ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

ASSESSMENT OF TUBERCULOSIS TREATMENT AND QUALITY OF ANTI-TB DRUG MANAGEMENT IN HEALTH FACILITIES IN GAMBELLA REGIONAL STATE, ETHIOPIA

BY

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MAY 2010

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List of abbreviations

AAU	Addis Ababa University
AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CDC	Centre for Disease Control and Prevention
CI	Confidence Interval
DACA	Drug Administration and Control Authority
DHF	Department of Health and Families Affair
DOTS	Directly Observed Treatment Short-course
DST	Drug Sensitivity Test
E	Ethambutol
EPTB	Extra pulmonary Tuberculosis
FDC	Fixed Dose Combination
FDREPCC	Federal Democratic Republic of Ethiopia Population Census Commission
FEFO	First-Expiry/First-Out
FIFO	First-In/First-Out
FMOH	Federal Ministry of Health
GNRS	Gambella National Regional State
H	Isoniazid
HIV-	HIV negative
HIV	Human Immunodeficiency Virus
HIV+	HIV positive
ICN	International Council of Nurses
MDGS	Millennium Development Goals
MDR-TB	Multi-Drug Resistant Tuberculosis
NGO	Non-governmental Organization
PIHCT	Provider Initiated HIV Counselling and Testing
PLWHA	People living with HIV/AIDS
PTB	Pulmonary Tuberculosis
PTC	Pharmacy and Therapeutics Committee

R	Rifampicin
S	Streptomycin
SD	Standard Deviation
TB	Tuberculosis
TBL	Tuberculosis and Leprosy
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
WHO	World Health Organization
WIC	Walta Information Centre
Z	Pyrazinamide

Abstract

Introduction: Tuberculosis is among the chronic infectious diseases in the world which is responsible for a great number of global mortality and morbidity. Its prevalence is highest in developing countries among which the Sub-Saharan Africa is in the front line.

Effectiveness of tuberculosis treatment is measured by the level of treatment success and cure rates achieved. The main factors contributing to low tuberculosis cure rate are prevalence of multi-drug resistant tuberculosis, high level of TB/HIV co-infection, inappropriate prescribing practices by service providers, low quality of DOTS, low level of knowledge among TB patients about their treatment and infrequent and poor quality drug supply to TB patients. This study is, therefore, intended to assess tuberculosis treatment in health facilities in the region in general and the factors which may influence tuberculosis cure rate in particular in order to conclude whether these factors are really contributing to the problem at hand or not. This will greatly help in taking appropriate measures against tuberculosis and the associated factors.

Objective: To assess tuberculosis treatment and quality of anti-TB drug management in health facilities in Gambella Regional State, Ethiopia.

Methodology: A cross-sectional health institution based survey was conducted from 10th July to 20th August, 2009 in six health institutions, where records were reviewed for 823 patients, exit interviews were done among 113 outpatients, key informant interview were done among six tuberculosis care providers and six pharmacy personnel. Observation was made to the store and dispensary units of the respective health institutions. Data was entered using Epi Info version 2002 and analysed using SPSS version 15 statistical soft wares. Qualitative data was manually processed and analysed.

Results: The results of this study showed that total TB/HIV co-infection level in the region was 46.7%, above the national level (31%). There was no significant difference in HIV positivity among female and male tuberculosis patients. Extra pulmonary tuberculosis patients were 1.95 times at a higher risk of contracting HIV than pulmonary tuberculosis patients.

Similarly, re-treatment tuberculosis patients were 2.63 times at a higher risk of contracting HIV than new cases.

Non-adherence to the treatment guide lines was one major prescribing problem among prescribers in all weight categories of patients. Among the anti-TB drugs, Isoniazid, Rifampicin and Pyrazinamide were the most common drugs prescribed in either under doses or over doses.

Around forty-eight percent (47.8%) of the total patients interviewed reported to have been directly observed during the intensive phase and 50.6% of new cases, 39.3% of re-treatment cases, 48.1% of male and 46.7% of female tuberculosis patients said that they were directly observed during the first two months of their treatment. About seventy five percent (75.5%) of the total respondents confirmed that they were informed about the duration of their treatment. But this was 69% among new cases, 75%, 68.75% and 73.3% among re-treatment, male and female TB patients, respectively. Nearly fifty percent (49.6%) of the interviewees reported that the disease would relapse and 46.9% said that they would die of the disease if they failed to take their anti-TB drugs as prescribed.

There was poor drug storage conditions in two out of the six health facilities and moderately adequate in the regional store. Some facilities in support of TB care like water, sputum cups and slides were not available, some in all health facilities and others in certain health facilities. There was staffing problem in the TB clinics and the stores of the health facilities.

Conclusion and Recommendations: The study concluded that the level of TB/HIV co-infection was high in Gambella Regional State. Non-adherence of prescribers to national guide lines and low degree of DOT implementation were prevalent problems in health facilities in the region. It can also be inferred from the study that inadequate storage conditions, staffing and unavailability of facilities in support of TB care were problems in health facilities in the region. Hence, it is recommended that mechanisms should be devised to tackle TB and HIV in a coordinated manner, enforce prescribers to follow national guide lines, facilitate provision of facilities to improve anti-TB drug storage condition and facilities in support of TB care and solve staffing problems.

1. INTRODUCTION

Ethiopia, located in horn of Africa lies between 3 and 15 degree latitude and 33 and 44 degrees East longitude. With a total area of 1.1 million square kilometres, it borders with five countries. These are Eritrea in the north, Djibouti in the east, Sudan in the west, Kenya in the south and Somalia in the south east (FMOH, 2007).

With a total population of 77 million, Ethiopia has become the second populous country in Africa next to Nigeria. The country is administratively divided in to nine regional states namely Oromiya, Amhara, Tigray, Southern Nations, Nationalities and Peoples Regional State, Afar, Harari, Benshangul-Gumuz, Gambella and Somali Regional States and two city administrations namely Addis Ababa and Dire Dawa. Gambella is located at the western tip of the country bordering with Sudan in the west, south and north, Southern Nations, Nationalities and Peoples Regional State in the south and east and the state of Oromiya in the north and east (FMOH, 2007; GNRS, 2008).

Tuberculosis is among the major contributors to global burden of diseases and has received considerable attention in recent years, particularly in low and middle income countries where it is closely associated with HIV/AIDS. According to the WHO Global Report 2007, one-third of the world's population is estimated to be infected with mycobacterium tuberculosis and hence at risk of developing active disease. Globally, in 2005, the annual incidence of TB expressed as the number of new TB cases was about 8.8 million people (7.4 million of these in Asia and sub-Saharan Africa), and the annual number of deaths due to TB was 1.6 million. TB comprises 25% of all avoidable/preventable adult deaths (Yadav et al., 2006; Thakur, 2008; FMOH, 2008).

Nationally, TB is among the top causes of morbidity and mortality. According to the 2007 WHO estimates, the incidence of TB of all forms and smear-positive TB stand at 341 and 152 per 100,000 population, respectively. The prevalence and mortality of tuberculosis of all forms is estimated to be 546 and 73 per 100,000 population, respectively. In the year 2006/07, Ethiopia registered 129,743 cases of TB. According to latest estimates, Ethiopia stands seventh in the list of 22 high burden countries for tuberculosis. According to the ministry of health hospital statistics data, tuberculosis is the leading cause of morbidity, the third cause of

hospital admissions (after deliveries and malaria), and the second cause of death in Ethiopia after malaria (FMOH and AAU, 2005; FMOH, 2008).

