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# Adherence with Evidence-based TB Standards and Guidelines in Selected Health Facilities in Kenya

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**APRIL 2013**

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April 2013

Jhpiego Corporation

University Research Co., LLC

**DISCLAIMER**

The views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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# Acronym List

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
CHW	Community Health Worker
CME	Continuous Medical Education
CNR	Case Notification Rate
CTX	Cotrimoxazole
DOTS	Directly Observed Therapy Short Course
CB-DOTS	Community-based Directly Observed Therapy Short Course
DLTLD	Division of Leprosy Tuberculosis and Lung Disease
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counseling
IP	Infection Prevention
IPC	Inter-Personal Communication
KEMSA	Kenya Medical Supply Agency
MEDS	Medical and Equipment and Medicines Supply
NTP	National Tuberculosis Program
PPMDOTS	Public Private Mix for DOTS
TB	Tuberculosis
TOT	Trainer of Trainers
URC	University Research Company
WHO	World Health Organization
MDR-TB	Multi-Drug Resistant Tuberculosis

# Background

According to the Division of Leprosy, TB & Lung Disease (DLTLD) 2010 annual report, Kenya has a large and rising tuberculosis (TB) disease burden and is ranked 13th among the 22 high burden countries that collectively contribute to about 80% of the world's TB cases. The TB case notification rate (CNR) rose from 51 to 338 per 100,000 population between 1987 and 2007. As in the rest of Sub-Saharan Africa, the large increase of TB is attributed primarily to the rise in the spread of the Human Immunodeficiency Virus (HIV) (CDC 2010, DLTLD 2010).

The DLTLD, in line with international trends, has launched several new approaches aimed at increasing access to Directly Observed Treatment Short course (DOTS) and truly expand population DOTS coverage. These approaches include: Community-Based DOTS (CB-DOTS); Public-Private Mix for DOTS (PPMDOTS); collaboration between TB and HIV control programs; and the development of an elaborate advocacy, communication and social mobilization strategy aimed at influencing communities to seek care early when TB symptoms occur and for patients initiating treatment to remain on treatment until it is completed. Despite these efforts, the World Health Organization (WHO) estimated that Kenya's TB case detection rate (proportion of incident cases that are diagnosed and treated out of the total estimated new cases in the country) was 70% in 2007.

The country offers drug resistance surveillance for all Pulmonary Tuberculosis retreatment cases. Results from this routine multi-drug resistance Tuberculosis (MDR-TB) surveillance on retreatment confirmed 112 MDR-TB cases as of end of 2010 (DLTLD, Annual report 2010). The DLTLD 2010 Annual Report recognizes several factors which may be responsible for MDR-TB cases including: patient factors such as poor adherence; system factors such as stock-out of medications and poor quality medicines; provider factors such as misuse of anti-TB medicines and inadequate monitoring; as well as environmental factors where there is a huge population of refugees.

Adherence to long-term therapies is a multidimensional phenomenon determined by the interplay of five sets of factors (dimensions) namely:

social and economic factors, health care team and system-related factors, condition-related factors, therapy-related and patient related factors (Ayisi et al 2011, Mauch et al 2011, WHO 2003). As poor adherence to treatment leads to the emergence of multi-drug-resistant bacilli, ensuring adherence is of utmost importance to control TB and halt the MDR TB epidemic at its beginning (Mature et al 2011, Pablos-Mendez et al 1997, Hong Kong Chest services 1991). DLTLD 2010 TB guidelines provide standards to effectively deal with TB in Kenya (DLTLD 2010). A study by Kwamanga et al. 2010 indicated that while the current TB activities being implemented in Kenya have resulted in stable TB transmission, the activities are insufficient to reduce TB disease. As such more needs to be done to address TB in Kenya.

Over the years, a large number of TB evidence-based standards have been established at national and service delivery levels. Many of these standards are not being fully complied with by either the providers or patients as noted in the Kenya 2009 TB treatment guidelines. The extent to which there is non-adherence with guidelines is not known.

The health system in Kenya is currently organized into 6 levels: the highest being a tertiary University teaching hospital, level 5 the regional referral hospital, level 4 District hospitals, level 3 health centres, level 2 dispensaries and level 1, community level. These levels reflect the kind of services provided. For example, while level 1 is mainly focused on promotive and preventive services, the tertiary level provides the most comprehensive state of the art services.

As part of activities to improve TB care and management, TB CARE II supported the implementation of comprehensive multi-country studies in select high burden TB countries (Kenya, Zambia and Bangladesh) to assess provider and patient adherence to established evidence-based standards and guidelines. This report provides a summary of the study carried out in Kenya from March to July 2012. Study results from Kenya will provide specific information that will then be used by TB CARE II and DLTLD to better target interventions to improve provider and patient adherence to TB standards.

The key findings are expected to provide information regarding factors influencing provider adherence to guidelines, such as providers' TB-related knowledge and attitudes, environmental factors and resources necessary to adhere to TB diagnosis and treatment standards (such as sufficient human and infrastructural resources and commodities), as well as the effective coordination with other facilities in order to provide the patient an effective and comprehensive continuum of care.

## Objectives

This study was undertaken from March to July 2012 as part of the multi-country study to determine providers' and patients' adherence to national TB treatment guidelines. Specifically, the objectives of this study were to:

- Generate information on the level of knowledge and skills of providers in order to provide “standard” TB services;
- Measure the extent to which providers follow national and service-delivery standards;
- Generate information on the efficiency of existing systems for maintaining TB service delivery capacity; and
- Generate information on patients' understanding of TB treatment guidelines and perceptions of quality of care at provider and facility levels.



# Methods

This was part of a multi-country study on adherence to evidence based standards and guidelines. The following section describes the study design; study populations; sampling; and the data management.

## Study Design

The study utilized a cross-sectional design.

