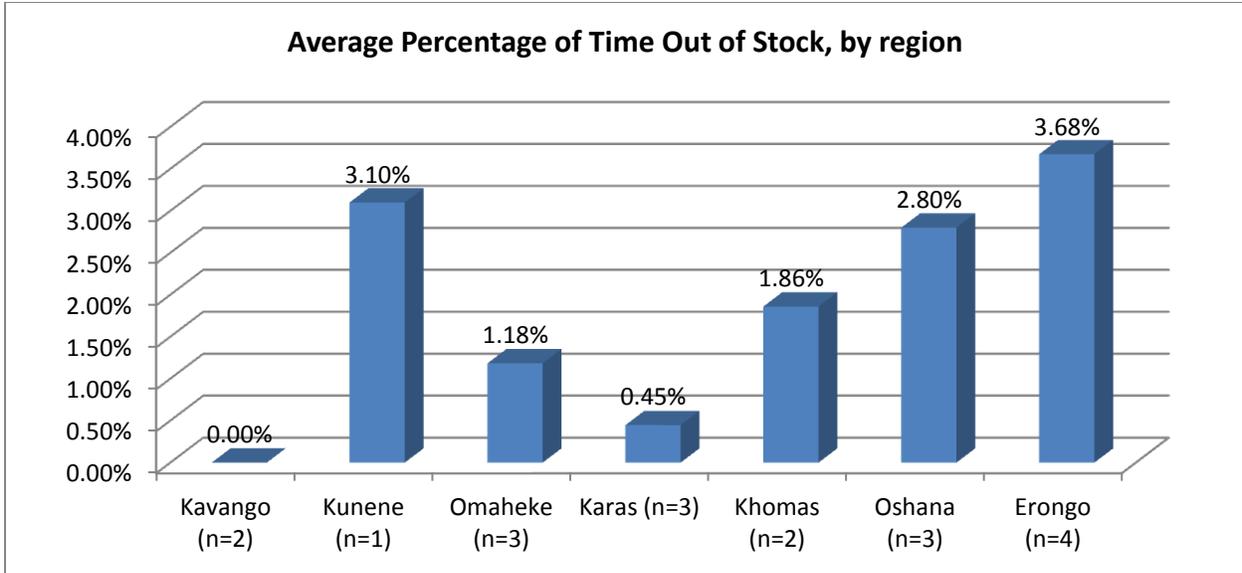


Figure 6. Time out of stock of anti-TB medicines distributed by region

It was found that in Kavango region, anti-TB medicines never ran out of stock for the 12 months preceding the assessment whereas Erongo and Kunene regions presented with the highest percentages of out of stock of anti-TB medicines, but still had stock over 96% of the time.

At the CMS, 100% of the set of TB tracer medicines were found to be available on the day of the visit. For the health facilities, an average of approximately 93% of a set of first-line TB tracer medicines was found to be available on the day of the visit. For second-line TB medicines, 100% of the set of TB tracer medicines was available at the health facilities on the day of the visit.

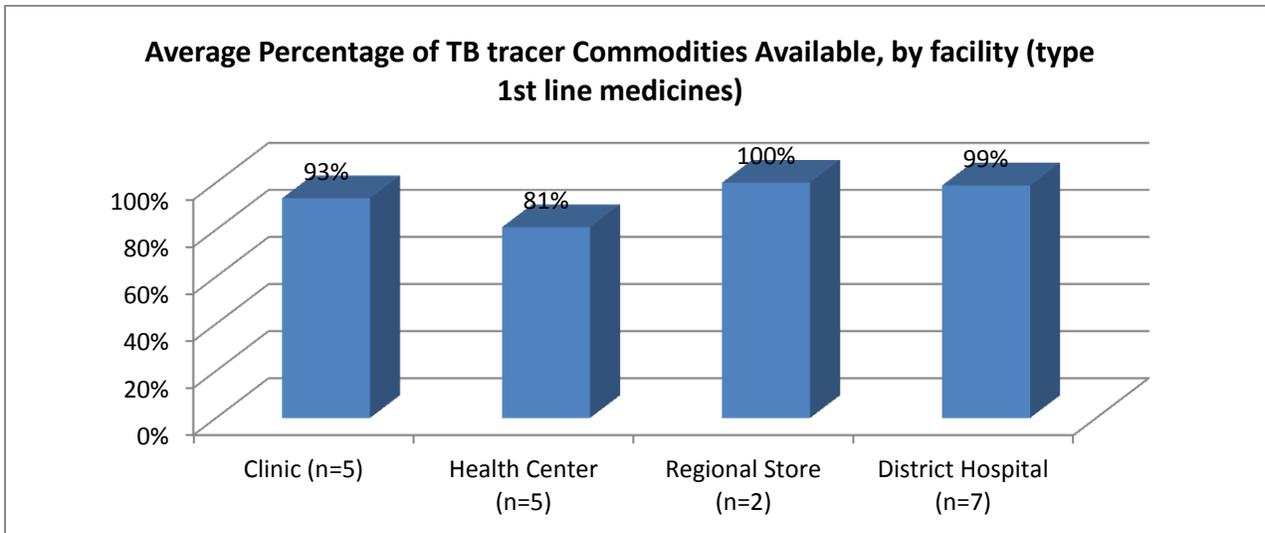


Figure 7. Distribution by facility type of the availability of first line anti-TB medicines

Regional stores kept the full range of anti-TB tracer commodities whereas health centers and clinics did not. The reason is that because regional stores serve most of the health facilities within the region, they are bound to have medications that meet the different needs of the different health facilities. Some health facilities reported that they stored medicines depending on the type of patients they have and would order from the regional stores as soon as the medicines were needed.