One of the indicators used to monitor and assess the tuberculosis prevention and control programme is the tuberculosis case detection rate which is defined as the percentage of new sputum smear positive tuberculosis cases detected out of the estimated number of new sputum smear positive tuberculosis cases. DOTS programme has detected an estimated 53.0% of all new cases and 60.0% of new smear-positive cases in 2005. In 2007/08, a total of 40, 794 new sputum smear positive tuberculosis cases were detected in Ethiopia. The total target has been to achieve 60.0% tuberculosis case detection rate. However, since the current rate stands at 33.9%, the performance is far below the planned target. The case detection rate also varied from one region to another. At 20.3% and 21.0% for Somali and Amhara regions respectively, followed by Tigray (28.6%), Oromiya (35.8%) and Benshangul-Gumuz (38.8%). Gambella, Harari, Afar and Addis Ababa have relatively higher case detection rates than the other regions with 76.9%, 71.4%, 70.0% and 68.0%, respectively (FMOH, 2008; FMOH[a], 2008).

The trend of tuberculosis treatment success rate has shown down ward fluctuations over time around 80% to 85%. In 2007/08, tuberculosis treatment success rate was 84% which is slightly near the international standard (85.0%) excluding 1, 400 cases who were missed and not evaluated. Treatment success rate was good in most of the regional state except in Somali (58.8%). In addition to Somali, It is below 80.0% in Benshangul-Gumuz (76.2%), Addis A baba (77.1%) and Dire Dawa (79.9%). The highest rate was recorded in Afar Regional State (96.5%) (FMOH[a], 2008).

In 2007/08, Tigray, Dire Dawa and Amhara showed the highest cure rate (78.9%, 74.0% and 73.2%, respectively). The lowest tuberculosis cure rate was recorded in Gambella Regional State (39.2%). The cure rate for the other regions was in between the two extremes values mentioned above (FMOH[a], 2008).

This study is therefore, designed to assess the knowledge of tuberculosis out patients about their treatment, the level of TB/HIV Co-infection, DOTS implementation, the storage condition of anti-tuberculosis drugs and the prescribing practice of service providers in Gambella Regional State

2. STATEMENT OF THE PROBLEM

In 2007/08, tuberculosis cure rate went down compared to (67.4%) to 2006/07 level of 69%. The lack of improvement signifies problems related to lack of capacity at the grass-root levels. This issue requires thorough review and taking appropriate measures. Tigray, Dire Dawa and Amhara showed the highest cure rate (78.4%, 74% and 73.2%, respectively) where as Gambella showed the lowest tuberculosis cure rate (39.2%) but higher tuberculosis treatment success rate (greater than 80%). The low tuberculosis cure rate in the region might be due to poor management of anti-tuberculosis drugs by service providers or poor management of anti-tuberculosis drugs in the stores and dispensaries, high level of TB/HIV co-infection, Multi-Drug resistant tuberculosis, and low quality of DOTS in the health facilities in the region (Jindal, 1997; Glynn et al., 1998; WHO[a], 2005; FMOH[a], 2008; WHO[a], 2008).

In order to take appropriate measures against the root causes of the low tuberculosis cure rate prevailing in the region in particular and tuberculosis treatment in general, drug storage conditions, information provision to patients, DOTS implementation and prescribing practice of service providers have to first be thoroughly investigated as to whether they are being implemented in accordance with the standards set in the guide lines or not. In addition, the level of TB/HIV co-infection has to be assessed. This helps to exactly pin point the determinant factors which are not on the right track and target our measure more specifically.

This study is, therefore, intended to assess tuberculosis treatment in health facilities in the region. In addition, the status of the aforementioned factors which can influence tuberculosis cure rate will be dealt with in order to conclude whether these factors are really contributing to the problem at hand or not. This will greatly help in taking appropriate intervention measures against tuberculosis and the associated factors.

3. LITERATURE REVIEW

3.1. Definition and Classification of Tuberculosis

Tuberculosis is a disease caused in most cases by bacteria known as Mycobacterium tuberculosis. This disease primarily affects the lungs, but can attack any organ of the body. Tuberculosis is spread through droplets from one person to another. It spreads from the initial location in the lungs to other parts of the body via the blood stream, the lymphatic system, via the airways or by direct extension to other organs (Enarson et al., 2000; Michalak et al., 2005; Jabar and Haider, 2007; FMOH, 2008; CDC, 2009).

Tuberculosis is a great problem in most low income countries; it is the single most frequent cause of death in individuals aged 15 to 49 years. For this reason, activities directed against tuberculosis as a public health problem are the direct responsibility of government health authorities (Enarson et al., 2000).

Depending on which organ it attacks, tuberculosis may be classified as pulmonary and extra pulmonary tuberculosis. Pulmonary tuberculosis is the most frequent infectious form of the disease, occurring in over 80% of cases. The second category is extra pulmonary tuberculosis which is a type of tuberculosis affecting organs other than the lungs, most frequently pleura, lymph nodes, spine, joints, genitourinary tract, nervous system or abdomen. Tuberculosis may affect any part of the body (Enarson et al., 2000; Askar, 2008; FMOH, 2008).

3.2. Mechanism of Transmission of Tuberculosis

How likely it is that a patient with tuberculosis may infect another person is determined by the concentration of micro-organisms within the lungs and their spread into the surrounding air. Patients with pulmonary tuberculosis in whom the micro-organisms are so numerous as to be seen on microscopic examination of sputum specimens (smear positive cases*)* are the most infectious cases. Those in whom micro-organisms cannot be seen directly under the microscope (smear negative cases*)* are very much less infectious and the severity of their disease is usually less than that of the smear positive cases. Extra pulmonary cases are almost never infectious, unless they have pulmonary tuberculosis as well (Enarson et al, 2000; CDC, 2007; Jabar and Haider, 2007; FMOH, 2008).

The infectious tuberculosis patient expels micro-organisms into the air in tiny droplets when coughing, laughing or sneezing. These small droplets dry rapidly, become droplet nuclei carrying the micro-organisms, and may remain suspended in the air for several hours. Any person entering the room may inhale these droplet nuclei. If the micro-organisms establish themselves in the lungs of the person who inhaled them, and begin to multiply, infection has occurred. Exposure to the micro-organisms is greatest among those in close and prolonged contact with infectious cases i.e. those living in the same household.

The micro-organisms are rapidly destroyed by exposure to sunlight and their concentration in the air is reduced by good ventilation. Except in the event of close and prolonged contact with an infectious case of tuberculosis, the chance of becoming infected from a single contact with a tuberculosis patient is very small. Most individuals who become infected have no symptoms or evidence of illness in association with this infection (Enarson et al., 2000; Jabar and Haider, 2007).

3.3. The Chance of Progression of Tuberculosis Infection to Disease

Among those who do become infected, most (possibly 80-90%) will never become ill with tuberculosis unless their immunity is seriously compromised. The micro-organisms remain dormant within the body and their presence is indicated only by a significant size of induration in reaction to a tuberculin skin test. Some individuals who have become infected subsequently develop disease from this infection (termed tuberculosis). They are less likely to develop disease in the period immediately following infection, but continue to experience a risk of tuberculosis throughout the remainder of their lives (Enarson et al., 2000; ICN, 2004).