## Study Area

The study was undertaken in one of the 12 TB control regions with some of the highest TB case loads in Kenya, namely the South-Eastern region. In the DLTLTD 2010 Annual Report, this region in Kenya was responsible for the third highest amount of TB cases notified, contributing 12,081 (11.3%) TB clients (DLTLTD 2010 Annual Report) out of a total 106,083 cases reported, Jhpiego supported the logistics for this study through the APHIAplus Kamili Project in the region where Jhpiego is the prime partner.

## Study Populations

Six sub-populations were targeted for this study (see Table 1). The groups interviewed were: DLTLTD senior managers, District TB focal persons, Health facility TB focal persons, TB health care providers, TB patients/suspects and community health workers (CHWs). Data collection instruments consisted of questionnaires/ tools administered to the different target groups.

## Sampling Method

The sampling frame, which included all facilities in the selected region offering TB services available at DLTLTD, was used. Random sampling was done to identify 23 health facilities that had an estimated 20 TB patients at the time of the study. All levels of healthcare facilities were targeted up to level 5, including a similar number of level 4, 3 & 2 facilities. At the district, TB focal persons were interviewed. For TB health care providers, simple random sampling was used to identify at least 2 interviewees dedicated to providing TB care services in a facility. For exit interviews and provider clinical session observations, up to 20 clients who had received TB services at the facility on the day of data collection were included in the study. For the chart audits (patient medical records), systematic sampling was done to identify 10 TB patients' records per facility. All available TB register and notification documents were reviewed with focus on records for the current TB patients at each facility. CHW were selected randomly (up to 3 CHWs per facility) from the list of CHWs registered with each facility assessed.

## Data Collection

Data were collected from NTP managers, public and private health care providers who were actively screening and treating TB patients/suspects; and TB patients/suspects. Observation of treatment sessions was also done. Data were collected from the various groups of respondents using self-administered questionnaires and

Table 1. Inclusion/Exclusion Criteria

Study Population	Inclusion Criteria	Exclusion Criteria
DLTLTD manager	A DTLC in the study districts either current or acting	Not a DLTLTD in any of the study districts
Facility manager	Current or acting facility manager	Not a current or acting facility manager
TB healthcare providers	Current or acting health care providers designated to the TB clinic	Not a current or acting HC designated to the TB clinic
Patient	Any current TB patient registered at the facility and visiting at that particular day Children and persons under the age of 18 with guardian present	Not a current TB patient
Chart audits	Charts belonging to any current TB patient registered at the facility	Charts belonging to past TB patients
CHWs	Any current and active CHW aligned to the facility	CHWs not active and currently aligned with the facility

through patient medical chart reviews as listed in Table 1. All interview responses were anonymous as no personal identifying information of the respondents was recorded. In addition, patient care chart audits were conducted to determine how well patient data is being recorded for managing TB patients. Survey tools were based on internationally accepted standards for TB health services which have been adapted for Kenya.

## Study Tools and Variables

The purpose of each specific tool and the main variables of interest assessed is provided in this section.

- a. **DLTLD manager's questionnaire** – Assessment of potential barriers to provider adherence; including available and updated guidelines; mechanisms of forecasting, procurement, and distribution of drugs; staff training; supervision and monitoring; and capability of laboratories to perform TB tests.
- b. **Questionnaires for the TB health care providers** – Assessment of providers' knowledge about key TB guidelines, norms and protocols, and assessment of potential barriers to provider adherence.
- c. **Patient exit interviews** – Determination of patient satisfaction with the quality of care provided and adherence to treatment guidelines/standards.
- d. **Facility assessment tool** – Assessment of the availability of basic inputs for the provision of quality services, including TB services (whether integrated or stand-alone); equipment; staff; and basic consumables (drugs, syringes, etc.); issues surrounding commodity logistics; and current referral processes at facilities that do not provide TB and/or related services (diagnostics, treatment and/or follow-up).
- e. **Chart audits form** – Used to abstract information to determine how well patient data is being recorded for managing TB patients and clinician adherence to guidelines (e.g., correct dosaging with changes in weight, investigations, etc.). TB registers/TB notification sheets will also be reviewed to establish completeness of documentation.
- f. **A structured check list** – Used to collect information during observation of clinical sessions to further enhance the measurement of provider adherence to TB standards and the general standards of interpersonal communication and counseling.
- g. **CHW tool** – Assessment of CHW knowledge, attitudes, and practices (KAP) regarding TB.

## Quality Assurance

All the tools developed by the TB Care II team were reviewed and adapted to the Kenya situation. The tools were pretested prior to data collection. The pre-test was used to: improve the quality of the data collection tools; check for correct translation; guide the investigators on the average time required to complete each questionnaire and for field data collection; test the whole system of communication and supervision; assess the suitability of the study tools (interviews and questionnaire); and assess the performance of the data collectors and quality of the training. The tools also tested for content validity to determine if it actually measured what it was intended to measure.

## Training of data collectors and field supervisors

Data collectors were newly graduated doctors. The supervisor was a TB expert from DLTLD. A three-day training of the data collectors and field supervisor was conducted in March 2012. This covered: General knowledge on TB disease and treatment as per the National guidelines; TB program, objectives and importance of the study and orientation about the questionnaires. A field visit was done as part of the training and the team pre-tested the questionnaires to facility managers and patients exiting the facility chosen for training. Human subjects' protection training was also included and all data collectors completed the online Biomedical Research Investigators ethics training and certification prior to embarking on data collection.

## Ethical Considerations

Ethical approval of the study was obtained from Kenyatta National Hospital/University of Nairobi Ethics and Research Board (KNH/UON-ERB). In addition, the study protocol and instruments were approved by the University Research Company's (URC) internal review board (IRB). Informed consent (written) was obtained from all study participants and the participants.

## Data Management

The field supervisors reviewed the data collection tools from the enumerators for completeness, consistency and accuracy before sending them to the Jhpiego Nairobi office. Data entry and analysis was done using SPSS version 19. Cross checking of data was done to ensure that the questionnaires were completed properly. To ensure accuracy in data entry, 10% of the sample were entered twice by two separate data entry clerks. Descriptive statistical analysis was performed by the Kenya field team.

