Prescription and Dispensing of TB Medicines: A Survey of Practices in the Private Health Sector of Kenya, July 2007

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ABBREVIATIONS AND ACRONYMS

CDR	case detection rate
CHW	community health worker
DADR	Daily Activity Drug Register
DOTS	internationally recommended strategy for TB control
DTLC	District Tuberculosis and Leprosy Coordinator
E	ethambutol
ECSA	East, Central, and Southern Africa
FBO	faith-based organization
GDP	gross domestic product
GoK	Government of Kenya
H	isoniazid
KAPTLD	Kenya Association for the Prevention of Tuberculosis and Lung Diseases
KEMSA	Kenya Medical Supplies Agency
KES	Kenyan shilling
MDG	Millennium Development Goal
MDR-TB	multidrug-resistant tuberculosis
MoH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
NLTP	National Leprosy and Tuberculosis Program
OTC	over the counter
PTB	pulmonary TB
PTLC	Provincial Tuberculosis and Leprosy Coordinator
R	rifampicin
RPM	Rational Pharmaceutical Management
S	streptomycin
TB	tuberculosis
USD	U.S. dollar
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis
Z	pyrazinamide

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Since 2001 the Rational Pharmaceutical Management (RPM) Plus program has provided technical assistance to the tuberculosis (TB) program and Ministry of Health personnel of various countries within East, Central, and Southern Africa (ECSA) to improve pharmaceutical management for TB. Most of these activities have been coordinated through the Regional Economic Development Services Office and Regional Logistics Initiative and Africa Bureau portfolios of the U.S. Agency for International Development. In August 2005, the Ministers of Health from 46 Member States of the Africa region unanimously declared TB an emergency in the region (the Maputo Declaration). In the same spirit, Kenya declared TB an emergency in March 2007. Multidrug-resistant TB (MDR-TB) has remained within low rates in ECSA countries, so one of the priorities is to control its emergence in the early stages. The use of TB medicines not following national guidelines may be contributing to the increase in MDR-TB.

RPM Plus supported this assessment of the TB treatment practices in the private sector in Kenya. The results of the study will be disseminated to ECSA countries, the WHO/AFRO office and through regional and international TB meetings.

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EXECUTIVE SUMMARY

The private health sector in Kenya, especially the private health care facilities, contributes significantly in prescribing and dispensing anti-tuberculosis medicines. The trouble is that most of these transactions and prescriptions are incorrect mainly because of deficient knowledge on the part of clinician, medicine vendor, or pharmacist. More important, these institutions are profit driven and will sell inappropriate medicines or less medicine than required, depending on how much money the client has. The loose anti-tuberculosis medicines (rifampicin and streptomycin) most commonly available in the private retail medicine outlets are used to treat other conditions besides tuberculosis (TB).

Nevertheless, in the midst of this gloomy scenario, positive observations arose from this study. First, 11 percent of the private pharmacy operators were promoting the free TB care services offered in Ministry of Health (MoH) health care facilities by educating the patient on them and referring TB patients and suspects to seek this free service. Second, besides selling medicines to the patient, 99 percent of pharmacy operators referred TB patients or suspects to seek TB care in nearby MoH and MoH-allied private health care facilities. Third, 17.2 percent of the pharmacy operators offered their clients counseling on the importance of anti-TB medicine adherence. Finally, 20 percent of the pharmacies did not stock or prescribe anti-TB medicines, hence did not misuse this lifesaving commodity.

The National Leprosy and TB Program (NLTP), MoH, and partners offering free anti-TB medicines provided the lion's share of medicines consumed in private sector health care facilities. The private health care facilities allied to the MoH and its partners were manned by staff with better understanding of rational TB medicine use (DOTS) and the need to report TB patient treatment outcomes to the NLTP.

INTRODUCTION

Kenya is one of the three East African countries along with Uganda and Tanzania. With an annual per capita gross domestic product (GDP) in 2006 of 1,200 U.S. dollars (USD), 46 percent of Kenya's population lives below the poverty line (CBS 2005/06). The country's land mass has an area of 582,650 square kilometers, with an estimated population of 33 million in 2006 (CBS 1999). It borders the Indian Ocean and Somalia to the east, Ethiopia and Sudan to the north, Uganda to the west, and Tanzania to the south.

Life expectancy at birth is 47.99 years, having dropped from 65 years because of the effects of HIV/AIDS. Kenya is ranked 11th among the 22 countries with the highest TB burden in the world. The case detection rate (CDR) stood at more than 500 TB cases per 100,000 population in 2005 (WHO 2006a; WHO 2006b).

Tuberculosis Control Services in Kenya

The NLTP is the MoH agency responsible for the coordination of all activities in treatment, prevention, and control of TB and leprosy in Kenya. The program was launched in 1980, combining the then-existing TB control activities that had been in place since 1956 with several leprosy control projects in Western, Coast, and Eastern provinces into one program—the NLTP.

Currently in Kenya, 218 hospitals and 3,098 health centers and dispensaries serve 33 million people. The MoH is the major provider of health care services, accounting for 52 percent of all health care facilities, while the private sector, including faith-based organizations (FBOs), provides 48 percent. Table 1 shows the distribution of health care facilities in Kenya by type and provider.

By the end of 2005, 1,605 health care facilities managed by the MoH and other stakeholders that include nongovernmental organizations (NGOs), FBOs, and other private organizations were involved in providing TB diagnosis and treatment. The tuberculosis and leprosy services are integrated into the general health care services at all levels. A group of trained staff is designated to the NLTP; they are responsible for coordination, supervision, and technical services of TB and leprosy control at each health care level.

At the national level are the head of NLTP and several technical officers based at the central unit. At the provincial level, 11 Provincial Tuberculosis and Leprosy Coordinators (PTLCs), and at the district level, 110 District Tuberculosis and Leprosy Coordinators (DTLCs) are responsible for coordinating the delivery of TB and leprosy services at the provincial and district levels, respectively. The national guideline on TB control requires that all the health units providing TB services in the country send their reports on case finding and treatment outcomes to the NLTP quarterly.

According to the NLTP 2005 annual report, 108,401 cases of all forms of TB were recorded. This number was an increase of 2 percent over the cases of TB reported in 2004. Also, Nyanza province had the highest number of smear-positive pulmonary TB (PTB) cases, with a total of 8,047 cases, while North-Eastern had the lowest at 1,300. The country's CDR was 500 cases per 100,000 population (WHO 2006a).

A summary of the national TB report for 2005, showing details about program performance at the various levels categorized by districts, age group, and types of TB is contained in Appendix B, table 24.

Tuberculosis treatment results in Kenya have been impressive since the advent of DOTS, the internationally recommended strategy to control TB. For instance, in 2005 the treatment success rate was 82 percent for new smear-positive PTB cases (n = 36,855), 75 percent for smear-positive retreatment cases (n = 3,257), 77 percent for new smear-negative PTB cases (n = 35,432) and 76 percent for extra-pulmonary TB cases (n = 12,804) (NLTP Annual Report 2005).

Pharmaceutical Management of TB Medicines

The NLTP coordinates quantification and procurement of all TB commodities including TB medicines for the public sector. These commodities are then procured by the MoH through Kenya Medical Supplies Agency (KEMSA). Currently, three main sources of TB medicines are used in the public sector in Kenya: direct procurement by the government of Kenya (GoK), the Global TB Drug Facility, and the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria.

The procured medicines are stored at the KEMSA warehouse in Nairobi from where they are distributed to the health care facilities either directly or through KEMSA regional depots. At the KEMSA regional depots, the PTLC in that region is responsible for the medicines while the DTLC is responsible at the district drug stores. The medicines are sent out based on the distribution list provided by the pharmacist-in-charge at the NLTP. The distribution list is prepared based on the quarterly reports from the facilities indicating their demand and on available stocks.

Depending on the phase of treatment, TB patients collect their medicines from the health facility. According to the national TB guidelines, patients in the intensive phase should collect TB medicines weekly whereas those in the continuation phase should do so monthly. The patients on retreatment have to visit the health facility on a daily basis during the intensive phase to receive a streptomycin injection and to swallow the other anti-TB medicines (a fixed-dose combination of RHZE).[1]

Daily intake of anti-TB medicines is observed mainly by patients' relatives. However, in areas with community-based DOTS, the community health workers (CHWs), also called treatment supporters, help encourage the TB patients to take their medicines as required by direct observation and by educating the family members on the need to ensure patients swallow all their medicines as prescribed. In some instances, the CHWs may collect the medicines for the patient under their care, especially when the patients are too sick to get to the facility.

[1] Rifampicin (R), isoniazid (H), pyrazinamide (Z), ethambutol (E); regimen = 2 months RHZE and 6 months EH.

STUDY JUSTIFICATION

Besides HIV/AIDS, tuberculosis is the most important infection currently causing deaths among adults globally. According to the World Health Organization (WHO), 35 percent of the world's population is already infected with TB, and annually 9 million active TB cases occur, resulting in about 2 million deaths.