3.4. The Impact of HIV on Tuberculosis

Infection with the human immunodeficiency virus (HIV) leads to extensive destruction of the immune defence mechanisms of the body. As a result, those infected with HIV become ill with severe and often deadly diseases to which persons without HIV infection would not usually be susceptible. The development of tuberculosis following infection with tuberculosis micro organisms is usually prevented by the actions of the immune system; this explains why only a relatively small proportion of those individuals who have been infected with

tuberculosis go on to become ill with the disease. When the protection provided by the immune system is reduced by HIV infection, the tuberculosis micro-organisms that are dormant within the body of an individual who has been infected begin to multiply, causing tuberculosis (Yew and Leung, 2007; WHO, 2008; FMOH[a], 2008).

3.4.1. The Level of TB/HIV Co-infection in Ethiopia

Ethiopia is one of the highly affected countries by TB/HIV co-epidemic. The WHO Global Report 2008 estimates that in Ethiopia, 40% of adult TB patients tested for HIV are HIV positive, while routine data from 2006/07 estimates that 31% of tuberculosis patients are HIV positive (FMOH, 2008).

HIV is the primary reason for failure to meet tuberculosis control targets in settings with a high prevalence of HIV. Tuberculosis is a major cause of death in people living with HIV/AIDS (PLWHA). Although sub-Saharan Africa bears the brunt of HIV-fuelled tuberculosis epidemic, the rapidly increasing HIV epidemic in countries in Eastern Europe and in China will also increase the number of people with tuberculosis resulting from HIV infection (WHO, 2005; Nunn et al., 2007).

HIV fuels the tuberculosis epidemic in many ways. HIV promotes progression to active tuberculosis both in people with recently acquired and with latent tuberculosis infection. HIV is the most powerful known risk factor for reactivation of latent tuberculosis infection to active disease. HIV infected people are more susceptible to tuberculosis infection when they are exposed to M. tuberculosis. The life-time risk of active tuberculosis in persons with tuberculosis infection alone is estimated to be only 5-10%, but the annual risk of developing tuberculosis in people living with HIV/AIDS (PLWHA) who are co-infected with M. tuberculosis ranges from 5-15% with an estimated life time risk above 30% (Vaidyanathan and Singh, 2003; Devi et al., 2005; Dessie, 2007).

As indicated in table 1 below, the highest TB/HIV co-infection rate (39%) was recorded in Gambella National Regional State followed by Addis Ababa City Administration (33%) and Amhara National Regional State (27%). The lowest TB/HIV co-infection rate was recorded in Hareri (7%) (FMOH, 2010).

In the table below, the percent of tuberculosis patients tested for HIV for Harari Regional State is more than hundred percent (171%). This is because people who get diagnosed for tuberculosis and HIV in Harari are referred out to health facilities out side Harari (Oromiya Regional State). During calculation, the number of tuberculosis patients who were registered in the health facilities for tuberculosis treatment in Harari Regional State was used as a denominator. But both registered and referred out tuberculosis patients who were tested for HIV were used as a numerator.

Table 1: TB/HIV co-infection level by region in Ethiopia, FMOH, Addis Ababa, 2009

Region	Percent of TB patients tested for HIV	Percent of TB patients co-infected with HIV
Tigray	66	19
Afar	3	21
Amhara	24	27
Oromiya	43	15
Somali	30	6
Benishangul-Gumuz	32	16
Gambella	27	39
Hareri	171	7
Addis Ababa	54	33
SNNPR	29	17
Dire Dawa	50	21
National	**38**	**20**

Source: FMOH, 2010

3.5. Treatment of Tuberculosis

Treatment of tuberculosis has now been standardized by putting patients in to different categories based on smear status, seriousness of the illness and previous history of treatment for tuberculosis. The objectives of anti-tuberculosis treatment are the following: 1) To cure

the patient of tuberculosis by rapidly eliminating most of the dormant bacilli, 2) To prevent death from active tuberculosis or its late effects, 3) To prevent relapse of tuberculosis, 4) To prevent the development of drug resistance by using a combination of drugs, 5) To decrease transmission of tuberculosis to others (DACA, 2004; FMOH, 2008)

The drugs used as first line treatment of tuberculosis both in the intensive phase and continuation phase with their mode of action are the following: Isoniazid (bactericidal), Rifampicin (bactericidal), Pyrazinamide (bactericidal), Ethambutol (bacteriostatic) and Streptomycin (bactericidal) (WHO, 2002; FMOH, 2008).

3.5.1. Phases of Tuberculosis Chemotherapy

Treatment of TB has two phases: intensive (initial) phase and continuation phase. The intensive phase is the phase where three or more drugs are taken for eight weeks (two months) for new cases and twelve weeks (three months) for re-treatment cases with the assumption of making the patient non-infectious by rapidly reducing the load of bacilli in sputum, usually within two to three weeks except in case of drug resistance. During this phase, the drugs must be collected daily by the patient and swallowed under the direct supervision of a health worker. Whereas, the continuation phase is the phase that immediately follows the intensive phase with two or more drugs for four to six months with the assumption of making the patient permanently cured and prevent relapse (DACA, 2004; ICN, 2004; Girma, 2007; FMOH, 2007; FMOH, 2008).

The most important point in any treatment in general and tuberculosis treatment in particular is adherence of patients to their treatment. Tuberculosis patients take three or more drugs in the intensive phase and two or more drugs in the continuation phase. Each drug has its own characteristic side effects which may compromise patient adherence to treatment. This is especially very critical in the intensive phase since patients are new to the side effects of the different anti-tuberculosis drugs. Therefore, different measures may be taken to increase patient adherence and among these the Directly Observed Treatment (DOTS) is the most commonly used.

When used consistently, DOTS increases tuberculosis cure rates by 20 to 50 percent and decreases the proportion of patients who die by 10 to 30 percent. DOTS is also believed to

prevent further emergence of drug resistant strains of tuberculosis. The success of this strategy depends on direct observation during the first two months that the patient follows treatment. Treatment can be observed by any one who is willing, trained, responsible, acceptable to the patient and accountable to the tuberculosis control services (MSH, 2001; Obiri-Danso et al., 2009; Gopi et al., 2006)

The main advantages of DOTS are that the patient does not bear sole responsibility for adhering to treatment. Health care workers, public health officials, government and communities all share responsibility and provide a range of support services necessary for patients to continue and finish treatment. With this in mind, effective tuberculosis treatment emphasizes integrating tuberculosis services in to health services and giving each patient flexibility in where he or she receives treatment (MSH, 2001).

3.5.2. Tuberculosis Treatment Regimens

Table 2: Treatment regimen for category **I** and **III** patients (new cases) FMOH, Addis Ababa, 2009

Patient's weight	Regimen	
	Initial phase (2 months):2(HRZE) daily H 75 mg+R 150 mg+Z 400 mg+E 275 mg	Continuation phase (6 months):6 (EH) daily H 150 mg+E 400 mg
	Number of tablets	
20-29 kg	1 ½	1
30-39 kg	2	1 ½
40-54kg	3	2
55-70 kg	4	3
Over 70 kg	5	3

Source: FMOH, 2008

Table 3: Treatment regimen for category **II** patients (re-treatment cases) FMOH, Addis Ababa, 2009.