# Results

## General Overview

Structured interviews were held with 9 regional TB managers and 23 TB facility managers from two dispensaries, 9 health centres and 12 hospitals to assess potential barriers to provider TB-related adherence including available and updated guidelines, TB registers, and TB/MDR TB notification systems; mechanisms for forecasting, procurement, and distribution of drugs; capability of laboratories to perform TB tests; staff training; supervision and monitoring; and mechanisms of obtaining patient feedback. At the facility level, interviews were held with 39 TB health care providers and 73 community health workers from the district to community levels to assess availability of basic inputs to provide quality services, including TB services; TB/MDR TB drugs; TB focal persons; availability of policies/guidelines; turn-around times for lab results; TB registers; TB/MDR TB notification systems; infection control policies; supervision and monitoring systems. Two hundred and twenty one (221) chart audits were conducted at public and private sector facilities from the regional level to determine the quality of patient records as well as exit interviews with 404 clients who had received TB services. Table 2 provides the summary of the data collected. The main findings of these assessments are presented in this section.

Table 2. Summary of the Data Collected

Study Population	Numbers included from sample size calculation
DLTLD Managers (Level 4-2)	9
Facility Manager (Level 4-2)	23
TB healthcare providers (Level 4-2)	39
Provider observation (Level 4-2)	39
Patient (Level 4-2)	404
Chart audits (Level 4-2)	221
CHWs (Level 1)	73

## Annual Performance Targets

All regional TB managers both from public and private facilities responded that the DLTLD establishes annual performance targets. About 67% (6/9) of these managers said the program had reached its targets while two said no and one said they did not know.

## Guidelines

**Adult TB:** Almost all, 96% (22 of 23), facility TB managers in the facilities visited said that their offices have access to national TB guidelines. These guidelines were last updated in 2009, and hope to be revised in the next year.

**Pediatric TB:** In Kenya, old TB guidelines covered both adult and pediatric TB. Therefore, access to pediatric TB guidelines is similar to that of adult TB guidelines. It should be noted however, that in 2012, national pediatric TB care guidelines were formulated and are awaiting dissemination. In this report, National TB guidelines were assessed covering both pediatric and adult guidelines.

**MDR/XDR TB:** Only 57% (13/23) of the facilities had MDR TB guidelines (2010) with one hospital not having the guideline and 39% (9/23) not responding. Currently there are no separate XDR TB guidelines in the country.

**TB/HIV:** About 83% (19/23) of facility TB managers reported they had TB-HIV guidelines.

**Mobile/vulnerable groups:** This was not assessed though the national DLTLD is in the process of developing guidelines to address TB in special circumstances such as prisons, refugee camps etc.

**Infection prevention:** About 87% of the facilities reported having an infection prevention control strategy in place. About 75% of facility managers from the 20 facilities responded to the question on how successful the IPC strategy is of whom 55% considered the strategy very successful, 15% somewhat successful and 5% not successful.

## TB Registers/TB MDR Notification System

All the TB regional managers reported that they have defaulter tracing mechanisms which include generating a defaulter list. Facilities have staff members employed to trace defaults. Using the list generated by TB managers. All the regional managers have a TB district register system as well as TB notification in place and in use. About 89% (8/9) have a drug resistance TB notification. Twenty one of the 23 facility TB managers (91%) reported that their facilities have a functioning TB register with 83% having a functional TB notification system. Only two facilities reported they do not have a functioning TB notification system.

## Laboratory Services

According to 44% (4/9) of regional TB managers, drug resistant TB specimens are transported mainly using a courier system. Three (33%) (3/9) of the Regional managers noted the specimens are sent daily to diagnostic facilities with another two (22%) noting that it is done every 2-3 days. Three (33%) others did not know the frequency, and one did not respond. For sputum microscopy, two of 9 regional managers noted that the results are obtained same day while the majority, 67% (6/9), noted the results are obtained in 1-3 days. Only one noted the results are obtained in more than two weeks. On average, 57% (13/23) of the facility TB managers noted that the turn-around time for sputum microscopy results was 1-3 days; 35% (8/23) one week; while 11% (1/9) noted it takes 2 weeks and one did not respond.

For MDR specimens, the majority, 67% (6/9), noted results are obtained after more than five weeks.

## Drug Procurement/TB Drugs

In Kenya, the central level of the DLTLD is responsible for the planning, procurement, and supply of anti-TB drugs, laboratory consumables and providing documentation materials to its implementing partners. Quantification of the requirement of anti-TB drugs is done at the central DLTLD level, which includes information about drug consumption and stock at facility levels, together with case finding and treatment result reports.

While only the regional managers were asked the question on procurement of TB drugs, all levels of health facilities are able to request for TB drugs. There is no standardized protocol for forecasting TB drugs according to responses given by regional managers. Various reports stated that procurement is based on consumption, request from facilities, pull system, consumption multiplied by six months or using consumption drugs reports (CDR). TB drugs are ordered from a national supplier such as the Kenya Medical Supply agency (KEMSA) or the Medical and Equipment and Medicines Supply (MEDS).

In the assessment, most regional level TB managers (8 of 9) reported that they have a supervisory mechanism in place to ensure appropriate drug forecasting and procurement with 8/9 of them conducting monthly supervision and 8/9 providing feedback to the facility staff. Feedback is provided in a report form which offices keep on file. However, adequate follow-up is not being conducted.

Despite having a fairly strong supervisory system for drug procurement in place, 8 of the 9 regional managers reported stock-outs of more than 3 weeks with one reporting 52 weeks. Only one of the 9 managers reported that the stock-out resulted in patients' treatment interruptions. Three of the 9 noted the stock-out was due to delays in procurement and 4 noted it was due to late delivery. One did not know the reason while another did not respond to the question.

## Provision of TB Services

TB services in Kenya are integrated in the primary health care system at the service delivery level. The DLTLD implements TB control in partnership with faith-based facilities (FBF) and private sector through public private mix (PPM), Table 3. Community based DOTS is mainly implemented through community health workers and community health volunteers as well as using the buddy system or treatment supporter.