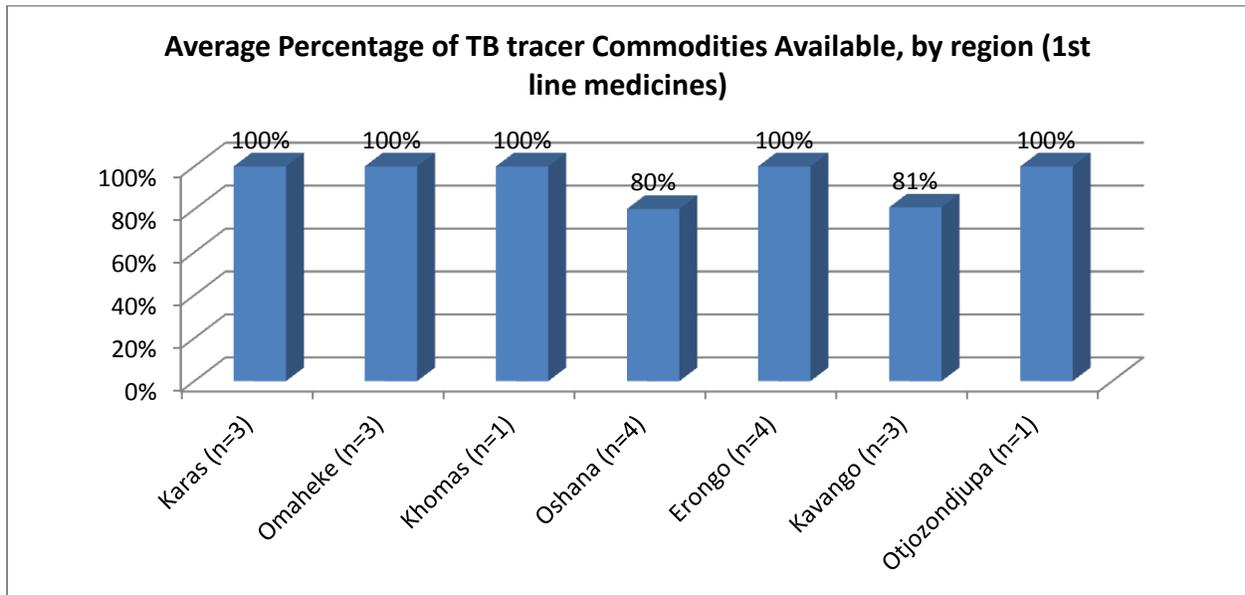


Figure 8. Distribution by region of the availability of first line anti-TB medicines

Of the seven regions assessed, anti-TB tracer commodities were found in their full range in five regions, i.e., Karas, Omaheke, Khomas, Erongo, and Otjozondjupa regions whereas Oshana and Kavango regions had 80% and 81%, respectively, of the set of TB tracer commodities were available.

TB Medicines Wastage through Medicine Expiry

In the health facilities visited, no expired TB medicines were found on the shelves except at a few facilities. For example, Otavi clinic was issuing a TB medicine (3FDC) that expired January 2011 to patients without knowing it had expired. The average percentage of a set of expired TB tracer medicines found within the usable stock at the health facilities visited was 4% (range min 0% and max 38%) for first-line TB medicines. There were no expired second-line TB medicines on the shelves.

Health centers and clinics were found to perform poorly in stock rotation when compared to regional and district stores. Upon further stratification of data across regions, it was found that Oshana region had the highest percentage (18%) of expired first-line TB medicines found within usable stock.

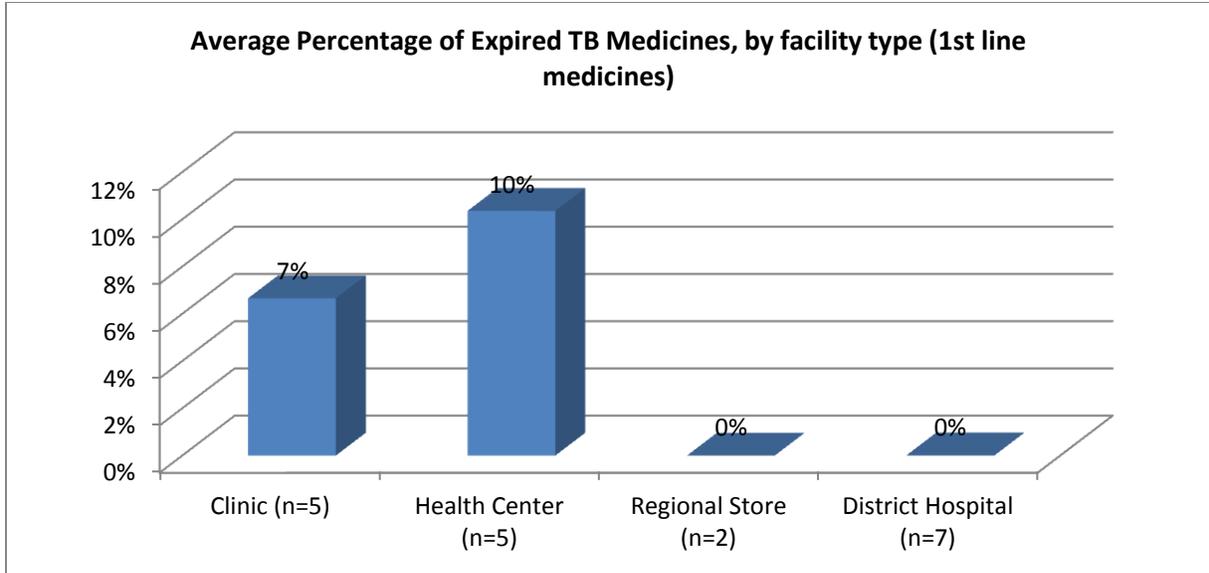


Figure 9. Average percentage of expired anti-TB medicines distributed by facility type