In Kenya, 116,000 cases of TB were recorded in 2006; 11 percent of these were retreatment cases that are suspected to be at least mono- if not multidrug-resistant TB (MDR-TB). An estimated 10 percent to 15 percent of all TB cases reported in Kenya die every year (NLTP 2005).

Although TB is a curable disease, the last two decades have seen a very rapid increase of TB cases and deaths in the world. The most-affected areas are sub-Saharan Africa, Asia, and Russian Federation countries (WHO 2006c). WHO and the Stop TB Partnership have come up with several strategies to combat this worsening TB situation. It has had significant success in the Americas and Asia-Pacific regions. Countries in those regions are on course to attaining the Millennium Development Goals (MDGs).

Most countries in other regions of the world have stagnated and fallen short of their targets. Stop TB and other key stakeholders in global TB control attribute this worsening TB control situation to the following—

- The high HIV/AIDS prevalence in these countries, which fuels exponential TB case increments annually
- Poverty and worsening socioeconomic status
- The increase of MDR-TB associated with poor case management, poor-quality anti-TB medicines, or both

MDR-TB and extensively drug-resistant TB (XDR-TB) constitute the most worrying phenomena that are currently threatening to reverse all the gains attained in TB control over the years. In 2004, 40 percent of all TB cases reported to WHO were resistant to either one anti-TB medicine (mono-drug-resistant TB) or resistant to isoniazid and rifampicin (MDR-TB). More recently, XDR-TB has gained world attention as a form of TB that is resistant to isoniazid and rifampicin as well as three of the six main classes of second-line TB medicines.

Unfortunately, the MDR-TB situation in Kenya, as in most of the other 22 high-burden countries for TB, is not well documented. In these countries, the burden of controlling the ever-expanding TB case burden is more than the public sector can handle on its own. Most patients seek medical attention first from the private sector facilities before visiting public health care facilities. These private health care facilities appeal more to clients because of the perceived confidentiality, easy access, and shorter waiting time.

In Kenya, the NLTP, like other national TB control programs, has set policies that aim at preventing the spread of TB and alleviating the suffering and premature deaths caused by TB through early diagnosis and proper TB case management. One of the aims of the NLTP is to minimize the

development of medicine resistance by promoting combination anti-TB medicine therapy and DOTS.

The current wave of increasing MDR-TB cases in the world is attributed to single anti-TB medicine exposure, that is, *monotherapy*, which may occur under various circumstances, such as the following—

- Patients' poor adherence to treatment
- Inappropriate prescriptions, not in line with TB guidelines
- Interrupted medicine intake caused by stock-outs or a patient's defaulting on treatment
- Poor-quality anti-TB medicines

In Kenya, as in most other developing countries, failure to follow the national TB guidelines, not implementing DOTS, defaulting patients, and illegal sale of anti-TB medicines over the counter without prescription are thought to be the main reasons for the rise in MDR-TB cases. These almost criminal acts are thought to be rampant in the for-profit private sector health care facilities. As a result of their profit motive, they freely sell anti-TB medicines to any patient without regard to policy on prescription medicine or TB guidelines. This fact is well documented in the Global Plan for TB control by the Stop TB Partnership, which states that most sectors of the health system in most countries are not yet implementing DOTS (WHO 2006c).

Knowing that 48 percent of the health care services in Kenya are provided by the private sector, the importance of this sector in health delivery cannot be overemphasized. This huge and rapidly expanding health industry is very important to the success of TB control in Kenya. Hence, the failure of the private sector to adhere to TB guidelines may doom all the efforts to control TB in Kenya. Yet, to date, most of the health care facilities in this sector are not planned for or formally involved in national TB control activities. As a result, most private health care providers have little if any information on the current TB case management protocols and practice. When confronted by patients, many private providers are thought either to resort to outdated treatment regimens or, worse still, to offer over-the-counter (OTC) monotherapy.

Faced with this disturbing but unconfirmed scenario on usage of anti-TB medicines in Kenya, the NLTP and the Rational Pharmaceutical Management (RPM) Plus Program of Management Sciences for Health (MSH) decided to conduct a study to generate facts on these critical issues. The purpose of this study was to determine the prescribing habits of the private health care providers and their dispensing pattern of anti-TB medicines in Kenya. The results of this study are expected to shed light on the role played by the private sector in TB control in Kenya.

BACKGROUND

The Health System

The National Health Sector strategic plan covering the period 1999–2004 was launched with the purpose of reforming the entire heath sector. The reforms were part of the larger economic reforms contained in the economic recovery strategy for Employment and Wealth Creation of 2003–2007. The thrust of the Ministry of Health was to strive for provision of sustainable quality services accessible and affordable by all Kenyans. The country's second MoH strategic plan (2005–2010) was formulated with the aim of reversing the downward trends in health indicators. Among other things, the strategic plan focuses on a sectorwide approach to health care services and defines the resource envelope required to implement it. The central level is mainly responsible for policy formulation and lays down the vision and mission of the country on all health matters. In particular, it sets standards for quality of services, mechanisms for monitoring and supervision as well as resource mobilization, and provides the overall coordination and leadership functions.

Since independence, the country has striven to fight poverty, ignorance, and disease and over the years has expanded its health care delivery system by establishing a primary health care system. From the early 1990s, Kenya pursued and promoted the strategy of decentralization of health services to the periphery to reach the rural poor and most vulnerable populations. In addition, the MoH has encouraged partners to initiate health services in rural areas, especially in the underserved areas, through policies that support development of health care facilities by the government and private practitioners, both for profit and nonprofit. Faith-based organizations have taken advantage of this policy to cover especially the parts of the country that are considered hard to reach, where motivation rather than incentives is important in retaining health care workers.

Through this policy, consumer communities have been involved in the decision making of health care facilities and have contributed greatly to the infrastructure development of the facilities. Presently, 218 hospitals and 3,098 health centers and dispensaries serve 33 million people. Table 1 shows the distribution of health care facilities in Kenya and Table 2 summarizes the MoH's health care workforce.

Table 1. Distribution of Health Care facilities

Type of Facility	MoH	FBO/NGO	Private for Profit	Total
Hospital	109 (50%)	67 (30.7%)	42 (19.3%)	218
Health Center	460 (80%)	100 (17.4%)	15 (2.6%)	575
Dispensary	1,537 (60.9%)	595 (23.6%)	391 (15.5%)	2,523
Nursing and maternity	0 (0%)	11 (58%)	180 (94.2%)	191
Medical care	43 (0.1%)	72 (10.2%)	592 (83.7%)	707
Total	2,149 (51%)	845 (20.1%)	1,220 (29%)	4,214

Table 2. MoH Workforce

Cadre	n	Percentage	Number per 100,000 Population
Doctors/dentists	5,585	10.2	15.3
Clinical officers	4,804	8.7	15.7
Pharmacists	1,881	3.4	5.8
Pharmaceutical technicians	1,405	2.5	4.3
Public health officers	1,216	2.2	3.6
Registered nurses	9,869	17.9	33.1
Enrolled nurses	30,212	54.9	100.2
Total workforce	**54,972**	**100%**	**192.1**

Kenya spends about 8 percent of its GDP on health. Per capita expenditure per person stood at USD 11 in 2003, of this amount USD 6 came from budgetary resources and the balance came mainly from out-of-pocket expenditure. This apparently large out-of-pocket free flow of funds has created a lucrative field for the private sector and has enabled rapid growth of the informal health sector in Kenya. Out-of-pocket expenditure accounted for 53 percent of the total cost of health care with the remainder being government contribution through taxation (25 percent), social health insurance (15 percent), private prepaid health plans (5 percent), and nonprofit institutions (2 percent) (MoH 2005).

Of all health care facilities in Kenya, the MoH controls and runs 52 percent, while the private sector, mission organizations, and the local governments run 48 percent.

The pharmaceutical sector consists of three segments: manufacturers, distributors, and retailers. Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa, supplying about 50 percent of the region's market. Kenya has 30 pharmaceutical manufacturers.

Pharmaceutical Policy

The patent protection of pharmaceuticals in Kenya is based on the Africa Regional Industrial Property Organization patent system that is based in Harare, Zimbabwe. Additionally, Kenya passed the Kenya Industrial Property Bill in 2001, which allows the country to import and to produce more-affordable medicines for HIV/AIDS and other diseases.

Manufacturers

The pharmaceutical manufacturers consist of 30 licensed concerns, including local manufacturing companies and large multinational corporations, subsidiaries, or joint ventures. Most are located within Nairobi and its environs. The bulk of locally manufactured preparations are nonsterile OTC products. Only one local company manufactures anti-TB medicines.

Distributors

KEMSA, a division of the Ministry of Health, largely carries out the distribution of pharmaceutical products in Kenya. It distributes medicines to government health care facilities and private health care facilities. KEMSA competes with other suppliers, including the mission-based medical supply facility (MEDS) and private wholesalers.