At the time of data collection, none of the health facilities selected for this study was offering TB culture and GeneXpert services. However, DLTLD has installed several GeneXpert machines around the country. About 61% (14/23) of the facilities provide free TB diagnostic services with about 87% (20/23) providing free TB drugs. Of the 23 facilities, 74% (17/23) also provide HIV medicines. Fifty-two percent (12/23) of facility managers reported experiencing shortage of TB medications in the last 3 months preceding the assessment. In addition, 91% (21/23) of the facilities use the national TB screening tool to identify TB suspects and 96% (22/23) are offering routine HIV testing of TB patients.

## TB Focal Person

Of the 23 facilities, 83% had a TB focal person. About 65% of the TB focal persons also had other responsibilities in the facilities. One dispensary and two health centres did not have TB focal person. The TB focal person from one health centre and four hospitals also had other responsibilities.

**Table 3.** Areas of Government-FBF-Private Collaboration in TB DOTS in Kenya

Area of collaboration	Government	FBF/Private
Implementation	National guidelines	Specific areas
	Overall coordination	
Case finding and Case holding	Equipment/supplies Referral centres	Diagnosis, Treatment and Follow-up
Training	Training materials	Local training
	Training of Trainers (TOT)	
Drug supply	Central procurement	Local storage
	Distribution	Supply indent
Monitoring and Supervision	Registers/forms	Registration/reporting
	Overall monitoring and supervision	Local monitoring and supervision
Advocacy, Communication and Social Mobilization (ACSM)	National campaigns	Local campaigns

## Supervision

About 89% (8/9) of the regional managers have a TB supervisory mechanism with 88% of them conducting monthly supervision and 88% providing feedback to the facility staff. Eight out of 9 regional managers reported having active laboratory supervision of whom 4 reported this is done monthly, 3 reported it is done quarterly and one did not know how often it is done. Eight of the 9 regional managers reported laboratory supervision feedback is given of whom, 75% reported there is written report.

Of the facilities visited, 91% (21/23) of TB managers reported there was TB supervision of whom 61% (14/23) noted it occurred monthly, 3 facilities had it quarterly and one had annual TB supervision. TB supervisors are engaged in the following activities during supervision: laboratory supervision 83% (19/23), drug procurement supervision 91% (21/23), reporting and notification 83% (19/23), treatment compliance 91% (21/23), MDR management 26% (6/23), referrals 65% (15/23) and clinical care quality assurance 74% (17/23). These were based on multiple responses.

The provider self-assessment showed that while the majority of TB providers (82%) received supervision and mentoring on TB, those who received supervision/mentoring on a monthly basis accounted for only 64%. Seven out of 39 said they received supervision on a quarterly basis, two, said once a year and two reported it occurs every two weeks.

About 81% (58/72) of the CHWs reported they receive supervision support on TB activities of whom 70% had received about 12 supervision visits within the last year.

## Training

Only two regional managers had staff trained in pediatric TB treatment with 10 out of 23 (43%) having staff trained on MDR TB management. None of the managers had staff trained in a TB managers course, and only 2-3 had staff trained in laboratory, infection prevention and control and community activities. Four of the regional managers noted refresher courses are done quarterly while two did not know the frequency and two did not respond.

Fourteen out of 23 (61%) health facility managers responded to the question regarding the number of

staff in their facilities trained on TB. Three facilities had no staff trained on TB, 30% (7/23) had staff trained pediatric TB and 44% (10/23) on MDR TB. The common TB training staff had received was TB-HIV (12/23) followed by TB diagnosis (11/23). About 35% (8/23) of the staff received training at the sites where they provide services (on the job training). Of the 65% (15/23) of facility managers who responded, over 26% (4/15) did not know how often refresher training is done with 13% (2/15) reporting it occurred monthly and another 13% (2/15) that it occurred quarterly.

From the provider's self-assessment, only about half of the providers had undergone the 5-day TB training while 5% (2/39) reported that they had not received any TB training post-graduation. TB-related training was offered during annual and quarterly trainings; and to some extent through continuous medical education (CME) sessions in health facilities. The majority of the providers 64% (25/39) reported that the most recent training had been offered sometime during the 12 months preceding the survey.

Among the 73 CHWs interviewed, of the 69 who responded to the question on training, about 73% reported they had received training on TB. The CHWs training package which is delivered in 10 days covers broad topics including elements of TB diagnosis, treatment, care and support.

## Patient Feedback

Of the 9 regional TB managers, 7 reported they have a mechanism to solicit patient feedback, one of whom had a patient complaint box, 4 reported they conducted patient exit interviews and 2 reported they had received short messaging services (SMS).

Of the 23 facility TB managers, 83% reported their facilities have a mechanism for soliciting patient feedback, 44% had a complaint box, 48% had patient exit interviews, 9% used SMS and one facility used community forums. Additionally, one facility had a patient service office and none used emails or social media.

## Causes of Non-adherence

### Health Care Providers

The top five causes of provider non-adherence to TB guidelines according to regional managers include: lack of provider skills/knowledge, issues of switching

from old to new guidelines, overburdened providers, as well as providers attitude and behavior. Among the 23 facility managers, the following were listed as the causes of providers non-adherence to TB guidelines: 10/23 (43%) lack of provider skills/knowledge; (10/22) 45% lack of materials and supplies; 1/23(4%) lack of drugs; 4/23(17%) provider attitude and behavior; 2/23(9%) lack of providers; 5/23(22%) issues surrounding switch from old to new guidelines with 1/23(4%) attributing this to forgetting or being ignorant.

Self-reports by TB health providers show that the four main causes of provider non-adherence to the guidelines were: overburdened providers; limited provider skills on TB; and provider attitudes/behaviors (see Table 4).