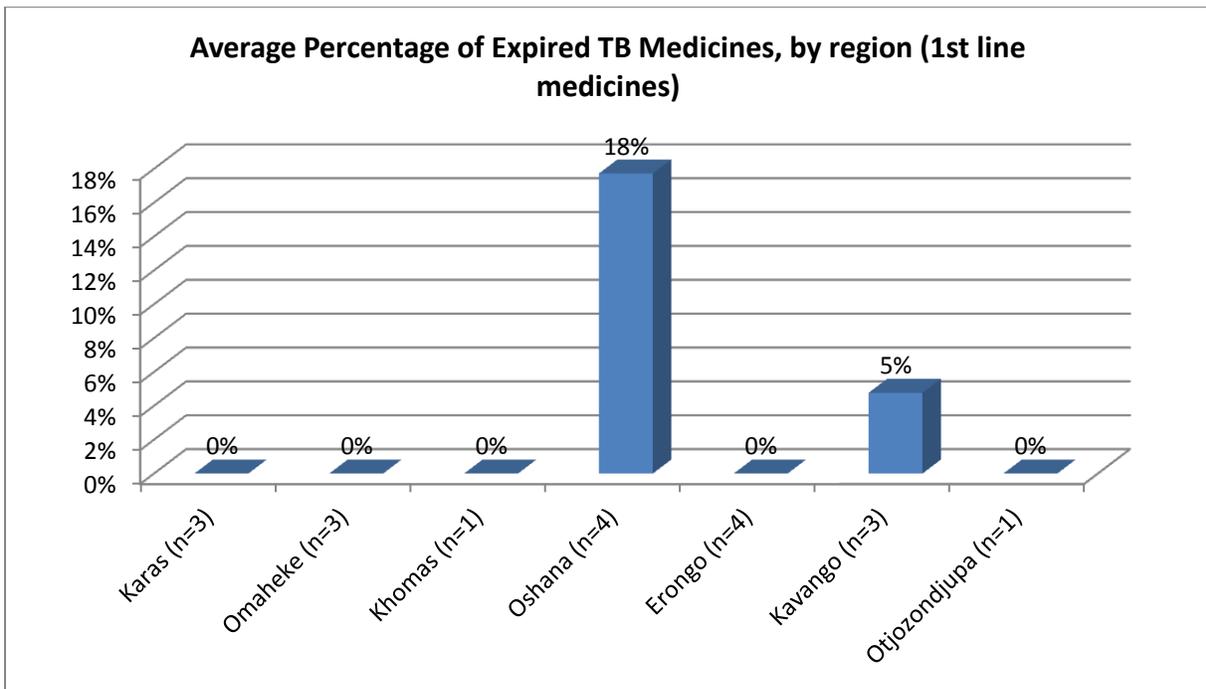


Figure 10. Regional average percentage distribution of expired anti-TB medicines

Most of the facilities visited had lost some quantities of TB medicines because of expiry in the last 12 months. In almost all the facilities visited, TB medicines with less than 6 months shelf-life were found—

- Ethambutol 100 mg (expired February 2011)
- Kanamycin injection 1 g (expired May 2011)
- PAS powder 4 g (expired May 2011)

The expired quantities found at the health facilities were small and were not quantified or analyzed but each health facility and the regional pharmacists where these short dated medicines were found were alerted to the need to use up and transfer stock to other facilities or regions where they are needed to minimize the total quantities that will eventually expire.

In addition, large quantities of PAS power 4 g and Kanamycin injection 1 g expiring in May 2011 were found at the CMS.

Table 9. Value of Expired PAS Powder and Kanamycin Injection

Medicine name	Quantity	Estimated number of patients on medicine	Estimated wastage	Estimated cost of wastage
PAS powder 4 g	387,660 sachets	62	354,180 sachets	N\$502,345.00
Kanamycin injection 1 g	133,500 vials	248	111,180 vials	N\$304,284.00
Total				N\$806,629.00

When CMS inventory records were reviewed, large quantities of second-line TB medicines were found to have expired in the last 12 calendar months preceding the visit. The total value of these medicines was estimated at N\$6,059,256. Some first-line medicines also expired during the review period but not as much as the second-line medicines. There were also some unexpired quantities of cefoxitin 1 g injection found at the CMS which no facility had requested in the past seven months. These are likely to expire on the shelf.

The main reasons reported by the CMS for medicine expiry included—

- Inaccurate quantification of second-line TB medicines because minimum and maximum stock levels for ordering may not reflect actual reality on the ground because there was no information sharing between the TB program and CMS about their activities. The CMS welcomes the idea of the NTP quantifying the needs for second-line TB medicines according to patient numbers. They can easily adjust their ordering procedure to ensure correct quantities are ordered and that wastages are reduced.
- Supply of short-dated medicines from suppliers which they are forced to accept when the products are stocked out.
- Policy change and implementation of new regimens by TB program without appropriate planning by CMS.

For the health facilities visited in the field, the main reason reported during key stakeholder interviews for TB medicines expiry in the last 12 months reported included—

- CMS sent short-dated items and followed it with a circular disallowing any returns back to the CMS. In the circular by CMS, the central store will not accept back from any facilities any medicine with only three months of shelf life. The circular provides further instructions on what actions facilities should take.
- They do not always practice first expiry, first out (FEFO) in their inventory management
- Insufficient and untrained staff to properly manage medicines

Namibia has a policy document in place for handling and destruction of expired medicines. Once medicines are expired, they should be removed from the shelves and from the inventory records; arrangements should then be made with the municipality disposal site for disposal following specified protocols. No large physical stock of expired TB medicines was found at any facility visited.

TB Medicines Distribution

Namibia has a fixed schedule for distribution of medicines and related supplies (including TB medicines) from the CMS to other facilities. This schedule is not always followed; key stakeholder interviews at health facilities reported that their facilities sometimes receive their medicine delivery late. This is one of the reasons attributed to their stock out situations and not meeting their minimum and maximum stock level requirements.

Although the CMS reported having limited trucks and drivers for distribution of supplies, it was also reported that their trucks and drivers sometimes spend up to two days just waiting for a health facility to off load their medicines from the trucks, preventing the drivers from proceeding to the next facility. On the other hand, some health facilities that are prepared to off load the medicines from the truck wait all day and by the time the truck arrives the following day, all the people they had mobilized to off load the truck are no longer available causing further delays.