Retailers

Products are channeled through pharmacies, chemists, health care facilities and shops. There are about 195 registered wholesale and 936 retail outlets manned by registered pharmacists and pharmaceutical technologists. Medicines are sold according to medicine categorization: free sales (OTC), pharmacy technician–dispensable, and pharmacist-dispensable (prescription only). The distribution of the outlets is shown in Table 3. Clearly, most of the retail and wholesale outlets are located in the major towns of the country, with Nairobi, the capital city, taking the lion's share.

Health Institutions

In line with the government's efforts to provide accessible and acceptable services to all Kenyans, the country has enjoyed a commendable expansion of health care facilities in the provinces. This number grew from 4,499 in 2002 to 4,557 in 2003, an increase of 1.3 percent. Rift Valley tops the list with the largest number of health care facilities 1,267 (27.8 percent) while North-Eastern has the least at 88 (1.9 percent). Table 4 shows the distribution of the health care facilities in Kenya by province.

Medical Personnel

To complement the growth in the health sector, continuous training of medical personnel is important. The number of medical personnel grew by 2.6 percent from 2002 (59,049) to 60,603 in 2003.

Table 3. Distribution of Retail and Wholesale Medicine Sellers

Town	Number of Retailers	Number of Wholesalers
Webuye	4	0
Thika	20	4
Nyeri	16	0
Nyahururu	9	0
Nakuru	37	4
Nairobi	421	145
Murang'a	8	0
Mumias	5	0
Moyale	3	0
Mombasa	52	10
Molo	4	0
Migori	7	0
Meru	9	0
Maua	5	0
Malindi	6	0
Machakos	11	0
Litein	5	0
Kitale	10	0
Kisumu	21	11
Kisii	7	0
Kilifi	4	0
Kikuyu	4	2
Kerugoya	6	0
Kericho	6	2
Karatina	8	0
Kapsabet	4	0
Kakmega	14	0
Isiolo	8	0
Garissa	7	0
Embu	6	0
Eldoret	25	5
Bungoma	10	0
Others	174	12
Total	**936**	**195**

Table 4. Distribution of Health Care Facilities in Kenya

Province	Hospitals, Health Centers, and Dispensaries	
	2002	**2003**
Nairobi	485	493
Central	517	526
Coast	435	440
Eastern	831	837
North-Eastern	83	88
Nyanza	539	548
Rift Valley	1,259	1,267
Western	350	358
Total	**4,499**	**4,557**

RESEARCH QUESTION

How significant is the role played by private sector health care providers in anti-TB medicine prescription and dispensing in Kenya?

Hypothesis

Most private health care providers in Kenya that either prescribe or dispense anti-TB medicines do not adhere to the national TB guidelines, resulting in misuse of these precious medicines.

Null Hypothesis

Most private health care providers in Kenya follow the national TB guidelines to prescribe or dispense anti-TB medicines to clients.

Objectives

- Determine the proportion of private health care facilities in Kenya that follow the national TB guidelines
- Determine the cost of medicines from a private health care facility for the full course anti-TB treatment for an adult TB patient
- Determine the prescription practices of anti-TB medicines in the private retail medicine outlets in Kenya
- Estimate the number of TB patients diagnosed and treated for TB by the private sector in Kenya over the last year

METHODOLOGY

Study Design

This study was a descriptive cross-sectional survey designed to collect data concerning the knowledge and practices of private pharmacists dispensing TB medicines. It was designed to establish the sources of TB medicines available in the market, including the formulations available, and the knowledge and practices of TB treatment in the private sector in Kenya in relation to existing government policies.

Study Area

The study covered the following 12 main towns in Kenya: Mombasa, Malindi, Kilifi, Nairobi, Machakos, Embu, Meru, Isiolo, Kisumu, Bondo, Migori, and Rachunyo. The aim was to cover 30 percent of the private sector treatment facilities and 30 percent of the private pharmacies where TB medicines were available and on sale to the general public, including TB patients and suspects. The study targeted both private for-profit and private not-for-profit health care facilities. Most of these pharmacies are located in the main towns in each selected district.

Study Population

The study population consisted of the staff in the country's 936 private pharmacies selling TB medicines to the public and in the 1,000 private health care facilities. The calculated sample size was 83 health care facilities and 93 medicine retail outlets. Specifically, the study targeted the pharmacies in the established urban areas, where the flourishing private sector was expected to be involved in TB treatment. In addition, 83 private health care facilities offering TB diagnosis and treatment were also surveyed on knowledge and practice.

Sampling Methods

Sampling of Private Health care facilities for Inclusion in the Study

Of 11 provinces in TB control program administrative regions, the investigators selected the four provinces with the highest TB case loads based on the 2005 NLTP annual report. The selected provinces were Nyanza, Nairobi, Coast, and Eastern.

In each of these provinces, one-third of the districts were selected purposely, choosing the district with the highest number of TB cases. Then, in each district about one-third of the different health care facility categories (hospitals and nursing homes, faith-based facilities, and clinics) were randomly selected.

Sampling of the Medicine Outlets

In the 12 districts selected, 60 percent of the private retail outlets selling medicines were randomly identified for this survey. Half (30 percent) of these retail medicine outlets were visited to collect data using a simulated TB patient ("mystery buyer").

The other half (30 percent) was visited to collect data on TB medicines available in the market and medicine strength and dosage commonly recommended. For this purpose, the investigators used the self-administered questionnaire, which the "pharmacist" in the outlet visited filled in personally.

In Nairobi, however, because of the large number of retail medicine outlets, the study randomly selected 20 percent only: 10 percent for simulated TB patient data collection and 10 percent for TB medicine stock and dosage data collection purposes.

Study Tools

The study was designed to determine the sources of TB medicines available in the market, including the formulations available, and the knowledge and practices of TB treatment in the private sector in Kenya in relation to existing government policies—in a nutshell, the role of private sector in TB control in Kenya.

The focus was on two primary areas, the retail medicine outlets (pharmacies) and the private treatment health care facilities. The investigators used three data collection tools, two in collecting data from the pharmacies and one in collecting data from the private health care facilities.

To determine the TB medicines available in the private pharmacies in Kenya, including the formulations, and cost, the investigators used two data collection tools—

- First, a "patient simulation guide," which involved the data collector pretending to be a TB patient seeking to buy anti-TB medicines. This "mystery patient" visited a private pharmacy and engaged the pharmacist dispensing TB medicines in face-to-face discussion. This part of the study was aimed at collecting data on cost of anti-TB medicines and the treatment practices used in these facilities in Kenya in relation to existing government policies.

- Second, a structured, self-administered questionnaire, which the pharmacist or vendor selling medicines in the retail outlets visited, read and completed. This tool was used to document the formulation, strength, and dosage of anti-TB medicines they would commonly dispense.

To determine the kind of TB care, practices, and workload in private health care facilities, the study used a structured questionnaire administered by a data collector. The data collectors interviewed the health care providers present in the private health care facilities offering TB treatment and diagnosis.

Protocol

Identification and Training of Field-Workers

The principal investigator identified a four-person team that he trained over a period of two days on how to conduct this study. The team consisted of a team leader (research assistant) and three data collectors. On day three, the team practiced using the pre-piloted data collection tools in Thika, a town outside the study area. Each data collector specialized in collecting data using one of the three tools.

Between February and March 2007, the team visited the 12 selected towns/districts to collect data. In each town, the teams first visited the District Officer of the MoH and the DTLC as a courtesy call and to confirm authority to conduct the study. In addition, the team received an updated list of private health treatment facilities and pharmacies in that district/town to aid in random selection of the functioning private sector health care facilities to be visited.

Data Collection

Data were collected over a period of 30 working days, between February 8 and March 21, 2007.

The following is an example of activities that took place on a typical data collection day. After the morning briefing meeting, the team dispersed. Each data collector was armed with the list of the facilities to visit and data collection tools. All the data collectors were in telephone communication with the field supervisor in case of any question or problem.

The supervisor kept track of the data collectors and met each during the course of the day to ensure proper data collection and attend to any unforeseen issues. In the evening, the team met and handed in the completed questionnaires. The supervisor scanned through the completed questionnaires to ensure they had been properly filled out and note any missing data for correction the next day.

Finally, the research assistant physically brought the completed questionnaires to Nairobi and handed them over to the principal investigator after completing each province and before proceeding to the next selected province**.**

Data Analysis

The principal investigator delivered the completed questionnaires to the MSH/RPM Plus research consultant and the biostatistician. The biostatistician designed data entry screens in Epi Info 2000 for Windows into which data were entered. Data were analyzed using SPSS version 14.0 after importing the data from Epi Info. The investigators restricted the analysis mainly to percentages and other nonparametric measures as shown in the results in the next section.

RESULTS

The study sought to establish the prescription and dispensing practices of TB medicines in the private sector in Kenya. Data were collected from two main categories of health care facilities: private health treatment points and private retail medicines outlets or pharmacies. The sample size consisted of 83 private treatment health care facilities and 93 private medicine outlets or pharmacies. They were sampled using stratified purposive sampling technique.