### TB Patients' Adherence

According to the regional managers, lack of transport and lack of information are the two main reasons why patients may not adhering to the with TB treatment guidelines. Others include ignorance or patients feeling well and stopping the medications.

According to the 23 facility managers, the first five causes of patients non-adherence to TB treatment include: lack of transport 8(35%), lack of food 5(22%), too many medicines 4(17%) and lack of information given 4(17%). Others include providers attitude 1(4%), staff shortage 1(4%) and inconsistent services where there are days clinics are not providing services. Other factors mentioned include use of alcohol, poverty and stigma.

From the providers' self-assessment, patient factors most likely to cause non-adherence are lack of transport, food, adequate information on TB, and too many medicines (see Table 5).

### Quality of Care

According to the TB regional managers, the top five skills TB providers need to improve on include: appropriate follow up, MDR-TB management, adherence counseling, side effects management and appropriate drug regimens. Providers skills can be improved using approaches such as guidelines dissemination, providing specific training programs as well motivating the available staffs. Frequent supervision was also mentioned.

**Table 4.** Frequency of Potential Causes to Provider Non-adherence to Standards, TB Guidelines, and Providers' Self-assessment

Potential barriers to adherence (N=23)	Percent*
Lack of providers (overburdened)	71%
Lack of provider skills/knowledge	53%
Provider attitude or behavior	47%
Issues surrounding switch from old to new guidelines	36%
Lack of guidelines and standards	31%
Lack of materials/supplies	29%
Lack of drugs	18%

**Table 5.** Frequency of Potential Causes to Patients' Non-adherence to TB Guidelines, and Providers' Self-assessment

Potential barriers to adherence (N=23)	Percent*
Lack of transport	74%
Too many medicines	68%
Lack of food	64%
Lack of information	63%
Provider attitude or behavior	39%
Side effects	33%
Inconsistent services (where there are days no service is provided)	28%
Staff shortage	18%
Lack of drugs	9%
Others	12%

\* Multiple responses

According to the 23 facility managers, the five skills TB providers need to improve most include: appropriate follow up of patients 9(39%); management of side effects 7(30%), MDR-TB management 4(17%) appropriate drug dosaging 3 (13%) and appropriate request for lab tests 3(13%). Others mentioned include commitment to TB work as well as learning more about TB 2(9%). The providers suggested that the areas they felt they should improve on were: patient follow-up, MDR-TB management and treatment of side effects (see Table 6).

**Table 6.** Skills That TB Providers Should Improve in Most Providers' Self-assessment

Potential barriers to adherence (N=23)	Percent
Appropriate follow-up	79%
MDR-TB management	64%
Side-effect treatment	59%
Appropriate drug dosing	42%
Appropriate drug regimens	39%
Request for appropriate lab test	30%
Others	7%

## Provider Interaction

A total of 39 provider observations were made (Table 7). The patients treated were at different phases with the majority in the continuation phase (41%) while 31% and 28% of them were in intensive and initiation phases respectively. Overall, the providers were observed to strike a good rapport with the patients maintaining eye contact during consultation, treating patients with respect and encouraging them to ask questions while at the same time reinforcing the importance of TB treatment.

In addition, the providers asked the patients their HIV status. However, in 31% of the observations, patients with

**Table 7.** Provider Observation Assessment Summary

Provider Assessment Area	TB Treatment Phase			Total (N=39)	Percent Observed
	Initiation (n=11)	Intensive (n=12)	Continuation (n=16)		
Greeted patient and introduced himself/herself	11	12	16	39	100%
Looked at patient directly from time to time	11	12	16	39	100%
Encouraged the client to ask questions	9	10	13	32	82%
Used words that are easy to understand	11	12	16	39	100%
Treated patient with respect	11	12	16	39	100%
Checked whether patient is under treatment for TB and taking it regularly	6	12	15	33	85%
Asked patient about previous treatments for their current symptoms	10	4	6	20	51%
Explained the treatment regimen	10	10	14	34	87%
Reinforced the importance of treatment	10	12	15	37	95%
Explained about possible treatment side effects	2	10	2	14	36%
Suggested to the patient that immediate contacts of TB patient (children) be screened for TB	8	6	7	21	54%
Prescribed HRZE regimen	7	11	9	27	69%
Prescribed SHRZE regimen	3	2	6	11	28%
Other meds prescribed - Supplement/vitamins	1	3	5	9	23%
Other meds prescribed - Other (Isonid, CTX, piriton)	3	1	0	4	10%
Asked about HIV status	11	11	16	38	97%
Offered HTC if HIV status unknown	11	6	10	27	69%
Referred HIV-positive patient for ARV treatment	8	8	8	24	62%
Checked patient treatment card provided by TB supporter	3	Not observed	3	6	21%
Patient support offered - Transportation vouchers	0	0	2	2	5%
Patient support offered - Food support	0	0	1	1	3%
Reviewed with patient Infection Prevention (IP) measures	8	9	13	30	77%
Reviewed with patient IP measures - Wash hands	7	6	12	18	46%
Reviewed with patient IP measures - Wear PPE	3	3	6	9	23%
Reviewed with patient IP measures - Ventilation	9	11	16	27	69%



unknown HIV status were not offered HIV Counseling and Testing (HTC), and in 38% of the observations, HIV positive patients were not referred for ART.

During the initiation phase, providers were observed to prescribe TB treatment following the DOTS protocol. However, in about a third of the observations, the provider did not offer the patient the option of DOTS at the community level. Only about half of the providers asked patients to get another sputum smear after two months of intensive TB treatment. Conversely, during the continuation phase, the providers in about 80% of the observations asked patients to get another sputum smear after two months of intensive TB treatment.

In general, the observations revealed that about half of the time, providers did not ask patients about previous treatment for their current presenting symptoms.

Other issues that the providers often did not address routinely included: asking the patients about other medications they were taking, explaining the side effects of the TB medications, advising newly diagnosed patients to take their children for TB screening, and offering TB patients food, transportation, referral to group therapy, and work support. In addition, in 23% of the observations, the providers did not review the infection prevention measures with the patients especially the importance of hand washing and use of personal protective equipment (PPE).