Rational Medicine Use

After quality-assured TB medicines that are safe and effective are procured and distributed to all the health facilities where they are needed, if the medicines are not prescribed according to the guidelines, dispensed according to the prescription, or taken by the patients according to the prescription, TB treatment targets for the country might still not be met.

Fixed-dose combination (FDC) medicines are used for TB treatment in the country. The treatment regimen used for category one (new patients) is 2 months of RHZE and 4 months of RH, with daily dosing. For category two treatment (retreatment cases), 2 months of RHZES, 1 month of RHZE, and 5 months of RHE, with daily dosing. Health worker compliance with TB treatment guidelines is monitored through periodic checks during supervisory visits.

Prescriber Compliance to National Treatment Guidelines

During field visits at health facilities, several patient treatment records were reviewed from each facility to find out if medicines were prescribed in accordance to the national treatment guidelines. The review looked at the medicine name, strength, and total number of tablets administered, which was compared with patient weight for intensive and continuation phases of first-line TB treatment. This review was also limited to smear-positive TB patients only. Findings showed that 86.6% (n = 172; range min 54.5% and max 100%) of prescriptions for intensive phase and 73.9% (n = 207, range min 0.0%, max 100%) of continuation phase prescriptions were in accordance with the standard treatment guidelines.

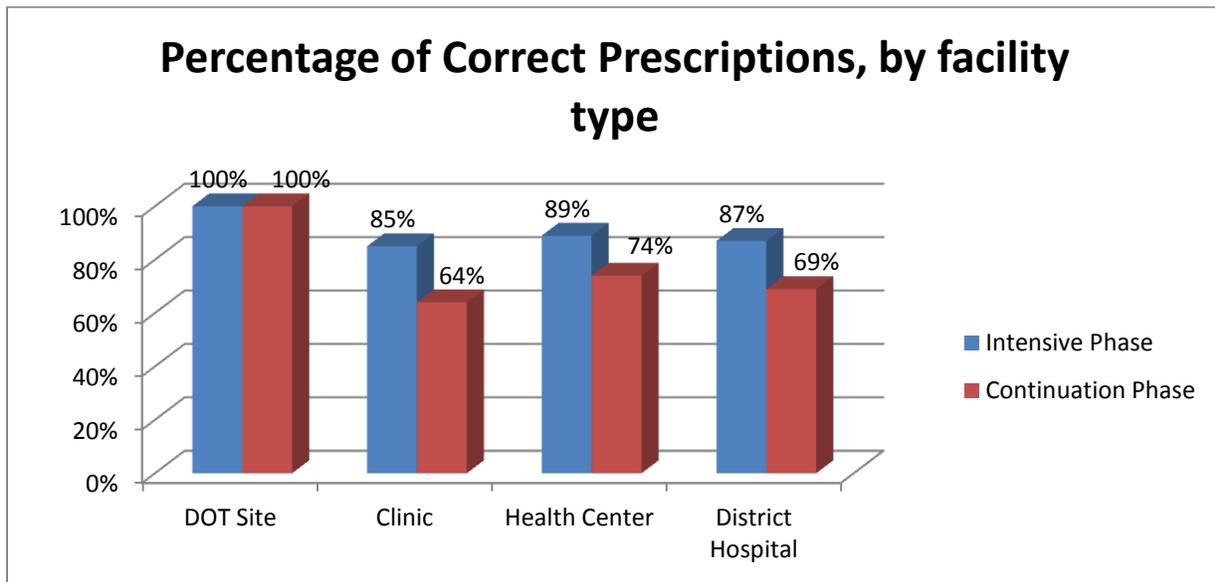


Figure 11. Percentage of correct prescriptions distributed by facility type in the intensive and continuation phases

Otjozondjupa, Omaheke, and Karas regions had lower levels of correct prescriptions for both the intensive and the continuation phases of TB treatment. This is shown in figure 12.

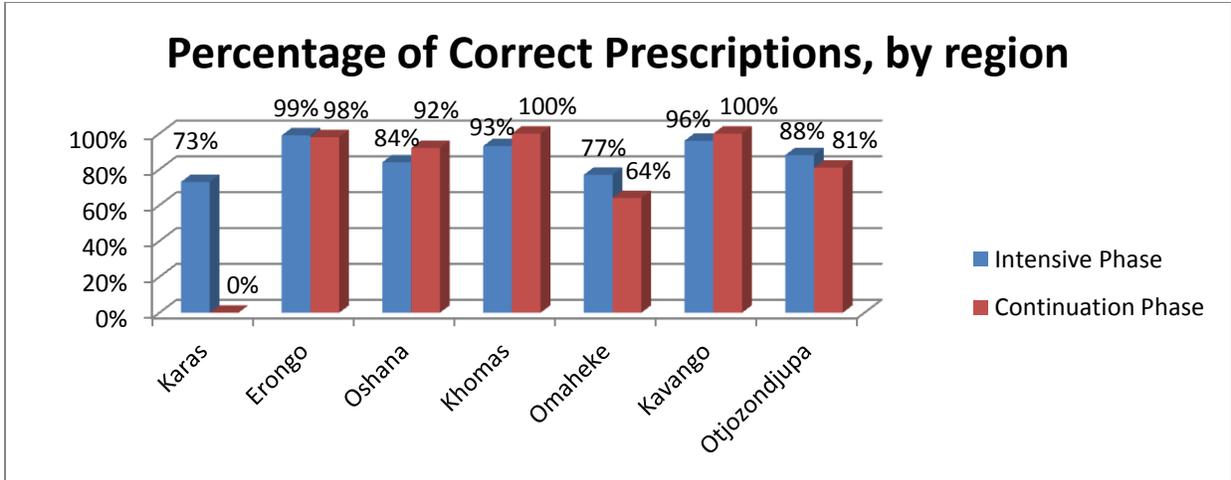


Figure 12. Percentage of correct prescriptions distributed by region in the intensive and continuation phases

Erongo, Khomas, and Kavango regions had high levels of correct prescriptions ranging from 93% to 99% for the intensive phase and 98 to 100% for the continuation phase. For the Karas region, no data was collected for the continuation phase because the patient medical records reviewed did not contain the weight of the patients and in some cases, the number of tablets the patient took.