Patient's weight	Regimen		
	Initial phase(3months):2(HRZE)S/1(HRZE) daily H 75 mg +R 150mg+ Z 400 mg+ E 275 mg+S 1g		Continuation phase(5months):5 (RH)3 E3 H 75mg+R 150mg+E 400mg
	Number of doses	S 1g	
20-29 kg	1 ½	½	1 ½ +1
30-39 kg	2	½	2+1 ½
40-54 kg	3	¾	3+2
55-70 kg	4	1g	4+3
Over 70 kg	5	1 g	5+3

Source: FMOH, 2008

Table 4: Recommended doses for paediatric treatment FMOH, Addis Ababa, 2009.

Drug	Recommended dose			
	Daily		Three times weekly	
	Dosage and range (Mg/kg of body Wt.)	Maximum (mg)	Dosage and range (Mg/kg of body Wt.)	Maximum (mg)
Isoniazid	5 (4-5)	300	10 (8-12)	-
Rifampicin	10 (8-12)	600	10 (8-12)	600
Pyrazinamide	25 (20-30)	-	35 (30-40)	-
Ethambutol	20 (15-25)	-	30 (25-35)	-
Streptomycin	15 (12-18)	-	15 (12-18)	-

Wt. = weight

Source: FMOH, 2008

3.5.3. Anti-TB Drug Resistance and Its Mechanism of Development

Clinically important resistance to medications is always a man-made problem. Because large populations of tuberculosis micro-organisms always contain some mutants naturally resistant to medications, a substantial population of resistant micro-organisms is always selected when a single medication is used to treat a patient with a large population of micro-organisms. This occurs because only the micro-organisms susceptible to the medications are killed, leaving the resistant micro-organisms to multiply. When the micro organisms in a patient are resistant to all but one of the medications given to that patient, the treatment has the same result as when a single medication is given alone (Enarson et al., 2000; WHO, 2007; FMOH[a], 2008).

There are two important types of resistance to medications in tuberculosis micro-organisms: the first one is acquired or secondary resistance which occurs due to incorrect treatment; for instance, treatment with a single powerful medication in patients with smear positive pulmonary tuberculosis, or administration of powerful medications to a patient harbouring tuberculosis micro-organisms resistant to all but one of the medications which the patient is given and the second one is primary resistance which occurs when a patient develops tuberculosis after being infected by another patient who has resistant micro-organisms. Micro-organisms with resistance to at least the two most important medications, Isoniazid and Rifampicin, are termed "multi-drug resistant" (Puri, 1999; Enarson et al, 2000; WHO, 2004).

The first study on drug resistance of Mycobacterium tuberculosis in Ethiopia was reported in 1984. This study showed resistance to Isoniazid and Streptomycin to be 14.8% and 4.9%, respectively. In 1998, among 179 cultures proven newly registered TB patients in Addis Ababa, only one isolate tested resistant for Rifampicin. However, drug susceptibility was tested in 72 newly registered culture-proven TB cases in Addis Ababa. A total of 46% were HIV positive. Multi-drug resistance was found in 11%. The first country-wide drug-resistance survey in Ethiopia was conducted between 2003 and 2006. The Drug Susceptibility Test (DST) was done for 880 sputum samples (804 new patients and 76 re-treated patients) randomly collected. The drug susceptibility test isolated MDR-TB strain in 1.6% of never treated patients (new cases) and in 11.8% of previously treated patients (FMOH, 2007).

3.6. Quality of Anti-TB Drug Management

The drug management cycle encompasses the process of drug selection, drug procurement, drug distribution and use together with effective management support. It is a systematic approach that you can use to ensure that all drugs for a complete course of treatment are available and appropriately used according to an effective management strategy and timeline. Proper selection, procurement, distribution and use ensures that quality-ensured drugs and medical supplies are reaching the community in general and patients in particular. This will have its own decisive role in achieving the desired treatment outcomes at the end of treatment (MSH, 1997; MSH, 2001).

Drug selection is the process of determining the type of drug products needed for a given health system. It involves reviewing the prevalent health problems, identifying the best clinical treatments for each health problem, choosing individual drugs for each dosage and dosage forms for each clinical treatment and deciding which drugs will be available at each level of the health system (MSH, 1997; MSH, 2001).

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The selected drugs and medical supplies have to be procured from a reliable source. Drug procurement is the process of acquiring drugs through purchase, donation or manufacture. Procurement includes quantifying drug requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring drug quality ensuring adherence to contract terms (MSH, 1997; MSH, 2001).

The procured drugs and medical supplies have to be properly distributed to where they are going to be consumed. Drug distribution includes the process by which an organization receives, transports and stores drugs. The distribution process includes clearing drugs through customs, transporting drugs and medical supplies from central point to depots and health facilities where they are dispensed, controlling stocks and managing stores (MSH, 1997; MSH, 2001).

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The distributed drugs and medical supplies have to be appropriately used by health care providers and patients. Drug use is the process of diagnosing, prescribing, labelling, repacking and dispensing drugs and medical supplies and of securing patient’s adherence to drug treatment. Achieving rational drug use requires effective interventions such as active use of

standard treatment guidelines; training linked to improved drug supply and guided discussion among patients and health care providers (MSH, 1997; MSH, 2001).

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The success of a country's tuberculosis control efforts depends on political commitment from the government and support for the DOTS programme from health professionals. A framework of drug policies and laws upholds public commitment to essential drug supply and so supports the complete drug management cycle. Each country's policy and legal framework needs to define the national goals for drug management. It is important for concerned health policy makers and programme managers to participate in developing and advocating for pharmaceutical laws and regulations that promote a national drug policy with tuberculosis component, registration or licensing of anti-tuberculosis drugs, authority to assure quality, procurement and distribution of high quality anti-tuberculosis drugs, rational use and responses to global tuberculosis control initiatives (MSH, 1997; MSH, 2001).

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The different anti-tuberculosis drugs that are being used in Ethiopia are nationally selected and procured. The management cycle components that are subject to mismanagement are the distribution and use of drugs and medical supplies. Therefore, the prescribing practice of service providers (prescribers), storage condition of anti-tuberculosis drugs in the stores and dispensaries of health facilities needs a thorough investigation in order to know to what extent prescribers are sticking to the standard treatment guide lines and drugs and medical supplies are maintained under appropriate storage conditions (MSH, 1997; MSH, 2001).

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3.6.1. Prescribing Practice of Service Providers

A survey of prescribing pattern among doctors for tuberculosis treatment was conducted in Bolivia. Among 80 prescribed regimens that could be evaluated, there were 58 different regimens: 17(21%) followed the National Tuberculosis Control Program's Standard regimen, but overall 35 regimens (60%) were incorrect-18 regimens (31%) were non-curative and 17(31%) could not be recommended. Frequent errors were the prescribing of medicines not available in the market (7%) or not included in the national regimen (34%), the prescribing of insufficient medication (9%) or of only one in the continuation phase (16%) or for too short (9%) or too long (12%) a period (Olle-Goiq et al., 1999).

Another study was conducted on the topic "Survey of prescribing pattern for osteoarticular tuberculosis". In this study, a questionnaire regarding what anti-tubercular drugs, their dosage and for how long was asked to attending faculty in an international conference on musculoskeletal infection. Thirty different prescriptions were obtained from a total of 52 respondents. Forty-two respondents voted against short course (6 month regimen). The mode value for duration of treatment in the study with Isoniazid and Rifampicin was 12 months; for Pyrazinamide, it was 3 months. There was almost no consensus over the duration of treatment for Ethambutol (Agrawal et al., 2009).