Table 5. Sample Size Distribution per Province

Province	Treatment Health Care Facilities	Pharmacies
Nairobi	23 (27.7%)	25 (26.9%)
Coast	14 (16.9%)	15 (16.1%)
Eastern	23 (27.7%)	26 (28.0%)
Nyanza	23 (27.7%)	27 (29.0%)
Total	**83 (100.0%)**	**93 (100.0%)**

The following findings are grouped into two categories—

- Findings from private treatment health care facilities
- Findings from private medicine outlets/pharmacies

Findings from the Assessment of TB Medicines in Private Health Care Facilities

The study of the private treatment health care facilities was done in the following provinces: Nairobi, Coast, Eastern, and Nyanza. It covered 22 high-burden districts from the four provinces (see Table 5).

The majority, 45.8 percent (n = 38), of the health care facilities in the study were private clinics. Table 6 shows the distribution of health care facilities by type of health institution studied.

Table 6. Types of Health Care Facilities

Type of Institution	n	Percentage
Private hospital	22	26.5
Private/medical clinic	38	45.8
Nursing home	6	7.2
Not-for-profit organization	17	20.5
Total	83	100.0

TB patients seen the previous year (2006) ranged from none to 405. The majority, 76 percent (n = 60), of the health care facilities had less than 40 patients for the year, and only 12 percent had at least 10 new patients per month.

Table 7. TB Patients, 2006

Number of Patients	n	Percentage
0–39	60	76
40–79	9	11
80–119	1	1
120–159	3	4
>160	6	8
Total	**79**	**100**

TB patients seen so far this year (2007) ranged from 0 to 144. Most (70 percent, n = 53) facilities had fewer than 10 patients for the first quarter of the year.

Table 8. TB Patients, 2007

Number of Patients	n	Percentage
0–9	53	70
10–19	13	17
20–29	4	5
>30	6	8
Total	**76**	**100**

Only one in three of the health care facilities treated patients diagnosed with TB. The rest referred TB patients to seek treatment in other health care facilities, most to MoH health care facilities (Table 9).

Table 9. Place Where Patients Receive Treatment

Where TB Treatment Received	n	Percentage
This treatment facility	28	33.7
Another private facility	4	4.8
MoH facility	51	61.4
Total	83	100.0

Kenyan law requires that diagnosis of TB and other notifiable diseases be reported to the MoH at once. Treatment outcome of such cases must also be reported. With this requirement in mind, the

investigators sorted and analyzed the data to determine whether various private health care facilities in Kenya comply with the notification requirement.

A positive correlation existed between the source of TB medicines and the likelihood of the health facility's reporting TB treatment outcomes to the MoH ($p<0.002$). Hence, health care facilities with close ties to the MoH, for example, and that received medicines from that source, reported the TB treatment outcomes as required (Table 10).

Table 10. Correlation between Source of TB Medicine and Likelihood of Reporting TB Treatment Outcome to MoH/NLTP

Source of Medicine	Report Outcome to MoH	Do Not Report Outcome to MoH	Total
KAPTLD	13 (100%)	0 (0%)	13 (100%)
MoH	20 (90.9%)	2 (9.1%)	22 (100.0%)
From direct importers	2 (66.7%)	1 (33.3%)	3 (100.0%)
Kenyan suppliers	3 (60%)	2 (40%)	5 (100%)
Others	0 (0%)	2 (100%)	2 (100%)
Total	**38**	**7**	**45**

No positive correlation existed between the source of TB medicines and knowledge of duration of TB treatment by private health facility health care workers ($p = 0.151$). Oddly, 20 to 25 percent of health care workers in private facilities receiving TB medicines and support from MoH and Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) were not fully conversant with TB treatment regimens (Table 11).

Table 11. Correlation between Source of TB Medicine and Knowledge of Duration of TB Treatment

Source of Medicine	Know Duration TB Treatment	Do Not Know Duration TB Treatment	Total
KAPTLD	8 (72.7%)	3 (27.3%)	11 (100.0%)
MoH	12 (70.6%)	5 (29.4%)	17 (100.0%)
Importers	1 (50%)	1 (50%)	2 (100%)
Kenyan suppliers	4 (100%)	0 (0%)	4 (100%)
Others	0 (0%)	2 (100%)	2 (100%)
Total	**25**	**11**	**36**

Only 4 percent (n = 4) of the staff manning these health care facilities mentioned correct medicine acronym, medicine name, strength, and duration of treatment. One-third of them (n = 32) cited the correct TB medicine acronym and correct duration of treatment.

Table 12. TB Medicine Knowledge

Acronym	Medicine Acronym and Strength		Medicine Acronym and Name	
	n	Percentage	n	Percentage
RHZE	3	3	4	4.0
RHZ	1	1	1	1.0
RHE	0	0	0	0.0
RH	1	1	3	3.0
E	0	0	0	0.0
S	3	3	5	5.0
EH	0	0	1	1.0
Total		**8**		**14**

R = rifampicin; H = isoniazid; Z = pyrazinamide; E = ethambutol; S= streptomycin.

Four of 10 respondents (health facility staff) did not indicate the strength for the regimen they mentioned. Thirty percent of the respondents said that they gave medicines according to the weight of the patient (indicating that they thought they were dealing with dosage).

Asked what sort of instructions the medical practitioners gave their TB patients, the majority, 72 percent (n = 60), cited medicine adherence or compliance. Twelve percent (n = 10), however, said they did not give any instruction to their patients.

Table 13. Instructions Given to Patients

Instruction Given	n	Percentage
Medicines	60	72.3
Follow-up/review	25	30.1
Diet/nutrition	24	28.9
Side effects	18	21.7
HIV counseling/DTC	17	20.5
Hygiene	15	18.1
TB treatment information	15	18.1
Contact invitation	9	10.8
Don't smoke/take alcohol	7	8.4
Total	**190**	*

*Some interviewees gave more than one response to this question.

Sixty-five percent of the health care workers said they observe TB patients take their medication. According to these health care workers, they observed 51 percent of the TB patients (n = 36), while the rest were observed by other persons, mainly household members, 40 percent (n = 28), and community health workers, 9 percent (n = 6).

Table 14. Person Observing TB Treatment

Observer	n	Percentage
Health care worker	36	51
Household member	28	40
Community health worker	6	9
Total	**70**	**100**

Asked how often the health care worker observed their intake of medicines, only 38 percent of patients responding quoted daily observation during the intensive phase.

Table 15. Frequency TB Treatment Observed: TB Patient Responses

Frequency of Observation	n	Percentage
Daily during intensive phase	20	38
Weekly during intensive phase	13	25
Monthly during intensive phase	9	17
Other	10	19
Total	**52**	**100**

The MoH is the largest source of TB medicines for private clinics offering TB services. Forty percent (n = 26) of their stock comes from the MoH, followed by KAPTLD (22 percent, n = 14).

Table 16. Source of TB Medicines

Medicine Source	n	Percentage
Ministry of Health sources	26	40
KAPTLD	14	22
Supplier within Kenya	11	17
Imported from supplier outside Kenya	6	9
Local pharmacy	6	9
Others	2	3
Total	**65**	**100**

Only in 50 health care facilities of the 83 surveyed did the interviewee respond to the question on cost of TB medicines dispensed in their health care facilities. Fifty-eight percent (n = 29) sold anti-TB medicines to TB patients on treatment in their health care facilities. Only the 22 health care facilities allied to KAPTLD, however, were able to state the cost of the full course of anti-TB medicines (category I). The price for the full course TB treatment for an adult TB patient in these KAPTLD-affiliated health care facilities ranged from 2,500 Kenyan shillings (KES) to KES 6,700, with a mean of KES 5,200 (USD 78.80). Contrasting this cost with the annual GDP per capita of USD 1,200, one can see that paying for TB treatment out of pocket would require 7 percent of a person's annual income.

Of the private health care facilities surveyed, 70.9 percent (n = 39) reported the treatment outcomes of their TB patients to the MoH through either the NLTP or KAPTLD. The remaining 16 private health care facilities (29 percent) do not submit any TB report to the MoH/NLTP.

TB treatment outcomes are reported to the MoH through a variety of tools and improvised forms. A quarter of responses (n = 20), indicated respondents were using the NLTP TB facility register. About 5 percent (n = 4) of the health care workers did not report the treatment outcomes to either NLTP or KAPTLD as required by law.

Table 17. TB Reporting Tool Use

Reporting Tool	n	Percentage
NLTP TB facility register	20	24.7
KAPTLD TB facility register	6	7.4
AFB register	8	9.9
TB referral form	4	4.9
NLTP Daily Activity Drug Register (DADR)	4	4.9
NLTP Consumption Drug Requisition Register	3	3.7
KAPTLD DADR	5	6.2
Custom-made tools	19	23.3
Others	12	14.7
No records	4	4.9
Total	81	100.0

On the issue of community participation in TB control, only a quarter (n = 17) of the facilities have the community DOTS strategy in place. The number of patients under this system ranged from 4 to 60, with a mean of 21 patients per facility.