Direct Observation of Medicine Intake and Patients’ Knowledge of their TB Medicines

In each of the health facilities visited, exit poll interviews were conducted for TB patients who had come to the clinic to take their medicines (outpatients and inpatients). The interview questions were structured to evaluate three main areas in rational medicines use to determine if TB patients were —

- Always observed while taking their medicines (DOT)
- Knowledgeable about how prescribed medicines should be used
- Knowledgeable about medicine side effects and consequences of not taking their medicines as prescribed

Lack of knowledge in these areas can be a useful measure of potential non-adherence to treatment and possible treatment failure. Finding revealed that 93% reported regular observation by a caregiver while taking their medicines; 75% of the patients interviewed could correctly describe how to take their medicines and 70% had correct knowledge of medicines side effects and consequences of not taking their medicines as prescribed.

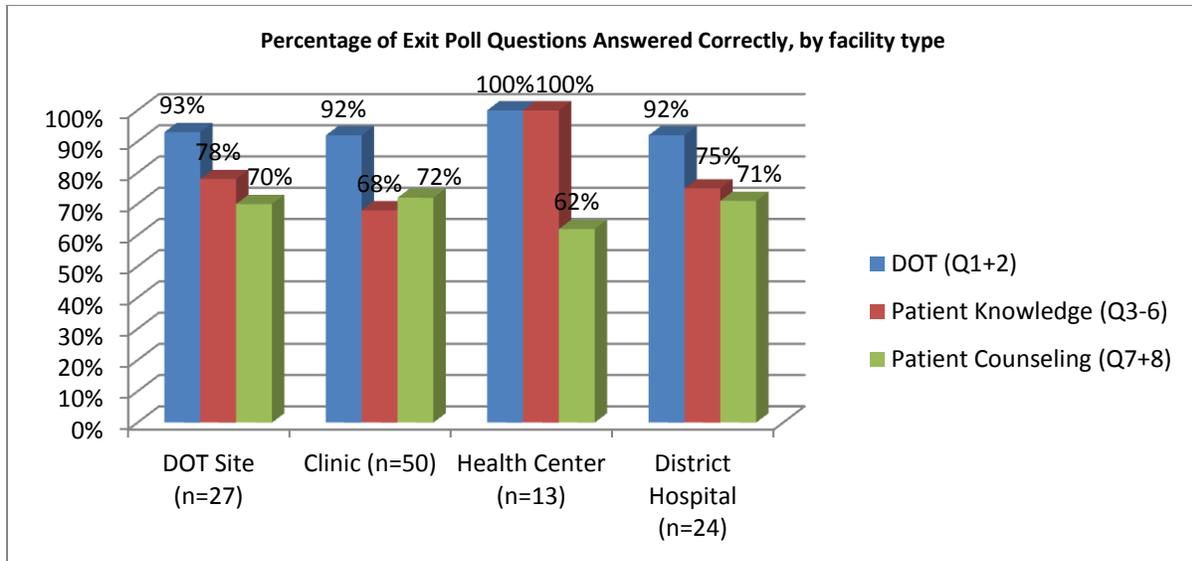


Figure 13. Percentage of exit poll interviews that were answered correctly distributed by type of facility

The figure above showed that at the health center level, more patients reported to be observed by a care giver when they took their medicines than in the DOTs sites, clinics, and district hospital surveyed. Patient counseling was reported to be more effective at the district hospital level than at the health centers. The variation in DOTs observation, patient knowledge of their treatment and patient counseling was compared among the various regions assessed.

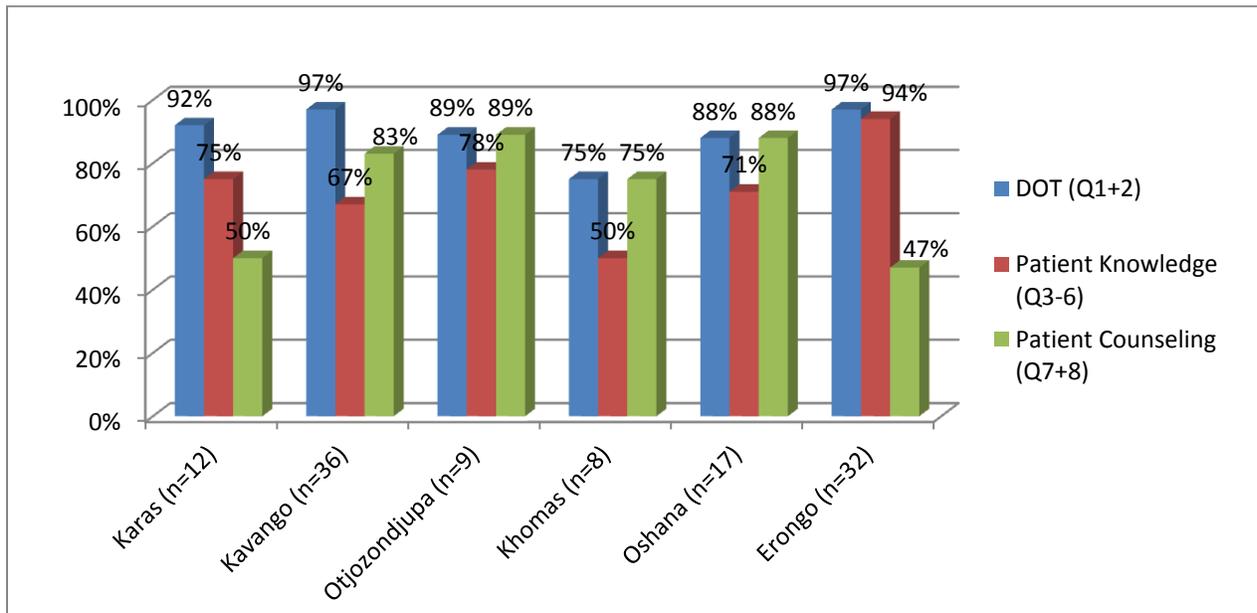


Figure 14. Regional percentage distribution of TB patients observed while taking their medicine and their knowledge of their medicines and knowing consequences of defaulting treatment

It was seen that the pattern in DOTS observation, counseling practice, and patient knowledge was similar across the regions. Patient counseling practice was approximately 50% in two regions (Erongo 47% and Karas 50%). Patient knowledge was 50% in Khomas and 67% in Kavango.