## Information Provision

TB patients in Kenya should be receiving basic information about TB from health facility providers, media, and community members. Based on data from the 404 client exit interviews, 85% of patients had ever received information or education about TB. For 46% of the patients, information on TB was provided by the public health nurse while 20% obtained information from the media and a further 20% from family and friends. The majority (80%) of the patients had received information on TB signs and symptoms and were also educated on how TB is spread (88%). However, there were gaps in providers' communication regarding TB treatment, screening of close contacts, and counseling patients on HIV.

## Communication Regarding TB Treatment

Provider observations showed that providers were asking about ongoing TB treatment 85% (33/39) of the

time, additionally previous treatments were discussed in 51% (20/39) of cases. Providers observed explained the treatment regimen in 87% (34/39) of the cases, reinforced the importance of treatment adherence 95% (37/39) of the time, but only 36% (14/39) explained/ followed-up on possible treatment side effects.

In exit interviews conducted with TB patients and suspects almost all patients, 96% (387/402), said they received information on the importance of treatment completion. However, there was a gap in providing information about treatment side effects and their management, with 37% of patients responding that they did not receive any information on that topic.

Ninety six per cent of the 73 community health workers interviewed reported that they provide information about TB to their clients, 71% provided information about treatment adherence, 67% on TB treatment, 87% on TB prevention, and only 2 out of 73 (3% provided information on treatment side effects.

## Screening of TB Contacts

In exit interviews the majority, 84%(338/404) of TB patients/suspects, were given information about the need to have family members and close contacts screened for TB while only 54% (21/39) of observed providers suggested to the TB patient that their immediate contacts be screened for TB.

## Communication Regarding HIV

The 39 provider observations also showed that communication about HIV with TB patients/suspects and identification of TB/HIV co-infected patients was found to be a common practice at the facility level with 97% asking about HIV status, 69% offering HIV testing and counseling for those with unknown status and 62% referring HIV positive clients to HIV treatment clinics. The foregoing shows deficiencies in provider initiated HIV testing where 31% of the clients would have missed this service as well as missed opportunities for TB patients to be linked to ART programs.

However, exit interviews showed that 95% (383/404) of those interviewed were advised to have an HIV test. Ninety three per cent reported they had been tested for HIV at some point in their lives. These high levels of HIV counseling and testing could be due to the rolled out guidelines on TB-HIV collaborative activities which emphasize HIV testing for TB patients and testing for TB among HIV infected patients.

## TB Diagnostic & Treatment Standards

The majority of the 38 out of the 39 service providers who responded about TB diagnostic and treatment standards had a good understanding (>75% score) of TB transmission, first line TB regimens for adults and children and the definition of MDR-TB. Only 13% correctly identified the differential diagnosis of TB-IRIS (Table 8). About 55% were not sure of confirmatory diagnosis for pulmonary TB with another 50% not knowing how to treat TB in pregnancy.

## TB Case Detection

Of the 23 TB facility managers, 20 (87%) reported their facilities use a TB client intake form, 100% use smear microscopy and 12 (52%) use radiological investigation for screening and diagnosis of TB. One of the facilities

provided TB culture and GeneXpert services for TB diagnosis. About 61% of the TB facility managers reported their facilities provide free TB diagnostic services with about 87% providing free TB drugs. Of the 23 facilities, 74% also provide HIV medicines.

Ninety-eight percent of the 39 service providers reported that TB diagnostic and treatment standards were available in the health facilities; algorithms and guidelines being the most commonly mentioned. Sputum smear was the method most commonly used to diagnose TB patients (82%), followed by X-ray (60%), and symptomatic algorithm used alone (56%). The TB skin test was the least commonly used method (7%). Eighty-seven percent of the providers did not order a TB skin test for any TB patient, and 95% reported following WHO protocols to treat TB patients. Ninety-two percent of the providers always tested HIV patients for TB while the other 8% test them sometimes.

Table 8. Provider TB Knowledge Scores

Area of Assessment	Percent who answered correctly* (N=38)
Population groups at high risk of TB infection	84%
Modes of TB transmission	87%
Spread of TB infection	87%
Conditions that increase risk of TB infection	61%
Symptoms of pulmonary TB	71%
Pulmonary TB confirmatory tests	45%
First line anti-TB drugs	82%
Treatment of TB in pregnancy	50%
Treatment of TB in children	82%
TB diagnosis through smears	68%
Confirmation of TB infection	32%
Meaning of MDR-TB	79%
TB diagnosis – sputum culture & drug sensitivity tests	45%
Differential diagnosis for TB-IRIS	13%
HIV testing in TB patients	63%
Screening for TB active infections	66%
TB testing in immune compromised HIV-positive patients	29%

\* Multiple responses

Of the 73 community health workers interviewed, 74% reported that TB is a serious disease in their region, 23% said it is somewhat serious and only 3% said it is not serious. Community health workers do provide important TB services in the communities. Only, 8/73 (11%) said that they diagnose TB patients. Of those who diagnose patients, the most frequent mode of TB diagnosis used is to check for TB signs and symptoms (88%) or conduct or send patients for sputum smears (50%). Most of the community health workers (78%) said that they are not paid for their services though in Kenya there is a community health workers' strategy which will allow these CHW who are essentially volunteers to be paid a token equivalent to about \$25 per month.

## Correct Treatment/Adherence

### TB treatment

Provider observations showed that 69% of providers prescribed the HRZE regimen with 28% prescribing SHRZE.

While most (80%) CHWs said they did not treat patients for TB, 20% said that they did. Only 22% (16/73) of the CHWs did see TB patients on a monthly basis with 88% (14/16) of those seeing over 5 patients per month. When those CHWs who do not treat TB patients were asked what they do when they suspect

that a patient may have TB, only 24% responded. Of this group, 94% of them agreed that their response to a TB suspect would be to refer the patient to a health centre. Only one CHW mentioned that he/she refers patients to DOTS provider.