A study in Uzbekistan sampled 30 clusters of seven new tuberculosis patients and enrolled them in a study, interviewed them and their medical records were reviewed. In general the treatment regimens prescribed were correct; doses were higher rather than lower. Second line anti-TB drugs were rarely prescribed. In addition to anti-TB drugs, patients were prescribed with on average seven to eight non-tuberculosis drugs. The rationale for prescribing the non-TB drugs was, however, questionable. Patients incurred substantial cost for these drugs some of which were not without risk (Hasker et al., 2009).

An adequate and appropriate anti-TB drug prescription is of crucial importance in order to cure patients from their disease. A study in Pakistan looked in to the prescribing habits of doctors working in a private teaching hospital. The study showed that the majority of doctors (79%) choosing the correct four drug regimen RHZE in the intensive phase as recommended in the National Guidelines. However, the doses of some drugs were below the recommended ranges (43% of prescriptions for Pyrazinamide and 48% for Ethambutol) (Khan and Hussain, 2003).

3.6.2. Adequacy of Drug Storage Condition

Most drugs and medical supplies can be stored at uncontrolled room temperature. If the product has no special instructions, normal storage conditions apply. This means storage in dry, clean, well-ventilated premises at a temperature of 15 to 25^{O}C or depending on climatic conditions up to 30^{O}C. Less stable drugs must be stored at specific conditions to maintain their effectiveness and prevent contamination. Regarding anti-TB drugs, Isoniazid, Streptomycin, Ethambutol and Pyrazinamide should be stored at room temperature. Rifampicin may be stored up to 40 ^{O}C (MSH, 1997; DACA[1], 2004).

The purpose of studying adequacy of drug storage condition as an indicator of drug quality is to determine the status of anti-TB drugs storage condition in dispensary and stores of the selected health facilities and the regional store as one factor that affects quality. The following conditions are taken as an ideal drug storage conditions. These includes: Cleanliness (absence of litter and dust), signs of pests, security of roof ceiling, presence of vents, protection from direct sunlight, protection from moisture, absence of stock on the floor, separation of store and dispensing area, availability of functional thermometer, availability of stock card systems, if stock cards are in use, do records correspond to counts?

The storage condition in both the drug store and dispensary were assessed with regard to these criteria using a check list and rated according to the following scores (WHO, 2003; Rack et al., 2005; DHF, 2008).

Table 5: Storage condition rating WHO and FMOH, Addis Ababa, 2009.

Storage condition	Rating	Equivalent rating for quality of drugs
Poor	0-3	Quality may be poor
Not adequate	4-5	Quality may be adequate
Moderately adequate	6-7	Acceptable quality
Adequate	8-10	Acceptable quality
More than adequate	11	Good quality

Source: WHO, 2003

3.6.3. Presence of Expired Anti-TB Drugs at Health Facilities

The purpose of this indicator is to determine if expired anti-TB drugs are being distributed as one indicator of drug quality. The actual process involves checking the expiry dates of anti-TB drugs available in the health facilities (WHO, 2003).

A cross-sectional study utilizing interviews, document review, inspection of drug storage conditions, visual inspection of TB drugs and laboratory analysis of samples of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in three institutes, 11 hospitals 38 community hospitals was conducted in southern Thailand. The objective of the study was to assess the quality of anti-TB drugs used in TB treatment facilities and their anti-TB drug management

system. No stock out of anti-TB drugs was found at any level. Thirteen (25%) hospitals/institutes removed coated Ethambutol tablets from their foil packages for daily packing. Eleven (21%) of the hospitals/institutes bisected 400mg coated Ethambutol tablets before dispensing as a non-available 200mg tablet. On the day of inspection, grossly deteriorated Ethambutol was observed in 44% of the hospitals/institutes. All Ethambutol and Isoniazid samples passed the dissolution test. But 62% of Rifampicin and 26% of Pyrazinamide samples failed dissolution test (Rookkapan et al., 2005).

3.7. Other Researches Conducted on the Topic

3.7.1. TB/HIV Co-infection Level

In a study conducted in Oromiya National Regional State, Arsi zone, the overall HIV sero-prevalence rate was 37.2% among tuberculosis patients aged 15 years and above. The highest rate was observed in the age range of 20 to 39 years. Almost equal proportion of males was found to be HIV sero-positive compared to females. Being married was found to be associated with HIV sero-positivity. The divorced and widowed/widower patients had high HIV positivity. Being urban dweller was found to be associated with serum HIV positivity. The HIV positivity rate was higher for pulmonary tuberculosis patients compared to extra pulmonary tuberculosis patients. Smear negative tuberculosis patients were found to be significantly associated with sero-positivity compared with smear positive tuberculosis patients (Wajisso, 2003).

Another study conducted on TB/HIV co-infection rate in the Southern, Nations, Nationalities and Peoples Regional State indicated that among the total 1,308 tuberculosis patients enrolled in the study, 225(18%) were HIV positive. The rate of HIV co-infection was higher in TB patients from urban area (25%) than from rural area (16%). A similar study in the same region documented that the HIV prevalence was 18% for female and 21% for male TB patients. Fifteen percent and 30%, respectively, of the rural and urban patients with TB were HIV positive. Nineteen percent (51/261) smear-positive PTB, 26% (36/137) smear-negative PTB and 11% (10/94) of the extra pulmonary TB patients were HIV positive. The proportion of patients with EPTB varied from 11% to 38% across the centres and was highest in the zones with the lowest HIV prevalence (Datiko et al., 2008; Yassin et al., 2004).

A study conducted in Somaliland on TB/HIV co-infection indicated that out of 800 tuberculosis patients tested for HIV, 10.9% were HIV sero-positive. HIV sero-positivity/prevalence was 11.2% among male tuberculosis patients and 10.2% among female tuberculosis patients. Occupation and marital status were also associated with HIV infection (Askar, 2008).

In a study conducted in Israel among hospitalized tuberculosis patients between January 2000 and December 2006, 93% of them were found to be co-infected with tuberculosis and HIV. Most of the tuberculosis patients came from endemic countries (61.2% from Ethiopia, 20.4% from former Soviet Union, none was born in Israel). From all tuberculosis cases, only 10% were resistant to the first line anti-TB drugs and only 32% showed extra pulmonary involvement. The response rate to the treatment was high with a median hospitalization time of 70 days. The mortality rate was 3.2% (Bendayam et al., 2007).

A study in Eritrea assessed the prevalence of tuberculosis (TB) and human immunodeficiency virus (HIV) co-infection and identified risk factors for HIV infection in smear-positive TB patients diagnosed by the TB programme in Eritrea. Out of 365 notified TB patients, 220 (60.3%) could be traced and provided a blood sample that was tested. Of these, 26 (11.8%) were HIV-infected. Risk factors were age; urban residence and schooling level (van der Werf et al., 2007).

3.7.2. Patient Knowledge about Treatment

A study conducted in north and central regions of Vietnam on knowledge of new pulmonary tuberculosis patients about tuberculosis and its treatment indicated that out of 364 patients interviewed, 93% reported receiving TB information from the health staff. Apart from health education, many patients reported receiving tuberculosis information from television. This was more common among men than women (71.4% versus 51.3%). Patient knowledge was significantly associated with level of education and receiving health education. More than half of the patients expressed fear of being known as tuberculosis patients in the community (Hoa et al., 2009).