Namibia has low defaulter rates for TB. However, the rates vary across regions. During field visits, health workers reported that the main reason for the low default is because of the field promoters who go out to the communities to trace these patients.

The main adherence challenges reported during field visits by key stakeholders interviewed included some patients who—

- Do not have enough food to eat before taking their medicines
- Do not take all medicines because of side effects
- Are alcoholics
- Are not Namibians; they cross the borders to get treatment
- Transfer in and out, making it more difficult to monitor them
- Have other medical problems that require more immediate attention than their TB treatment

Monitoring and Reporting of Side Effects

Stakeholder interviews revealed that health workers did not always probe patients for side effects when they come to the health facility for their treatment. For second-line medicines, side effects are supposed to be monitored on the patient treatment card and reported to TIPC as required. Key stakeholder interviews at the health facilities reported that the most common complaints for patients on second-line medicines were gastrointestinal disturbances which are difficult to control even with ancillary medicines. Interviews with TIPC indicated that the most common adverse event reported to the department is ototoxicity and deafness due to the Amikacin injection and other medicines in the same family. The NTLP reported that necessary measures have already been taken to monitor patients on these medicines closely to prevent permanent hearing loss. The TIPC has not yet received any reports on gastrointestinal disturbances.

Management Support

Proper management of all TB medicines and related activities is essential for the success of the program. To manage TB medicines, pharmaceutical supportive supervisory visits are conducted to facilities. The central-level supervision team is supposed to conduct visits at least twice every year but in practice this is done once every year. Regional-level supervisors conduct this visit once a quarter and the district TB coordinators are supposed to carry out TB supervisory visits once a month.

During these visits, supervisors review a wide range of medicine management activities that include assessment of storage space and practices, inventory control, medicine ordering, pharmacy management information system, training needs, and others. Supervisors are also

supposed to mentor staff during these visits as needed and a feedback meeting is held after each visit to troubleshoot solutions and determine the right intervention to solve problems. The DSP arranges for a meeting with any facility that has issues that can be resolved through training to schedule an appropriate time for the training.

Workforce Capacity Building

Key stakeholder interviews at health facilities and pharmacies reported the need for training of staff to improve their knowledge and skills. In general, training needs were identified in the areas of quantification, ordering, and inventory management. The NTLP key stakeholder interviews reported that training is conducted for staff several times during a calendar year; doctors and pharmacists who have never been trained attend trainings once every quarter while advanced trainings (for people already trained) are conducted once every quarter. Nurses and nursing aids are trained through the regional health offices.

Further investigation revealed that training participants are selected by the regions and the selection criteria vary by region; some staff has attended several trainings and others have not had any training in the last three to four years. Stakeholder interviews from the field also reported the problem of high staff turnover and weak staff retention strategies from the national level.

Recommendations

General

- There appears to be suboptimal communication between the CMS under PhSs and the NTLP. This may have severe consequences for anti-TB medicine stock levels and functioning of NTLP generally. NTLP and CMS should improve communication about program activities that affect TB medicines. The PhSs pharmacist coordinator for the NTLP is the intermediary person responsible for interacting with CMS to both obtain and provide relevant information that can affect stock levels on a regular basis.
- It is recommended that CMS and NTLP develop a plan to implement the new TB guidelines. If this is done, stock outs and wastage of anti-TB pharmaceuticals will be minimized. A plan for quantification training and rational use should also be put in place to support reduction of TB medicine stock-out and wastage.

Medicine Selection and Registration

- NMRC should either require PAS suppliers to register it in the country or ensure QSL can carry out quality control testing for PAS. If both options are not feasible, consider sending random samples periodically to another laboratory for quality testing.
- Findings presented show that not all TB medicines on the tracer medicines list for Namibia are selected according to international recommendations. This should be looked into by the

NTP and any agreed changes should be incorporated into the new treatment guidelines to be published soon.

- Considering the need for good quality anti-TB medicines, it is recommended that all medicines that are used in Namibia for the treatment of TB infection be registered with NMRC.

Medicine Quantification and Procurement

- It is important to purchase from WHO prequalified manufacturers, especially when medicines quality assurance testing is infrequently done and costly to undertake as is the current case.
- A standardized approach and tools that consider actual patient numbers and actual consumption should be put in place both at facility and national levels by NTP and PhSs to support quantification of second-line TB medicines in the country.
- The PhSs pharmacist should quantify TB medicine needs for patients on second-line medicines based on the number of patients on treatment and should provide estimated quantities to CMS at specified periods for procurement.
- It is recommended that training and regular supervision on estimation of medicine needs for orders be carried out especially for staff at the lowest levels (DOTS sites). Appropriate estimation of TB medicines at the facility levels will eliminate wastage due to expiry resulting from overstocking and will eliminate stock outs of essential medicines, reducing the rate of interim orders and freeing staff to engage in more direct patient management activities.
- PhSs should support districts and health facilities to ensure the use of the first-line TB quantification guide provided during trainings and should address any issues reported as to why it has not been used.
- The PhSs pharmacist should request partner support to develop a quantification methodology and approach for second-line TB medicines.