## DOTS/TB Patient Support

Nearly two-thirds (63%) of the 39 service providers reported they provided TB DOTS support supervision, with the majority of them doing so weekly or more frequently.

Of the 395 TB patients/suspects who responded to the question on linkage with DOTS support, 71% reported they were linked to a DOTS supporter of whom 99% reported they were happy with support of their DOTS supporter.

## Infection Prevention

About 87% of TB the 9 facility managers reported their facilities have an infection prevention control strategy in place. Seventy five percent of facility managers from the 23 facilities responded to the question on how successful the IPC strategy is of whom 55% consider the strategy very successful, 15% somewhat successful and 5% not successful. Of the 23 TB facility managers, 16 (70%) responded to the question on the number of TB infections among providers have been reported in the last year of whom 63% had no cases, 19% reported one case and 19% reported two cases. Thirty percent (30%) of facility managers did not respond to this question. Four hospitals reported 1-2 cases while two health centres reported one case each.

## Knowledge and Awareness of TB

Seventy three percent (73%) of the CHWs respondents had received some TB related training. The majority (99%) of CHWs correctly identified that TB transmission occurs through the air when someone with TB coughs or sneezes. Several also identified common misperceptions such as believing that TB transmission occurs by sharing of dishes and eating from the same plate, 36% and 25% respectively. The majority of the respondents (95%) correctly identified that covering of the mouth and nose when coughing and sneezing as a preventive method from acquiring TB. A further 30% responded that avoiding sharing

dishes is also preventive. Only 78% and 32% correctly responded that opening windows at home and good nutrition are good preventative measures, respectively. Ninety nine percent (99%) correctly identified persistent cough as a symptom of TB infection, however fewer CHWs were able to correctly identify fever, weight loss, fatigue and tiredness as symptoms too, at 49%, 74% and 41% respectively (Table 9). Only 15% of the CHW respondents felt they were very informed on TB with the majority (76%) rating themselves only somewhat informed.

## Attitudes About TB

From the 39 providers' self-assessment, about two-thirds of the providers had fears of contracting TB from patients; 30% very worried, and 38% somewhat worried. Environmental measures (89%) were the most common way used by the providers to reduce their risk of TB infection, followed by administrative measures (34%), and PPE (22%). Twenty-one percent (21%) of the providers reported that the risk of infection affected the way they treat TB patients.

All CHW respondents agreed that TB can be cured with 88% of them agreeing that the cure is through taking specific TB drugs. Only 7.8% of the CHWs were not afraid of contracting TB with the rest ranging from 25% for only a little afraid and 22% very afraid.

**Table 9.** General Knowledge About TB among CHWs (N=73)

Variable	Responses*	
	n	Percent
<b>How one can get TB?</b>		
Through handshakes	3	4%
Through the air when a person with TB coughs or sneezes	72	99%
Through sharing dishes	26	36%
Through eating from the same plate	18	25%
Through touching items in public places	3	4%
<b>How can one prevent getting TB?</b>		
Avoid shaking hands	2	3%
Covering mouth and nose when coughing and sneezing	69	95%
Avoid sharing dishes	22	30%
Washing hands after touching items in public places	4	5%
Open windows at home	57	78%
Through good nutrition	23	32%
<b>What are the signs and symptoms of TB?</b>		
Close contact with active TB patient	16	22%
Cough that lasts longer than 3 weeks	72	99%
Fever	36	49%
Weight loss	54	74%
Fatigue/tiredness	30	41%

\* Multiple responses

# Discussion

This assessment describes the many possible reasons as to why providers may not fully adhere to evidence-based TB guidelines. In addition, the patient and health systems factors that may influence patient adherence to TB treatment are described. Evidence-based guidelines are key to improve the effectiveness and efficiency of the care that medical systems deliver. However, the providers seem to have knowledge and skills deficiencies in confirmation of TB through various tests and treatment of TB.

This assessment confirmed the availability of TB guidelines, yet there are many situations where optimal care was not being provided. Consistent was the finding that regional managers, TB facility managers as well as health care providers considered workload, limited provider skills and poor attitudes/ behaviors as the main causes of non-adherence for health care providers. These findings are consistent with other studies in Kenya and elsewhere (Ayisi et al 2011, Mauch et al 2011). On the other hand, the main causes of patient non-adherence were linked to the issue of inaccessibility to TB services (distance, lack of money), limited information on TB treatment, and provider behavior. These findings from both the providers and patients suggest that a holistic approach is required to address non-adherence to the recommended TB management.

The TB diagnostic capacity appears to be inefficient as patients have to wait in most cases for up to 3 days to receive their results. As noted, none of the 23 health facility that participated in this study had a GeneXpert machine which allows for a rapid and more reliable TB diagnosis. Although it may not be possible to make this revolutionary technology widely available, there is potential for improvement in providing timely TB diagnostics. For example, the TB patient defaulter tracing mechanisms reported to be functioning in many health facilities may help mitigate, to some extent, against the delays in diagnosing TB infection.

Of equal concern are the obvious knowledge gaps in TB diagnosis and treatment among health care providers as well as that many CHWs did not automatically know that all patients suspected of TB should be referred to DOTS providers. For the two cadres, regular training can mitigate this. For CHWs, emphasis should be on identifying suspicious patients and referring them to health facilities for diagnostic tests as well as supporting patients on treatment as treatment buddies or DOTs support. For the health care providers, though monthly supportive supervision with mentorship was reported, this did not seem to be effective in addressing the major gaps on knowledge found in this study. This study showed that providers have knowledge deficiency in confirmation of TB through various tests and treatment of TB during pregnancy and that only 63% of the providers correctly identified the various situations when TB patients should be counseled and tested for HIV infection with only 13% correctly identifying the differential diagnosis of TB-IRIS.

According to the health care providers, their attitude affects their management of TB patients. It is notable that about two thirds reported being fearful of contracting TB from their work. This needs to be addressed as part of the TB infection control within medical facilities which will be central in reducing the noted fear, thereby improving the overall quality of services.