Finally, it was encouraging to note that 90 percent (n = 74) of the private health care facilities offer HIV counseling and testing for TB patients.

Private Medicine Outlets/Pharmacies' Knowledge and Practices

Simulated TB Patient (Mystery TB Patient)

Results presented in this section were elicited through a conversation between a simulated TB patient and a private pharmacy operator.

Using the simulated TB patient technique, investigators found that 96.8 percent (n = 90) of private pharmacies visited had or claimed to have one or more anti-TB medicines. Surprisingly, only 14 percent of the retail medicine outlets visited stocked and sold the full course of anti-TB medicines. Most private pharmacies thus stock one or two anti-TB medicines that they mainly dispensed to treat other diseases. These common anti-TB medicines were rifampicin and streptomycin.

Table 18. Private Medicine Outlet/Pharmacy with TB Medicines

Question	Yes	No	Total
Does this facility have any anti-TB medicines?	90 (96.8%)	3 (3.2%)	93 (100.0%)
Does this facility have full course of medicines?	13 (14%)	80 (86%)	93 (100.0%)

The data collector who simulated the patient with TB recorded notes of his conversation with the "pharmacist" as soon as he left the private medicine outlet. The summary of these conversations is provided in Table 19. Note that some of the 93 responders gave multiple answers.

Table 19. Simulated Buyer Experience in Retail Medicine Outlets

Practices of Pharmacists/Medicine Vendors Visited by Simulated TB Patient	n	Percentage
Referred the TB "patient" to MoH facility, does not stock anti-TB medicines	16	17.2
Demanded a prescription (no prescription, no anti-TB medicines)	18	19.4
Sold rifampicin without prescription	15	16.1
Sold streptomycin without prescription	7	7.5
Sold ethambutol/RHZ without prescription and asked "patient" to "find rifampicin to combine"	4	4.3
Sold rifampicin and isoniazid without prescription	1	1.1
Sold other antibiotics without prescription	2	2.1
Sold unspecified "anti-TB medicines" without prescription	4	4.3
Sold TB medicines and gave adherence counseling	13	14
Gave TB/HIV counseling	1	1.1
TB medicines in stock were expired because of lack of customers who get free medicines in GoK facilities	1	1.1
Advised "patient" to come another day when the chemist receives anti-TB medicines	1	1.1
Issued free medicines and referred to GoK facility for free anti-TB medicines	1	1.1
Sold whole package of anti-TB medicines for KES 10,000 to 15,000 to patients with a prescription	13	14
Sold RHZ and rifampicin then referred to GOK facility	3	3.2
Discouraged "patient" from taking TB medicines from public facilities, claiming he had better cold chain management	1	1.1
Said TB treatment is free, go to GoK health care facilities	10	10.8
Sold cough syrup	3	3.2
Total	**114**	

Of the pharmacies surveyed, 17.2 percent sold rifampicin to patients with or without a proper prescription. A further 17.2 percent did not stock or sell anti-TB medicines. But the majority,

63.4 percent of these important sources of medicines to the public, stocked and sold one or more medicines to TB patients and suspects.
In addition, 14 percent of the pharmacies either claimed to have or were able to procure a full course of anti-TB medicines (Kits) for TB patients. Furthermore, 16 (17.2 percent) of private medicine outlets did not stock anti-TB medicines. Yet 96.8 percent had in an earlier question claimed to stock and dispense anti-TB medicines.

Self-Reported Practice by Vendors of Anti-TB and Other Medicines

Following is a list of anti-TB medicines on sale in retail medicine outlets as reported by "pharmacists."

Table 20. Anti-TB Medicines on Sale in Retail Medicine Outlets

Medicine Name	N	Percentage
A.K.T.U	1	0.4
Cycloserine	1	0.4
Doxy caps	1	0.4
EH	5	1.9
Ethambutol	32	11.9
Ghitamin	1	0.4
Isoniazid	24	8.9
Pyrazinamide	10	3.7
Rifacos	12	4.5
Rifadin	2	0.7
RiFaFour	7	2.6
Rifampicin	60	22.3
Rifater	16	5.9
Rifica	2	0.7
Rifinah	30	11.2
Rifinah kit	3	1.1
Rifitah kit	2	0.7
RiHaZ	12	4.5
Rihide	7	2.6
Rimactane	5	1.9
Streptomycin	35	13.0
Unirif	1	0.4
Total	**269**	**100.0**

The common anti-TB medicine formulations in the Kenyan private health sector market included those shown in Table 21.

Table 21. Common Anti-TB Medicines among Private Pharmacies

Medicine Name	Content/Symbol	Strength (mg)
Rifampicin	R	150 or 300
Streptomycin	S	1,000
Ethambutol	E plain	400
RiFaFour	RHZE	R150, H75, Z400, E275
Rifinah	RH	R150, H100
Rifater	RHZ	R150, H75, Z400
Isoniazid	H or INH	100

A total of 20 different formulations of anti-TB medicines were listed as present in the private pharmacies covered in this study. Eighteen were first-line anti-TB medicines and one (cycloserine) is a second-line anti-TB medicine reserved only for MDR-TB; doxycycline is not among the anti-TB medicines recommended by NLTP or WHO. One pharmacy in Mombasa was selling doxycycline to TB patients (see Table 20). Some uncommon anti-TB medicines, like A.K.T.U and cycloserine were on sale in Nairobi and Mombasa.

Over half of the private medicine retailers (52 percent) reported that they sell anti-TB medicines, with or without a prescription. More important, using the simulated TB patient technique, 63 percent of the pharmacies visited actually sold anti-TB medicines and other antibiotics without any prescription (see table 22). Table 22 compares what was said during interviews with what was found by simulated purchase.

Table 22. TB Medicine Prescription

Can the pharmacy sell medicines without a prescription?	Actually sold without prescription
Yes 48 (51.6%)	59 (63.4%)
No (no prescription, no TB medicines) 45 (48.4%)	18 (19.4%)
No TB medicines	16 (17.2%)
Total	93 (100.0%)

DISCUSSION

The purpose of this study was to determine the role played by the private sector in connection with TB control in Kenya, with special emphasis on anti-TB medicine prescription and dispensing. Given that 48 percent of all health care facilities in Kenya are privately owned, determining how this important and rapidly expanding health sector was using or misusing anti-TB medicines was necessary.

The discussion is divided into three main sections—

- General observations
- Role of the private care health care facilities in anti-TB medicine management in Kenya
- Role of pharmacies in TB control and anti-TB management in Kenya

Private Health Care Facilities and Anti-TB Medicine Use in Kenya

Role of Private Health Care Facilities in Anti-TB Medicine Management

Many papers on the private sector and health in the developing world estimate that most patients will have presented first in a nearby private medicine outlet before seeking medical attention from a public health facility (Dewan et al. 2006). The same situation was anticipated when conducting this study. The investigators assumed that many TB patients and suspects seek medical attention in the numerous retail medicine outlets and private clinics or health care facilities. The higher the number of private facilities, the larger the number of patients they see.

This study found that many private treatment facilities do offer diagnostic services for TB patients/suspects in addition to dispensing TB medicines.

Second, as most TB control experts predict, many of the private sector treatment facilities do not follow the DOTS strategy in their TB control activities. This finding was true mostly in facilities not allied to either the MoH (NLTP) or KAPTLD. However, most private health care facilities receiving medicines from NLTP or KAPTLD were using the national TB control guidelines. Hence, they were practicing DOTS, conducting follow-up sputum microscopy for their TB patients, and recording and reporting TB patient outcomes to NLTP/KAPTLD.

Given the willingness of the private sector clinicians to refer TB patients to the appropriate TB control centers, one is persuaded to believe that if they were well updated on TB control strategies and practices, they would make TB diagnosis earlier and treat or refer TB suspects more promptly. This goal can be achieved more efficiently by forging closer ties between the private sector and NLTP and KAPTLD, as exemplified by the high knowledge (>70 percent) on TB case management documented in both MoH- and KAPTLD-allied health care facilities.

Hence, in line with the recommendations the Stop TB partnership made in its 2006 strategic plan (WHO 2006c), if the private health care facilities are fully used in addition to the public health care system, national TB control programs in high-burden TB countries likely could reach most, if not all, TB patients early in their disease. This conclusion is based on the documented fact that private health care facilities are preferred by clients because of their perceived greater confidentiality, more-convenient locations, and shorter waiting times, which make them easily accessible (Lambert et al. 2005; Hurtig et al. 2000). Therefore, use of these private facilities seems to be an untapped gold mine for TB control. It is likely to minimize missed opportunities and health care worker–related delays in TB diagnosis. Early diagnosis and treatment has been shown not only to increase a country's case detection rates and cure rates but also to reduce TB transmission (Lambert et al. 2004). Ultimately, this outcome would be a major step toward reaching the WHO targets (WHO 2006c) and United Nations MDGs.