Quality Control and Assurance

- CMS and QSL should establish a system (either by linking information systems or by sending regular reports) to inform QSL about expected receipt dates for all pending orders
- CMS should allow QSL staff to either collect samples for testing or to follow-up with CMS about sending received medicine batches for quality testing.
- The fact that only 47% of samples received by QSL were sampled is a cause for concern. QSL should be strengthened to ensure that TB medicines samples are tested. It is important that CMS enforces the tender contract clause that requires suppliers to deliver each product

with an accompanying batch certificate for analysis and provide the QSL with product batch certificates at the time samples are sent to QSL.

Storage and Distribution

- Inventory management at all levels of TB medicine supply chain within the country should be strengthened. Each district hospital should have a trained pharmacist who in turn will train other pharmaceutical personnel to properly manage inventory and to adhere to guidelines. Inappropriate inventory management inadvertently leads to wastage and/or stock outs of TB medicines. Moreover, anti-TB medicines should be available at all times in the supply chain to ensure continuity in supply to the patients without which patients may go for some days without their medicines.
- PhSs should send a circular from the Permanent Secretary mandating hospital and facility managers to ensure CMS trucks are off loaded with 2-3 hours of arrival at the facility. Also consider appointing someone at each facility who will be held accountable if circular instructions are not followed. Perhaps certain conditions or incentives can be attached to the performance of each facility.
- CMS should communicate to facilities in advance and on the delivery day the approximate expected time of delivery for their orders so the facilities can prepare to off load trucks.

Rational Use

- PhSs should resend circular to all facilities about storage requirements for capreomycin injection 1 g (Svizera brand). Regional pharmacists should monitor storage of capreomycin during all supportive supervisory visits.
- Causes of prescribers' non-adherence to treatment guidelines should be investigated urgently by NTLP. Interventions must then be implemented to address the causes to minimize therapeutic inefficiency and treatment failure.
- To improve adherence to anti-TB medicines, patients counseling must be reinforced at every clinic visit, irrespective of the duration the patient has been on medication. Furthermore, DOTS supporters and nurses responsible for observing patients during treatment administration should provide appropriate information on medication use, duration on treatment, and also consequences of not completing the course of treatment.
- NTLP and CCRC should monitor second-line TB patient medicine profiles to ensure patients are placed on the right medicines they require according to the national guidelines for effective treatment.

ANNEX 1. LIST OF HEALTH FACILITIES VISITED

No.	Facility name	Facility type	Region
1	Tamariskia	Clinic	Erongo
2	DRC	DOTS site	Erongo
3	Mondesa	DOTS site	Erongo
4	Narraville	DOTS site	Erongo
5	Okangwena	DOTS site	Erongo
6	Kuiseb	Health centre	Erongo
7	Coastal	DOTS site	Erongo
8	Swakopmund	District hospital	Erongo
9	Walvis Bay	District hospital	Erongo
10	Tses	Clinic	Karas
11	Bethanie	Health centre	Karas
12	Keetmanshoop	District hospital	Karas
13	Rundu	Hospital pharmacy	Kavango
14	Ndama	Clinic	Kavango
15	Ekwafo center	DOTS site	Kavango
16	Sauyemwa	Clinic	Kavango
17	Sambyu	Health centre	Kavango
18	Rundu	Clinic	Kavango
19	Rundu	Regional Medical Store	Kavango
20	Robert Mugabe	Clinic	Khomas
21	Katutura	Intermediate hospital	Khomas
22	Epako	Clinic	Omaheke
23	Otjinene	Health Centre	Omaheke
24	Gobabis	District hospital	Omaheke
25	Eluwa	Clinic	Oshana
26	Ondangwa	Health centre	Oshana
27	Oshakati	Intermediate hospital (TB unit)	Oshana
28	Oshakati	Regional medical store	Oshana
29	Otjiwarongo	District hospital	Otjozondjupa
30	Osire	Clinic	Otjozondjupa
31	Otavi	Health centre	OtjozondjupaKhomas
32	Windhoek	Central Medical Stores	Khomas

ANNEX 2. LIST OF DATA COLLECTORS

Name	Affiliations
Hilma Ipinge	National Coordinator, TB DOTS Program
Linea Naango	Data Clerk, National Malaria Program
Mavis Liswaniso	Data Clerk, National TB and Leprosy Program
Naita Nashilongo	Pharmacist Coordinator, Directorate of Special Program, MoHSS
Francis Kalemeera	Coordinator, Therapeutics Information and Pharmacovigilance Center
Chinwe Owunna	Consultant, Country Program Manager, SPS/MSH, Arlington, USA
Christopher Ntege	Senior Program Associate, SPS/MSH, Windhoek, Namibia
Robert Chana	Senior Program Associate, SPS/MSH, Windhoek, Namibia

ANNEX 3. LIST OF PERSONS MET AT THE NATIONAL/CENTRAL LEVELS

Name	Organization	Contact number	Email address
R. Njiriri	NMRC/PC&I	061 203 2410	inspect@nmrc.com.na
N. Nashilongo	DSP/Pharmacist coordinator	0812356578	nashilongon@nacop.net
J. Gaeseb	NMRC/PC&I	061 203 2403	regmeds@nmrc.com.na
H. Masiyachengo	NMRC/QSL	061 233151	hmasiyachengo@cms-namibia.com
C. Ntege	MSH/SPS	0814331436	cntege@msh.org.na
A. Mengistu	NMRC/TIPC	061 203 2406	atmengistu@tipc.com.na
R. Chana	MSH/SPS	0816267108	rchana@msh.org.na
D. Sheehama	CMS	061 233151	dsheehama@cms-namibia.com
H. Lema	CMS	061 233151	hlema@cms-namibia.com
T. Ngulu	CMS	061 233151	tngulu@cms-namibia.com
G. Habimana	CMS	061233151	ghabimana@cms-namibia.com
F. Mavhunga	NTLP	061302738	mavhunga@hotmail.com
G. Platt	NTLP	061302738	plattg@NACOP.NET
R. Nunurai	NTLP	061302738	ncruswa@yahoo.com
B. Bayer	NTLP	061302738	bayerb@NACOP.NET
O. Ahmed Omer	KNCV	061302738	Omer_ahmedomer@yahoo.com