This study has a number of limitations which need to be considered in interpreting the results. The facilities included and clients as well as health care providers are not representative of the Kenyan TB program. The numbers of health care providers, regional and facility TB managers included are small. Only one private facility was included in the study. It was the only facility in the study area. These results are therefore not generalizable to the Kenyan program and did not provide an opportunity to examine differences between public and private facilities in management of TB. Despite these limitations, several recommendations are provided based on the study findings in the next section.

# Recommendations

Based on the findings of this study, these are the recommendations for improving provider compliance to evidence based TB guidelines:

## *Technical competence*

### Health Providers

#### TB Diagnosis

- Public health facility service providers need to be well trained on TB diagnosis. Staffs who were previously trained should get periodic refresher trainings. A standard training plan can be developed and implemented to determine routine and refresher training needs and schedules.
- There is need to improve diagnostic capacity of regional hospitals with new technologies such as GenXpert in order to increase the detection of cases of MDR-TB in a timely manner.

#### TB Treatment

- While the majority of providers support TB DOTS, refresher training in this area would be useful. Improvement in providers' skills to share information with TB patients on the importance of completing treatment, explaining treatment regimens, explaining possible TB drug side effects and management of TB s needed in order to reduce defaulter cases.
- CHWs training as well as a clearer definition of what they are able to do coupled with supportive supervision will need to be improved to avoid situations where CHWs make diagnosis of TB with attendant temptation to want to initiate treatment.

#### Health Counseling

- Training of health workers and CHWs on effective communication with TB patients or suspects is needed. Focus areas should, especially, include: asking the patient about other medications he/she is taking; explaining treatment regimens; reinforcing importance of treatment adherence; possible treatment side effects; need to screen TB contacts; and communicating about TB/HIV.

- Considering the importance of CHWs as a source of TB information, it is recommended to involve the CHWs in engaging communities to mobilize them for TB activities.

#### TB Knowledge

- Investigate current content of TB training program for health professionals, including continuing medical education and in-service training.
- Train TB providers in basic TB knowledge, including risk groups for TB, transmission of TB, and standard TB drugs used in Kenya.
- Given the one stop approach where TB and HIV services are provided by the same clinician, it is important for the clinicians to know the complications associated with such treatment including IRIS, which if not managed well could result in mortality.
- Diagnostic algorithms also need to be addressed to ensure all clinicians are knowledgeable about confirmatory diagnostic tests.
- Training of CHW should also address the problem of misconceptions noted in this study.

#### TB attitudes

Health care providers' attitudes as well as CHW misconceptions about TB need to be addressed. This is probably best addressed during trainings and mentorship.

#### *Health Management*

- The issue of long turn-around time for sputum microscopy needs to be addressed at all steps of the sample transportation system.
- Transportation of TB specimens where specimen rather than patient referral is practiced need to be addressed to reduce the potential danger of contaminating environments during the courier process.

## Effectiveness

### Clinical Guidelines

- Pediatric TB and infection prevention guidelines at the time of writing this report have been developed but not yet disseminated.
- Create a system to ensure dissemination, availability, and awareness-raising of existing, and newly developed, TB guidelines to all NTP managers at national and district levels, and public and private health care facilities from national to community levels.
- Develop and disseminate TB guidelines for XDR, and mobile/vulnerable groups.

### Supervision and Mentoring

- Strengthen supportive supervision such that all providers including CHWs receive regular supervision and mentoring on TB.
- Provide for fulltime or part-time staff dedicated to TB supervision capacity at the district, facility and community levels.
- Develop an adequate feedback and follow-up system for supervision (both for supervision of providers as well as supervisory system for drug forecasting and procurement) that goes beyond a written report, and is provided after each supervisory visit.

### Training

While the assessment showed that many of the providers were trained in TB; almost one-fifth said they were not. A training gap seems to exist – due to a lack of a proper record keeping and training system for training; turnover of employees both from the public and private sector; as well as TB training resource constraints.

- DLTLD needs to develop a functional Training Management Information System (TMIS) to coordinate with the facility level TB managers on newly recruited staff and those who were trained previously. A well-coordinated and continuous TB training mechanism needs to be developed, and ideally centrally funded.

### *Continuity of services*

Continuity of services refers to the delivery of care by the same health care provider throughout the course of care (where appropriate) and appropriate and timely referral and communication between providers.

In Kenya, while HIV is integrated in TB program and TB in HIV programs, there are still gaps in HIV testing among TB patients as well as screening of TB among HIV infected patients. There is need to strengthen the TB/HIV integration and coordination (i.e. referrals, diagnosis of co-infected patients).

### TB Drugs

It is notable that despite having a strong supervisory system, almost all the regional managers reported stock-outs of more than three months. Though the respondents in this assessment reported TB drugs stock-out did not affect patient treatment, the growing number of MDR-TB cases continues to be a concern. It remains important to:

- Ensure uninterrupted and timely supply of anti-TB drugs at all health care facilities.
- Adequate follow-up on supervisory mechanisms to ensure timely drug forecasting and procurement is needed.
- Strengthen the pull system of ordering medicines from higher levels
- Strengthen capacity for distribution

### DOTS support

- Ensure that all providers link TB patients with community DOTS providers.
- Ensure that providers follow-up and ask TB supporters about patient compliance with treatment regimens or check the patient treatment card provided by the TB supporter

### Other support

- Ensure that there is a system in place to provide TB patients with other support needed, so that they do not default on treatment. For example, support with transportation vouchers, food support, linkages to group therapy, and/or work support.

## Safety

### Infection Control

- Ensure adequate work practices and administrative controls in health care facilities, including:
  - Having each facility have a written infection control plan
  - Administrative support for procedures in the plan, including quality assurance
  - Training of staff in use of standard precautions for TB
  - Surveillance
  - Monitoring and evaluation
  - Education of patients and increasing community awareness
  - Coordination and communication with public health authorities



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