In their current strategy to control TB globally, WHO and the Stop TB Partnership have emphasized the need for involving all health care givers in the war against TB. In particular, they have singled out the need for private-public partnerships. These recommendations are based on several recent publications that have documented that the poor performance of most national TB control programs in TB control can largely be attributed to delayed TB diagnosis and noninvolvement of most health care providers in TB work. Hence, Stop TB Partnership's strategy recommends broadening the base of health care workers tackling TB by involving private sector health care workers in the fight to stop the disease.

In this study, most private health facility clinicians referred TB suspects and patients to the nearby public health care facilities, although only about 30 percent diagnosed, registered, and treated TB patients. The latter finding may explain the low (33 percent) knowledge of health care workers on TB treatment regimens recorded in this study. This kind of scenario is worrying because poorly updated clinicians are dangerous for TB control. They are most likely to miss early presentation of TB in patients, leading to missed opportunity and therefore delay in TB diagnosis. In addition, these ill-equipped clinicians would most likely prescribe the wrong TB treatment regimens to their patients.

Ultimately, the delay in TB diagnosis or incorrect treatment regimen will lead to poor TB case management and hence unfavorable TB treatment outcomes, such as prolonged patient suffering and complications, continued TB transmission, development of medicine resistance, or even a patient's death.

NLTP needs to quickly find a way of influencing the way TB control activities are conducted in all private health treatment facilities. This action is especially important in the case of anti-TB medicine prescribing and dispensing practices. The study showed that 40 percent of all private health care facilities treating TB were doing so using TB medicines from the MoH through the NLTP. As a result, 76 percent of all TB patients treated in the private sector received medicines from the MoH/NLTP. Moreover, 96 percent of the private health care facilities allied to NLTP were practicing DOTS and reported TB outcomes to MoH, using NLTP standard data collection tools. Therefore, NLTP can use its supply of free TB medicines to the private facilities in a tightly controlled manner, as motivation to promote the private sector clinicians' interest, knowledge, and practices in the proper use and handling of anti-TB medicines.

In this quest, NLTP can also effectively use KAPTLD as a link to private health sector involvement in anti-TB medicine management. This study found that KAPTLD supplied 22 percent of private health care facilities treating TB patients in the surveyed areas. The study also confirmed that all KAPTLD-allied health care facilities practiced DOTS and reported TB treatment outcomes to the NLTP through KAPTLD data capture tools. More important, only these KAPTLD-allied health care facilities knew the cost of the full course of anti-TB medicines. They sold the TB medicines to clients for between KES 5,200 and KES 6,500 per newly diagnosed adult TB patient (category I). These health care facilities received their anti-TB medicine packs from KAPTLD at a cost of KES 4,500. Each thus made its needed profit (KAPTLD internal guidelines 2006).

Interestingly, 43.4 percent of the private facilities claimed that their staff observed the TB patients swallowing anti-TB medicines daily. However, in a recent study focusing on health care facilities implementing community-based DOTS strategy in Kenya by MSH/NLTP (Ndege and Gitau 2007), health workers observed only between 2 and 5 percent of their TB patients. In essence, CHWs observe mostly the retreatment TB patients receiving the daily streptomycin injections.

General Observations

About half of the facilities sampled were medical clinics, with hospitals and nursing homes making 34 percent and FBOs contributing 20 percent. These medical clinics are usually small outlets without the laboratory facilities that are essential for processing sputum microscopy.

The TB patient load for 2006, the year preceding the study, was pretty low, and most private facilities had fewer than 10 patients the whole year. Only 12 percent had at least 10 patients over the course of the same year. This finding indicates that the majority of the outlets are small establishments. This fact is further reinforced by the number of health care facilities offering TB treatment after diagnosis. Only a third of diagnosing facilities treat TB.

It was, however, reassuring to note that the majority of these patients were referred to MoH facilities or nearby private clinics offering TB treatment. NLTP and KAPTLD, however, need to follow up with these facilities and provide them with medicines to capitalize on their ability to reach an extra number of TB patients (Hanson and Kibuga 2000).

Almost all respondents said they counseled or tested TB patients for HIV/AIDS. This finding is commendable. Chakaya et al. (2005) in their study on knowledge, attitude, and practices of health care workers on TB found that only 35 percent counseled TB patients on HIV/AIDS consistently. Forty-eight percent sometimes counseled and tested their patients, while 11 percent sometimes counseled but never tested and 7 percent never discussed HIV with their patients. However, their study was restricted to the Kibera slums of Nairobi, whereas the current study was countrywide, hence the different findings.

A wide range of TB outcome reporting tools exists, although almost a quarter of the respondents devise their own reporting and data-capture tools. This finding may be a strong indication of the isolation of these private facilities from the public health sector, resulting in their inability to

access the available standardized NLTP or KAPTLD reporting tools necessary to ensure uniformity of data collected.

The Role of Private Retail Medicine Outlets in Anti-TB Medicine Management

Several unpublished data sources and many experts in TB control in the high-burden TB countries have previously pointed a finger at the private sector, accusing this sector of misusing anti-TB medicines and neglect of TB patients (Lonnroth et al. 2006). In contrast, other TB experts see the private sector as the key to attaining TB control in these high-burden TB countries (Chakaya et al. 2005; WHO 2006c).

Misuse of TB Medicines by Retail Medicine Outlets

This study's findings support the notion that private pharmacies misuse anti-TB medicines to a large extent (Lonnroth et al. 2006); Suleiman et al. 2003). Of the 93 medicine retail outlets stocking and selling anti-TB medicines surveyed, only four (4 percent) were managed by a pharmacist/vendor who knew the correct TB medicine acronym and duration for treating an adult TB patient. Most pharmacists/vendors recommended monotherapy with one to two rifampicin tablets of any strength per day to their patient. None of these medicine outlets was practicing direct observation of TB patients swallowing their TB medicines, indicating their lack of knowledge of the national standard treatment procedures.

As previously mentioned, only 14 percent of "pharmacists" from these retail medicine outlets claimed to dispense a complete course of anti-TB medicines for the recommended duration of 6 or 8 months. Even these pharmacies offering complete TB treatment, however, did not have a mechanism for patient follow-up or ensuring anti-TB medicine compliance by their patient (DOTS). This and other findings in this study are similar to the conclusion reached by previous research on this topic: retail medicine outlets play a minimal and mainly negative role in anti-TB medicine dispensing (Lambert et al. 2005).

In addition, most (63.4 percent) of these medicine outlets did not comply with the MoH policy on sale of prescription medicines. They were selling anti-TB medicines to patients and TB suspects without proper prescription. Perhaps their sales were motivated by profit, because they sold any anti-TB medicine available to patients and for any duration that the patient could afford. Nearly a third of these retail medicine outlets (27.9 percent) sold only one of the four first-line medicines required to be used in combination, resulting in TB monotherapy, a practice known to promote development of medicine resistance. Worse still, 10 percent of the outlets sold unspecified medicines to TB patients, including doxycycline and cough syrups as therapies for TB disease.

Furthermore, no (100 percent) pharmacies surveyed followed the national TB guidelines when dispensing TB medicines to patients. This was evidenced by the fact that none followed up their patients or advised on follow-up sputum check or advocated for DOTS as required by WHO (Kellerman et al. 1998).

Rifampicin and streptomycin were the commonest anti-TB medicines on sale in private pharmacies. These medicines are also used to treat other medical conditions, such as sexually transmitted infections and brucellosis, but according to the MoH essential medicines list, these medicines by policy should be reserved for TB patients.

Finally, the investigators question the claim by 14 percent of private medicine vendors that they stocked or sold anti-TB patient packs (boxes containing all TB medicines needed for one patient's full-course treatment). To our understanding, no anti-TB patient packs were in circulation in the private sector in Kenya at the time this study was done. This leaves two possible scenarios; either the retail medicine shop owners were bluffing, or they were illegally selling NLTP/MoH anti-TB patient packs they had obtained in some way.

Positive Roles Played by Private Medicine Outlets in Anti-TB Medicine Prescribing and Dispensing

Of the retail medicine outlets, 17.2 percent strictly followed the MoH guidelines and would not dispense any prescription medicines without a proper prescription. This group of properly run medicine outlets duly referred all TB suspects/patients and other persons seeking anti-TB medicines to the nearby MoH or private health facility where proper TB diagnosis and treatment (DOTS) is offered. Surprisingly, some of these "good" retail medicine outlets that sold medicines to patients only with proper prescriptions also stocked rifampicin and streptomycin, which they sold to treat other medical conditions, mainly brucellosis and sexually transmitted infections.

The study found encouraging that a wide range of useful advice is given to patients. The most mentioned instruction is on medicine adherence or compliance. Other instructions included the need for follow-up/review, good nutrition, and what to do in case of side effects. All these efforts are important in increasing TB treatment success rates.

Some of the private pharmacies did not stock anti-TB medicines, preferring to refer and educate TB suspects/patients about the free TB treatment and medicines in MoH and mission health care facilities.