ANNEX 4. LIST OF INDICATORS ASSESSED

- **K-1.** Average percentage of time out of stock for a set of TB tracer commodities in TB facilities
- **K-2.** Average percentage of a set of TB commodities available in TB facilities and medical stores
- **K-3.** Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines utilized
- **K-4.** Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate
- **K-5.** Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement
- **C-1.** Percentage of NTP medicine products included on the Nemlist
- **C-2.** Percentage of NTP medicine products included on the WHO Anti-Tuberculosis Essential Medicines List
- **C-3.** Percentage of TB medicine samples that failed quality control testing out of the total number of TB medicine samples tested during the past year
- **C-4.** Percentage of TB facilities visited where the latest official manual of treatment guidelines for TB was present
- **C-5.** Percentage of TB outpatients who could correctly describe how the prescribed medication should be used
- **C-6.** Percentage of TB patients who reported regular observation by a health worker during medicine intake
- **C-7.** Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities

ANNEX 5. DATA COLLECTION FORMS

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 150mg (RHZ) tablet														
3. Rifampicin 60 mg/ isonaizid 30 mg (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. Isoniazid 300 mg (H) tablet														
9. Pyrazinamide 400 mg (Z) tablet														
10. Rifampicin 150 mg (R) capsule														
11. Rifampicin 450 mg (R) capsule														
12. Rifampicin 150 mg/isoniazid 75 mg/ethambutol 275 mg (RHE) tablet														

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
13. Streptomycin 5 g (S) injection														
14. Cycloserine 250 mg tablets														
15. Ethionamide 250 mg tablet														
16. Kanamycin injection 1 g														
17. Levofloxacin 250 mg tablet														
18. p-Aminosalicylate powder 4 g														
19. Amoxicillin/clavulanate 1 g tablet (875/125 mg)														
20. Capreomycin injection 1 g														
21. Clofazimine 100 mg tablet														
22. Amikacin injection 500 mg														
23. Cefoxitin injection 1 g														
24. Clarithromycin 500 mg tablets														
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)														

Row 2: Total number of commodities for which Col. 8 is greater than Col. 9	
Row 3: Total number of commodities checked “Y” in the Normal Stock column	
Row 4: Percentage of records corresponding with physical counts (Number in Row 1 × 100 ÷ number in Row 3)	
Row 5: Percentage of TB commodities available (Number in Row 2 × 100 ÷ number in Row 3)	
Row 6: Average percentage of expired commodities (Sum of Col. 10 ÷ number in Row 3)	

Inventory Data Form: Second Line TB Medicines

Facility Name:	Data Collector Code:		
Facility Type:	Location:	Date:	

Existing inventory control systems: Computer system
Manual ledger

Data collected from: Computer system
Manual ledger
Stock record cards
Tally sheets

Commodity	Counting Unit	Normal Stock?	Record Count	Unrecorded Receipts	Unrecorded Issues	Adjusted Total	Physical Count	Expired Stock	Percentage Expired
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9	Col. 10
38. Cycloserine 250 mg tablets	Tablet								
39. Ethionamide 250 mg tablet	Tablet								
40. Kanamycin injection 1 g	Vial								
41. Levofloxacin 250 mg tablet	Tablet								
42. p-Aminosalicylate powder 4 g	Sachet								
43. Amoxicillin/clavulanate 1 g tablet (875/125 mg)	Tablet								
44. Capreomycin injection 1 g	Vial								
45. Clofazimine 100 mg tablet	Tablet								
46. Amikacin injection 500 mg	Vial								
47. Cefoxitin injection 1 g	Vial								
48. Clarithromycin 500 mg tablets	Tablet								

Row 1: Total number of commodities for which Col. 7 equals Col. 8	
Row 2: Total number of commodities for which Col. 8 is greater than Col. 9	
Row 3: Total number of commodities checked “Y” in the Normal Stock column	
Row 4: Percentage of records corresponding with physical counts (Number in Row 1 × 100 ÷ number in Row 3)	
Row 5: Percentage of TB commodities available (Number in Row 2 × 100 ÷ number in Row 3)	
Row 6: Average percentage of expired commodities (Sum of Col. 10 ÷ number in Row 3)	

B: Medical Records Review Form (Continuation Phase of Treatment)

Facility Name:	Data Collector Code:	
Facility Type:	Location:	Date:

Data collected from: Medical records Is an official manual of treatment guidelines available? Yes___ No___
 Patient registry If yes, from what year?

Patient Number	Date	FDC (A or P)	R	H	E	Z	S	Patient weight	# of tabs given	Correct Drug? Yes/No		
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9	Col. 10	Col. 9		
										Correct medicine and strengths (A)	Correct dosage (B)	Summary
Row 1: Total number of correct prescriptions												
Row 2: Total number of patient records reviewed												

Exit Poll Interview Form

Facility Name:		Data Collector Code:	
Facility Type:	Location:	Interview Number:	Date:

#	Ask the Patient the Following Questions	YES	NO
1	How long have you been taking your medicines?		
2	Does anybody on the medical staff or a caregiver look at you when you take your medicine?		
3	How many different kinds of medicines are you taking? (Indicate name, color, or other marker of a pharmaceutical product)	Medicines	
		YES	NO
4	How many tablets of each medicine are you taking?		
5	How many days in a week or in a month do you come to take or collect your medicines?	___ Daily ___ Once a month ___ Other (specify)	
6	When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?		
7	Did your doctor/caregiver tell you to return to the clinic or health center if any sign of side effects such as fever, ringing in the ears, blurred vision, or vomiting occur?		
8	What will happen if you do not take your medicines as prescribed?		