In another study conducted in central Omdurman, Sudan on patient's knowledge about tuberculosis and its treatment, 1000 patients were randomly selected. Results revealed general appearance in knowledge about tuberculosis and its treatment among the interviewees. Only

36.2% had satisfactory knowledge about tuberculosis and its treatment. The level of knowledge was inversely proportional to patient's age. Males (38.7%) were more knowledgeable than females (31.4%). The level of knowledge increased with increasing educational level. Respondents treated at health facilities implementing the National Tuberculosis Program Guideline were more knowledgeable (34.5%) compared to those treated at general hospitals and private clinics where there is no commitment to the guideline (23.1%) (Mohammed et al., 2007)

Still another study conducted in Cambodia on "An Assessment Survey of Anti-tuberculosis Drug Management in Cambodia" in one hundred and seven public health facilities with tuberculosis service and sixty-six private pharmacies in fourteen provinces. The result of this study indicated that the prescribing pattern of tuberculosis service providers was acceptable. The level of new smear-positive tuberculosis out-patients' knowledge of tuberculosis treatment was high. The store keepers' inventory practices for tuberculosis drugs indicated a need for improvement. Various tuberculosis drugs were available in the private pharmacies. Tuberculosis drugs in the public sector were similar to international reference prices, although lower than the Global tuberculosis drug facility prices (Uchiyama et al., 2005).

A study conducted in Ethiopia East Showa Zone, Oromiya Regional State on "Assessment of knowledge of the community and tuberculosis patients about tuberculosis and its treatment and quality of anti-TB drugs management" has dealt with knowledge of the community about tuberculosis, patient's knowledge about treatment, TB drug storage condition, personnel working in TB clinics, quality of patient records on TB unit register, available facilities in support of TB care, TB treatment practices, pharmacy personnel and practices in relation to TB drugs and anti-TB drugs stock position. This study described that only 18.2% of the 170 respondents reported that they were directly observed during the first two months of their treatment. Fifty-one percent of the interviewees reported that they used to come daily to collect their drugs. Only 26.5% of the study participants reported that they were told the duration of their treatment, but the proportion of patients who were informed about the side effects of the anti-TB drugs was relatively higher (54.1%). Regarding the consequence of not taking drugs as prescribed, 68.8% reported that the disease would relapse and 30% said that they would die of the disease (Kura, 2007).

A cross-sectional study was conducted based on systematic sampling of consecutive patients with pulmonary tuberculosis symptoms who attended the tuberculosis clinic for their medication at Ilala district hospital, Tanzania. The study sample comprised of 153 patients who were equally distributed among men and women. Seventy-five percent of the subjects were vaccinated against tuberculosis with the majority being 40 years and younger. Half of the study subjects were diagnosed to have TB between the second and fourth month after their symptoms appeared. Chest X-ray was used to start anti-TB therapy in half of the study subjects. No consistency was followed in the diagnostic procedures done to confirm the disease. Over half of the patients admitted that they openly speak about their illness to others but only one-third of their friends and families responded in a considerate or sympathetic way. One-third of their friends and relatives became less friendly and the remaining one-third openly portrayed fear and tried to discriminate the patient even after commencement of medication (Irani et al., 2007).

A health care facility based study in rural and urban settings was conducted in Mwanza region, Tanzania. In this study, when correct answers to five out of seven questions asked was regarded as satisfactory knowledge, only 30% of the study population had satisfactory knowledge of disease and treatment. Persons with information on TB prior to diagnosis and those with higher education were more likely to have satisfactory knowledge. There was a negative correlation between the level of knowledge and patients' age. Knowledge was not significantly affected by sex or area of residence. The two most important sources of information about TB were health workers and former TB patients (Wandwala and Morkve, 2000).

3.8. Tuberculosis Prevention and Control Programmes

According to tuberculosis notification data for 2006 by 202 out of 212 countries and territories reported to the World Health Organization (WHO) in 2007, at global level, there was an estimated 9.2 million new cases of tuberculosis in 2006, including 4.1 million new smear-positive cases and 0.7 million HIV-positive cases. Among the fifteen countries with the highest estimated tuberculosis incidence rate, twelve are in Africa. The high incidence rate ranges from 2% to 15%. The incidence rate estimated for Ethiopia is 3%. One of the targets for the Millennium Development Goals (MDGS) is to halt and reverse the incidence of tuberculosis by 2015. The Stop TB Partnership strategy launched by WHO has set two

additional impact targets which are to halve tuberculosis prevalence and death rates by 2015, compared with their level in 1990 (FMOH[1], 2008; WHO, 2008).

The objective of the tuberculosis control programme is to reduce morbidity, disability and death from tuberculosis. The target for 2007/08 was to increase tuberculosis case detection rate from 32% to 60%. To meet this objective a number of key activities have been planned for implementation. One of the indicators used to assess and monitor tuberculosis prevention and control programme is the tuberculosis case detection rate which is defined as the percentage of new sputum smear positive tuberculosis cases detected out of the estimated number of new sputum smear-positive tuberculosis cases. The national target for 2007/08 has been to achieve a 60% tuberculosis case detection rate. However, the current rate stands at 33.9% far below the planned target, the rate for Gambella Region being higher (76.9%) (FMOH[1], 2008).

3.8.1. The DOTS Strategy

Since 1976, the World Health Organization (WHO) has recommended a strategy called DOTS through which national governments can meet their responsibility to treat patients and prevent the spread of tuberculosis. Ethiopia has adopted this strategy since 1992. DOTS strategy has five essential elements i) Political commitment with increased financing ii) Case-detection through quality assured bacteriology iii) Standardized treatment with supervision and patient support iv) An effective drug supply and management system v) Monitoring and evaluation system, and impact measurement (Elmahalli and Abdel-Aziz, 2007; FMOH[1], 2008).

A study conducted in southern Ethiopia entitled "DOTS improves treatment outcomes and service coverage for tuberculosis" indicated that the introduction and expansion of Directly Observed Therapy Short-course (DOTS) has led to a significant increase in treatment success and decrease in default and failure rates. The smaller institutions exhibited better treatment outcomes compared to the larger ones including the zonal hospital (Shargie and Lindtjorn, 2005).

3.8.2. The Stop TB Strategy

The Stop TB strategy was launched by World Health Organization (WHO) in 2006. It comprises the following elements, 1) Peruse quality DOTS expansion and enhancement involving case finding and cure through an effective patient-centered approach to reach all patients, especially the poor, 2) Address TB/HIV, MDR-TB and other challenges by scaling up TB/HIV joint activities and other relevant approaches, 3) Contribute to health system strengthening by collaborating with other health programmes and general services, for example, in mobilizing the necessary human and financial resources for implementation and impact evaluation and in sharing and applying achievement of tuberculosis control, 4) Involve all care providers, public, non-governmental and private sectors by scaling up approaches based on public-private mix and in sharing and applying achievements of tuberculosis control, 5) Engage people with tuberculosis and affected communities to demand and contribute to effective care. This will involve scaling up community tuberculosis care; creating demand through context specific advocacy, communication and social mobilization; and supporting development of a patient's character for the tuberculosis community, 6) Enable and promote research for the development of new drugs, diagnostics and vaccines. Research will also be needed to improve progamme performance (ICN, 2004; FMOH, 2007; FMOH, 2008).