From the preceding findings, one can conclude that most, if not all, the loose anti-TB medicines available in the private retail outlets are stocked and used for purposes other than treating TB patients. Hence, these loose anti-TB medicines are open to misuse by all pharmacies. Therefore, only the fixed-dose combination anti-TB medicines (containing all of the three or four oral first-line anti-TB medicines in one pill) should be used to treat TB patients in the private health sector.

LIMITATIONS

The list of registered pharmacies and private health care facilities used was not all-inclusive and left out many facilities operating in the field. Hence, the investigators find making an accurate generalization of what is happening in the private sector of the whole country difficult. Perhaps the most one can resolve from this study is that most private health sector providers, especially the pharmacies, are misusing anti-TB medicines. As a result, the NLTP and other TB stakeholders need to act fast to save Kenya and other countries with similar problems from the imminent disaster of MDR-TB.

Despite the poor TB case management occurring in these private health care facilities, evidence exists that TB patients and suspects will continue to seek treatment in the private health care sector. Thus, to promote TB control, one should concentrate on developing mechanisms to train, motivate, and supervise private sector personnel regularly to improve the quality of health services they provide rather than exclaiming about the poor quality of the services they provide.

Because the study did not record the level of training of interviewees, it could not specifically determine whether a particular level of personnel among the several levels who were encountered running these medicine outlets contributed more to the misuse of anti-TB medicines. Therefore, the NLTP/MoH needs to either train all personnel or carry out a second survey to specifically determine knowledge and practices of the various levels of personnel.

RECOMMENDATIONS AND CONCLUSION

Recommendations

The future of rational anti-TB medicine use in Kenya and other countries with similar problems can be significantly improved by eliminating the misuse of loose anti-TB medicines where available in the private sector and by introducing the following suggested strategies—

- Prohibiting importation or manufacture of loose anti-TB medicines in Kenya except for the TB control program
- Promoting cheaper alternative therapies instead of rifampicin and streptomycin to treat brucellosis and sexually transmitted infections
- Including most, if not all, registered private health care facilities able to diagnose and treat TB in the NLTP plan and budget, providing these health care facilities with free TB medicines, routine supervision, and regular training
- Designing and implementing TB control training modules for the health care workers running private health care facilities and especially retail medicine outlets
- Sharing this report with other countries in the East, Central, and Southern Africa (ECSA) region to indicate the potential of existing misuse of anti-TB medicines in those countries
- Conducting a similar study in other countries in the ECSA region to determine whether the widespread misuse of anti-TB medicines is also a problem in those countries

Conclusion

Most health care workers in the private sector in Kenya prescribe and dispense anti-TB medicines inappropriately, which is mainly attributable to the significant knowledge gap on TB management among this group of health care workers. The situation is worse among the retail medicine outlet vendors, probably because of their knowledge gap and the influence of the profit motive. Private treatment health care facilities are better off, especially those allied to MoH/NLTP or KAPTLD, which were rationally using TB medicines.

Nevertheless, a great opportunity seems to exist to reach the huge number of patients who prefer private health care over the public sector, especially as the first stopping-point in seeking health care. In this respect NLTP, KAPTLD, and other TB stakeholders should redouble their efforts to promote the DOTS private-public mix as a strategy to eliminate the misuse of loose anti-TB medicines in the private pharmacies and to include private providers in regular training programs for TB control.

REFERENCES

CBS (Central Bureau of Statistics). 1999. *Kenya Population Census*. Nairobi, Kenya: CBS.

CBS. 2005/06. "Kenya Integrated Household Budget Survey."

Chakaya, J. M., H. Meme, D. Kwamanga, W. A. Githui, W. O. Onyango-Ouma, C. Gicheha, F. Karimi, J. Mansoer, and A. Kutwa. 2005. Planning for PPM-DOTS Implementation in Urban Slums in Kenya: Knowledge, Attitude and Practices of Private Health Care Providers in Kibera Slum, Nairobi. *International Journal of Tuberculosis and Lung Disease* 9(4): 403–8.

Dewan, Puneet K., S. S. Lal, Knut Lonnroth, Fraser Wares, Mukund Uplekar, Suvanand Sahu, Reuben Granich, and Lakhbir Singh Chauhan. 2006. Improving Tuberculosis Control through Public-Private Collaboration in India: Literature Review. *BMJ* 332(7541): 574–78.

Hanson, C., and D. Kibuga. 2000. Effective Tuberculosis Control and Health Sector Reforms in Kenya: Challenges of an Increasing Tuberculosis Burden and Opportunities through Reform. *International Journal of Tuberculosis and Lung Disease* 4(7): 627–32.

Hurtig, A. K., S. B. Pande, S. C. Baral, J. D. Porter, and D. S. Bam. 2000. Anti-tuberculosis Treatment in Private Pharmacies, Kathmandu Valley, Nepal. *International Journal of Tuberculosis and Lung Disease* 4(8): 730–6.

Kellerman, S. E., D. Simonds, S. Banerjee, J. Towsley, B. H. Stover, and W. Jarvis. 1998. APIC and CDC Survey of Mycobacterium tuberculosis Isolation and Control Practices in Hospitals Caring for Children. Part 2: Environmental and Administrative Controls. Association for Professionals in Infection control and Epidemiology, Inc. *American Journal of Infection Control* 26(5): 483–7.

Lambert, M. L., R. Delgado, G. Michaux, A. Vols, N. Speybroeck, and P. Van der Stuyft. 2005. Collaboration between Private Pharmacies and National Tuberculosis Programme: An Intervention in Bolivia. *Tropical Medicine and International Health* 10(3): 246–50.

Lambert, M. L., R. Delgado, G. Michaux, A. Volz, and P. Van der Stuyft. 2004. Tuberculosis Control and the Private Health Sector in Bolivia: A Survey of Pharmacies. *International Journal of Tuberculosis and Lung Disease* 8(11): 1325–29.

Lönnroth, K., M. Uplekar, and L. Blanc. 2006. Hard Gains through Soft Contracts: Productive Engagement of Private Providers in Tuberculosis Control. *Bulletin of the World Health Organization* 84(11): 876–83.

MoH (Ministry of Health). 2005. "MoH Public Expenditure Review 2005." Health Care Financing and Expenditure.

National Leprosy and Tuberculosis Program (NLTP). 2005. *Annual Report to the Ministry of Health*. Nairobi, Kenya: Ministry of Health.

Ndege, S., and S. K.Gitau. 2007. *Community-Based DOTS: Report from a Rapid Assessment in Kenya, June 11, 2007.* Submitted to the U.S. Agency for International Development by the MSH/SPS Regional Office Nairobi. Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health

Suleiman, B. A., A. I. Houssein, F. Mehta, and S. G. Hinderaker. 2003. Do Doctors in North-western Somalia Follow the National Guidelines for Tuberculosis Management? *Eastern Mediterranean Health Journal* 9(4): 789–95.

WHO (World Health Organization). 2006a. *Stop TB Partnership: Annual Report 2005.* WHO/HTM/STB/2006.36. Paris: WHO.

WHO. 2006b. *From DOTS to the Stop TB Strategy: Building on Achievements for Future Planning: Meeting of 22 High Burden Countries and Core Groups of the Stop TB Partnership.* WHO: Paris.

WHO. 2006c. *The Global Plan to Stop TB, 2006–2015*. WHO/HTM/STB/2006.38. Geneva: WHO.

APPENDIX A. DATA COLLECTION INSTRUMENTS

Private Pharmacies

Scenario: Data collector will pose as a tuberculosis patient who has been diagnosed with TB by a doctor. Data collector will say to the person attending them at the private pharmacy:

“My doctor said that I have tuberculosis; can I get some medicines here for tuberculosis?”

If medicines are available, the “patient” will then ask:

“What medicines do you recommend?”

Purchase

For each pharmacy where simulated patient surveys are conducted, provide the information on the following page.

Simulated Patient Data Collection Form

Data collector name:

Name of site visited:_____			Generic name of each medicine received	Strength of each medicine received	Daily dose recommended (e.g., number tablets)	Number of doses purchased	Price of doses purchased	Dispenser gave any instructions to patient (see list)	Could purchase medicines without prescription
Province	District	Date						YES NO	YES NO

Simulated Patient: List of Possible Instructions from Dispenser

When you answer the question "Gave instructions to patient" on the Simulated Patient Data Collection Form, you can tick "yes" if the dispenser gave any of the following information—

- You must take all the medicines to get well.
- Your full treatment is for 6 months without stopping.
- If you do not take all the medicines for 6 months, you will infect others in your household with tuberculosis.
- If you do not complete the full treatment, you could die.
- Return to your doctor if you do not feel better in 2 months.
- Any other special instructions
- There are two phases of TB treatment.
- Follow-up sputum examination

Note: If the dispenser gives any other instructions to the simulated patient, please record those instructions below.

Private Treatment Facilities

Province: _____		District: _____
Type of institution: _____		Name facility: _____
Date: _____		

TIME INTERVIEW START: ……..

1. How many TB patients did you diagnose last year? _____
2. How many patients have you diagnosed this year? _____
3. After diagnosis, how do you proceed with treatment?
4. Where do patients normally receive their medicines for treatment?

This treatment facility	□
Another private sector facility	□
Refer to a Ministry of Health facility	□
Local private pharmacy	□
Other: (be specific)_____	□

5. If treated in this health facility, what is the treatment scheme prescribed including medicine name, strength and duration of treatment?

Treatment Scheme using acronyms*	**Medicine name**	**strength**	**duration**

For example: 2RHZE (150/75/400/275 mg)

6. Any instructions to patient?

_____

_____

_____

7. Is TB treatment observed? Yes No

8. If yes, who observes?
   a. Health care worker
   b. Community health worker
   c. Household member
   d. Others: Specify (----------)

9. If yes, how often do you observe intake of medicine?
   a. Daily during intensive phase
   b. Weekly during intensive phase
   c. Monthly during intensive phase
   d. Other (be specific): _____

10. If TB patients are treated in this facility, what is the source of the tuberculosis medicines you dispense?

Medicine supplier from Kenya	□
Imported from supplier in other countries	□
Receive from Ministry of Health sources	□
Donations	□
Other: (be specific)_____	□

11. If medicines are provided in this facility, do patients have to pay for the medicines?
    Yes □ No □

12. If yes, how much do patients have to pay for a full course of treatment?
    _____ Ksh

13. Do you report the outcomes of patients treated to the MOH?

    Yes □ No □

14. What are the reporting tools used by the health facility?

_____

_____

_____

(List them)

15. Is community DOTS practiced in the institution?

    Yes □ No □

16. How many patients are currently supervised by community workers / relatives?

    _____

17. Do you offer counseling and testing for HIV for the TB patients?

    Yes No

    END TIME: _____

TB Medicines Dispensing at Private Pharmacy Assessment Tool

I would like to purchase TB medicines; do you have them? Yes No

Can the pharmacy sell you medicines without prescription Yes or No

If yes, please let me have them, how much will they cost?

If Yes

Were these instructions given?	Yes	No	If yes Prompted?	
			Yes	No
• You must take all the medicines to get well				
• Your full treatment is for 6/8 months without stopping				
• If you do not take all the medicines for 6 months you will infect others in your household with tuberculosis				
• If you do not complete the full treatment you could die				
• Return to your doctor if you don't feel better in 2 months				
• Any other special instructions				
• There are 2 phases of TB treatment				
• Follow up sputum examination				

APPENDIX B. STUDY SUPPORTING DOCUMENTS

Table 23. Other Districts

Province	District	Private Clinics	Official Pharmacy	Mystery Buyer
Eastern	Makueni	2	3	3
	Mwingi	1	2	2
	Kitui	2	2	2
	Tharaka	2	2	2
	Mbeere	1	1	2
	Nyambene	2	3	3
	Total	**10**	**13**	**14**
Nyanza	Kuria	2	2	2
	Homa Bay	2	3	2
	Siaya	2	2	2
	Nyamira	2	2	2
	Bondo	2	2	2
	Rachuonyo	2	3	3
	Total	**12**	**14**	**13**

Table 24. TB Reported Cases 2005

District	Type	New Smear Positive	Retreatment					New Smear Negative			New Extrapulmonary			Total
			Sm. pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total	
Kamakunji	SCC	1,159	176	197	1	6	380	192	581	773	49	327	376	2,688
	%	43	7	7	0	0	14	29			14			100
Langata	SCC	1,221	222	402	0	31	655	505	1354	1859	103	657	760	4,495
	%	27	5	9	0	1	15	41			17			100
Kiambu	SCC	690	38	48	0	27	113	126	668	794	25	204	229	1,826
	%	38	2	3	0	1	6	43			13			100
Kirinyaga	SCC	578	20	6	1	22	49	92	241	333	15	82	97	1,057
	%	55	2	1	0	2	5	32			9			100
Nyeri	SCC	669	51	34	0	12	97	119	593	712	20	229	249	1,727
	%	39	3	2	0	1	6	41			14			100
Kwale	SCC	487	22	104	1	10	137	114	561	675	35	103	138	1,437
	%	34	2	7	0	1	10	47			10			100
Mombasa	SCC	2,937	258	246	1	58	563	310	1456	1766	115	488	603	5,869
	%	50	4	4	0	1	10	30			10			100
Taita Taveta	SCC	228	17	9	3	9	38	25	170	195	16	51	67	528
	%	43	3	2	1	2	7	37			13			100
Embu	SCC	428	28	36	1	5	70	257	1,024	1281	12	118	130	1,909
	%	22	1	2	0	0	4	67			7			100
Kitui	SCC	608	78	149	0	5	232	170	701	871	59	194	253	1,964
	%	31	4	8	0	0	12	44			13			100
Mwingi	SCC	241	42	29	0	1	72	66	220	286	16	75	91	690
	%	35	6	4	0	0	10	41			13			100
Machakos	SCC	893	80	159	3	29	271	257	1103	1360	77	456	533	3,057
	%	29	3	5	0	1	9	44			17			100
Meru	SCC	559	40	13	2	21	76	127	460	587	12	84	96	1,318
	%	42	3	1	0	2	6	45			7			100
Isiolo	SCC	232	36	38	0	0	74	48	272	320	9	36	45	671
	%	35	5	6	0	0	11	48			7			100
Nyambene	SCC	755	27	34	1	40	102	137	547	684	87	147	234	1,775
	%	43	2	2	0	2	6	39			13			100

District	Type	New Smear Positive	Retreatment					New Smear Negative			New Extrapulmonary			Total
			Sm. pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total	
Garissa	SCC	550	40	54	1	0	95	82	255	337	56	126	182	1,164
	%	47	3	5	0	0	8		29			16		100
Wajir	SCC	396	27	63	1	3	94	71	330	401	46	73	119	1,010
	%	39	3	6	0	0	9		40			12		100
Kisumu	SCC	1332	105	178	3	35	321	281	1939	2220	46	323	369	4,242
	%	31	2	4	0	1	8		52			9		100
Siaya	SCC	759	77	61	5	15	158	34	477	511	69	223	292	1,720
	%	44	4	4	0	1	9		30			17		100
Gucha	SCC	304	24	41	1	44	110	54	354	408	12	78	90	912
	%	33	3	4	0	5	12		45			10		100
Kuria	SCC	158	13	15	0	19	47	18	137	155	21	68	89	449
	%	35	3	3	0	4	10		35			20		100
Suba	SCC	357	16	10	0	2	28	27	241	268	11	98	109	762
	%	47	2	1	0	0	4		35			14		100
Bondo	SCC	631	72	41	2	13	128	67	508	575	11	150	161	1,495
	%	42	5	3	0	1	9		38			11		100
Nyando	SCC	728	11	5	0	2	18	112	428	540	44	150	194	1,480
	%	49	1	0	0	0	1		36			13		100
Kericho	SCC	691	37	35	0	15	87	102	431	533	20	143	163	1,474
	%	47	3	2	0	1	6		36			11		100
Nakuru	SCC	1769	76	91	1	74	242	473	1671	2144	101	498	599	4,754
	%	37	2	2	0	2	5		45			13		100
Nandi	SCC	359	26	30	1	51	108	91	354	445	27	101	128	1,040
	%	35	3	3	0	5	10		43			12		100
Trans Nzoia	SCC	419	26	8	0	16	50	378	544	922	39	89	128	1,519
	%	28	2	1	0	1	3		61			8		100
Koibatek	SCC	92	10	0	0	0	10	3	138	141	12	34	46	289
	%	32	3	0	0	0	3		49			16		100

District	Type	New Smear Positive	Retreatment					New Smear Negative			New Extrapulmonary			Total
			Sm. pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total	
Busia	SCC	392	25	48	2	9	84	160	534	694	47	160	207	1,377
	%	28	2	3	0	1	6	50			15			100
Teso	SCC	119	6	15	0	15	36	30	137	167	14	76	90	412
	%	29	1	4	0	4	9	41			22			100

SCC = short course chemotherapy; R.A.D. = return after default.

Table 25. Full List of Reporting Tools Cited by Respondents

Reporting Tool	n	Percentage
NLTP TB facility register	20	24.7
KAPTLD TB facility register	6	7.4
AFB Register	8	9.9
TB referral form	4	4.9
NLTP DADR	4	4.9
NLTP Consumption Drug Requisition Register	3	3.7
KAPTLD DADR	5	6.2
Custom made tools		
Improvised register	2	2.5
Improvised lab register	10	12.3
Chest X-ray register	1	1.2
Sputum collection form	1	1.2
Outpatient Department register	1	1.2
No records	4	4.9
Others		
NLTP appointment cards	4	4.9
KAPTLD appointment cards	1	1.2
Supervision tool	3	3.7
Other MoH forms	3	3.7
Referral letter to MoH	1	1.2
Total	**81**	**100.0**