3.8.3. Global Plan to Stop TB 2006-2015

The global plan for 2006-2015 fully adopts the WHO recommended Stop TB strategy and its implementation over a ten-year period should bring the following achievements. 1) Expansion of equitable access for all to quality tuberculosis diagnosis and treatment, 2) About 50 million people/patients will be treated for tuberculosis under the Stop TB strategy, including about 800,000 patients who are MDR-TB, and about 3 million people who have both tuberculosis and HIV will be enrolled on antiretroviral therapy (ART), 3) Some 14 million lives will be saved from 2006 to 2015, 4) The first new tuberculosis drug for 40 years will be introduced in 2010 with a new short course tuberculosis regimen (1-2 months) soon after 2015, 5) By 2010, diagnostic agents at the point of care will allow rapid, sensitive and inexpensive detection of active tuberculosis, 6) By 2012, a diagnostic tool box which accurately identifies those at higher risk of progression to disease, 7) By 2015, a new, safe, effective and affordable vaccine will be available with potential for significant impact on tuberculosis control in later years (ICN, 2004; FMOH, 2007).

4. OBJECTIVE

4.1. General Objective

To assess tuberculosis treatment and quality of anti-tuberculosis drugs management in health facilities in Gambella Regional State.

4.2. Specific Objectives

- To determine the level of TB/HIV co-infection in Gambella Regional State.
- To assess the prescribing practice of service providers for anti-tuberculosis drugs in Gambella Regional State.
- To assess the knowledge of TB outpatients about their treatment.
- To assess the supply and overall quality of anti-TB drug management in the selected health facilities in Gambella Regional State.

5. METHODOLOGY

5.1. Study Design

The study was both prospective and retrospective descriptive cross-sectional study using primary (observation and interview) and secondary data (record review) from the health institutions selected in Gambella Regional State. Quantitative and qualitative methods were employed in the data collection. The quantitative methods were retrospective review of patient medical records and structured interview to measure the knowledge of tuberculosis out patients about their treatment. The qualitative method was observation to measure TB drug stock outs, expiration, availability of facilities in support of TB care and discrepancy between inventory records and physical counts. Data collection was conducted from July 2009 to August 2009.

5.2. Description of Study Area

Gambella National Regional State is located in the western tip of Ethiopia bordering with Sudan in the west, south and north, the state of Southern Nations, Nationalities and Peoples Regional State in the south and east and the state of Oromiya in the north and east. The area of the state is estimated at 25,274 square kilometres. The region has four administrative zones and thirteen woredas. The main nationalities of the region are the Nuer, Agnuak, Amhara, Oromo, Mezhenger, Keffa, Mocha, Tigreway and other groups predominantly from the southern Ethiopia. The working language in the region is Amharic. The total population of the region is 306,916 of whom 159,679 are men and 147,237 are women (FMOH, 2007; GNRS, 2008; FDREPCC, 2008).

About ninety percent of the population of Gambella is rural inhabitant and most of the people are thus subsistence farmers, selling some of their produce at local markets. Major economy in the region appears to be the cultivation of coffee, exploration of gold and the government farms. The region has 212 primary and secondary schools and 3 colleges. With regard to health infrastructure, the region has one regional hospital, 9 health centres five of which are governmental and the other four are non-governmental. There are also 23 health stations, 32 health posts, and 12 private clinics not for profit. The total health coverage in the region is 55% (FMOH, 2007; FMOH, 2006; GNRS, 2008; UNICEF, 2006; WIC, 2010).

5.3. Variables

5.3.1. Dependent Variables

- Level of TB/HIV co-infection in Gambella Regional State.
- Knowledge of tuberculosis out patients about their treatment.
- Presence or absence of facilities in support of TB care.
- Management of anti-tuberculosis drugs in the health facilities.
- Prescribing practice of service providers.

5.3.2. Independent Variables

- Training level of service providers.
- Practice of pharmacy personnel related to anti-TB drugs.
- Socio-demographic (age, sex, marital status) and socio-economic (income, occupation) characteristics of patients.
- Prevalence of HIV/AIDS in Gambella Regional State.

5.4. Source Population

The source population includes all hospitals, health centres, tuberculosis out patients, pharmacy personnel, tuberculosis care providers and tuberculosis patient records in Gambella Regional State.

5.5. Study Population

The study population includes 113 tuberculosis out patients, 823 tuberculosis patient records, six pharmacy personnel, six tuberculosis care providers, Gambella hospital, Gambella health centre, Itang health centre, Abobo health centre, Pignido health centre and Meti health centre.

5.6. Inclusion and Exclusion Criteria

5.6.1. Inclusion Criteria

- Tuberculosis out patients who are under treatment during the time of data collection were included.

- Patient records from September 01, 2007 to March 30, 2009 were included.
- Government hospitals and health centres having adequate data and patient flow were included.
- Non-governmental health institutions that take drug and medical supplies from the regional health bureau and report to the regional health bureau were included.

5.6.2. Exclusion Criteria

- Tuberculosis patient records before September, 2007 were excluded.
- Health stations and Health posts were excluded.
- All except one non-governmental health centres, governmental health centres which started operation recently and a health centre with very low patient flow were excluded.

5.7. Sampling and Sample Size Determination

Four of the five governmental health centres in the region were included in the study. This was done because one of the governmental health centres (Lare health centre) did not have sufficient patient flow. One non-governmental health centre which uses all drugs and medical supplies from the regional health bureau and reports drug consumption and morbidity and treatment outcomes to the regional health bureau was included in the sample. There was only one hospital in Gambella regional state and that was included in the study. The sample size for patient record review was all tuberculosis patient records (823) from September 01, 2007 to March 30, 2009. This was done because there was no patient record in the hospital before September, 2007. The sample size for tuberculosis outpatients exit interview was 30 patients from each health facility and a total of 180 from the six health facilities according to WHO recommendation (WHO, 2003). But it was possible to interview only 113 tuberculosis outpatients because of limited patient flow.

5.8. Data Collection and Management

5.8.1. Data Collection Instruments

Standard questionnaires were developed to collect data on TB out patients' knowledge about their treatment and practice of pharmacy personnel related to anti-TB drugs. An observation check list was prepared for collecting data on the status of anti-TB drug management at storage and dispensary units and availability of facilities in TB care. Data abstraction format was developed for collecting data on prescribing practice of service providers and TB/HIV co-infection from patient records.

5.8.2. Data Collectors

Data collectors for data abstraction from patient records were nurses working in the tuberculosis clinics at each health facility. Data collected from observation and by interviewing pharmacy personnel in relation to their practice to anti-TB drugs were collected by the principal investigator himself. But exit interview was conducted by the principal investigator and trained data collectors who know the local language. Training was organized for all data collectors on the aim of the study and method of data collection.

5.9. Data Quality Assurance

Questionnaire prepared in English was carefully translated to Amharic, and then back translated to English to maintain its consistency. Training of data collectors about the objective, content and process of data collection was given until it was assured that the trainees clearly understood the content. The questionnaires and data abstraction format were pre-tested and appropriate modifications like number of tablets taken and the no service option in the data abstraction format were made on these instruments. In addition, the principal investigator checked for the completeness, accuracy and clarity of the questionnaire. Errors, ambiguities and incompleteness were being addressed on each day before starting the next day activities.

5.10. Data Entry and Analysis

Data was entered using Epi Info 2002 and analysed using SPSS Version 15 statistical packages. Frequency tables were used for presenting the descriptive results. Qualitative data was manually processed and analysed.

5.11. Operational Definitions

New TB patient: A patient who has never been treated before for a month or more.
TB treatment cure rate: proportion of new smear positive tuberculosis patients that successfully completed treatment with bacteriological evidence of cure.
TB treatment success rate: proportion of new smear positive tuberculosis patients that successfully completed treatment with or without bacteriological evidence of success.

5.12. Ethical Considerations

The research proposal was approved by the ethical committee of the School of Pharmacy, Addis Ababa University. Then letter of cooperation was written to Gambella Regional Health Bureau. Letters of cooperation were also written from Gambella Regional Health Bureau to the respective health facilities. Permission was secured from the health facilities in which the research was conducted. Careful attention was given to ensure that all those who participated in the study did so voluntarily, and verbal informed consent was obtained from each participant since the issue is not sensitive and hence does not need written consent. Those who agreed to participate were given a chance to ask any additional explanation about points on which they were not clear with or not addressed by the principal investigator. Confidentiality was maintained for all records reviewed as it was conducted by the nurses working in the tuberculosis clinics who already know the patients.

6. RESULTS

6.1. Record Review

6.1.1. Demographic Characteristics of Study Participants from Record Review

A total of 823 patient records were reviewed from the six selected health institutions. Out of the total study participants, 364 (44.2%) were females and 459 (55.8%) were males. The mean age of the study participants was 25 years (SD=13.56). Three-fourth of the study participants, 621 (75.5%) were within the age group of 15 to 49 years (Table 6).

The initial mean weight of the study participants was 41.3 (SD=15.13). The majority of the study participants, 449(54.6%) were within the weight range of 39.5 to 54.4 kilograms.

Table 6. Sex and age characteristics of tuberculosis patients from record review, Gambella Regional State, Ethiopia, 2009 (N=823)

Variable	N	Percentage
Sex		
Male	459	55.8%
Female	364	44.2%
Age group		
0-14	161	19.6%
15-49	621	75.5%
50-64	36	4.4%
≥65	5	0.06%
Weight category		
≤7.4	32	3.9%
7.5-9.4	14	1.7%
9.5-14.4	37	4.5%
14.5-19.4	34	4.1%
19.5-29.4	32	3.9%
29.5-38.4	95	11.5%
39.5-54.4	449	54.6%
54.5-70.4	128	15.6%
≥70.5	2	0.2%
Total	823	100.0%

Age = in years Weight = in kilograms

6.1.2. TB/HIV Co-infection Level

6.1.2.1. Total TB/HIV Co-infection Level

A total of 276 tuberculosis patients were tested for HIV in five of the health facilities. One health centre did have complete HIV status record for TB patients. The number of male and female tuberculosis patients who were tested for HIV was 144(52.2%) and 132(47.8%) respectively. The mean age of tuberculosis patients who were tested for HIV was 26.7 (SD=12.47). The total TB/HIV co-infection rate/level for the selected health facilities was found to be 46.7%; of whom 25.7% are males and 21% are females. There was no significant difference in the proportion of HIV positivity among female and male tuberculosis patients. There was also no significant difference in the proportion of HIV positivity among different age categories of TB patients (Table 7).

Table 7: Sex and age characteristics of study participants for TB/HIV co-infection, Gambella Regional State, Ethiopia, 2009(N=276)

Variable	HIV Positive N (%)	HIV Negative N (%)	Total 276(%)	Odds Ratio(95% CI)
Sex				
Male	71(49.3)	73(50.7)	144(52.2)	1.00*
Female	58(43.9)	74(56.1)	132(47.8)	0.81(0.41-1.33)
Age				
0-14	15(41.7)	21(58.3)	36(13.0)	1.00*
15-19	9(36.0)	16(64)	25(9.1)	0.79(0.24-2.55)
20-29	60(53.1)	53(46.9)	113(40.9)	1.55(0.70-3.63)
30-39	32(54.2)	27(45.8)	59(21.4)	1.66(0.66-4.18)
40-49	9(30.0)	21(70)	30(10.9)	0.60(0.19-1.88)
50-59	2(28.6)	5(71.4)	7(2.5)	0.56(0.06-4.02)
≥60	2(3.3)	4(66.7)	6(2.2)	0.70(0.08-5.43)
Total	129(46.7)	147(53.3)	276(100.0)	

6.1.2.2. TB/HIV Co-infection Level by Health Facility

The prevalence of HIV positivity varied depending on the number of study participants from each health facility. However, the highest TB/HIV co-infection level was found in Gambella hospital (53.5%) followed by Abobo health centre (20.2%) and Meti health centre (13.9%). The lowest TB/HIV co-infection rate was found in Pignido health centre (4.6%) (Table 8).

Table 8: TB/HIV co-infection by health facility, Gambella Regional State, Ethiopia, 2009(N=276).

Health Facility	HIV Positive N=129	HIV Negative N=147	Total N=276
Gambella Hospital	69(53.5%)	26(17.7%)	95(34.4%)
Itang Health Centre	10(7.8%)	23(15.7%)	33(12.0%)
Abobo Health Centre	26(20.2%)	50(34.0%)	76(27.5%)
Pignido Health Centre	6(4.6%)	19(12.9%)	25(9.1%)
Meti Health Centre	18(13.9%)	29(19.7%)	47(17.0%)

6.1.2.3. TB/HIV Co-infection among Pulmonary and Extra pulmonary TB Patients

The total number of HIV negative tuberculosis patients was 147, and among them 30(41.1%) presented with extra pulmonary tuberculosis and 117(57.6%) presented with pulmonary tuberculosis. Among the tuberculosis cases, 129 were HIV positive; of whom 43(58.9%) presented with extra pulmonary tuberculosis and 86(42.4%) presented with pulmonary tuberculosis. HIV positivity is higher among extra pulmonary TB patients than those with pulmonary TB and this difference was statistically significant with an odds ratio of 1.95(95% CI 1.09-3.48) (Table 9).

Table 9: HIV positivity among extra pulmonary and pulmonary tuberculosis patients, Gambella Regional State, Ethiopia, 2009(N=276)

TB category	HIV + N	HIV- N	Total N	Odds Ratio (95% CI)
Pulmonary	86(42.4%)	117(57.6%)	203(73.5%)	1.00*
EPTB*	43(58.9%)	30(41.1%)	73(26.5%)	1.95(1.09-3.48)
Total	129(46.7%)	47(53.3%)	276(100.0%)	

EPTB* = Extra pulmonary

6.1.2.4. TB/HIV Co-infection among Smear-positive and Smear-negative Cases

The total number of HIV negative tuberculosis patients was 147, and among them 73(61.3%) presented with smear-positive tuberculosis and 44(52.4%) presented with smear-negative tuberculosis. Among the pulmonary tuberculosis cases, 86(42.4%) were HIV positive; of whom 46(38.7%) presented with smear-positive tuberculosis and 40(47.6%) presented with smear-negative tuberculosis. The proportion of HIV positivity is higher among smear-negative TB cases than those with smear-positive tuberculosis even though this difference is not statistically significant with an odds ratio of 1.44(95% CI 0.79-2.64) (Table 10).

Table 10: HIV positivity among Smear-positive and Smear-negative tuberculosis patients, Gambella Regional State, Ethiopia, 2009(N=203).

Smear Status	HIV Positive	HIV negative	Total	Odds Ratio (95% CI)
Smear-positive	46(38.7%)	73(61.3%)	119(58.6%)	1*
Smear-negative	40(47.6%)	44(52.4%)	84(41.4%)	1.44(0.79-2.64)
Total	86(42.4%)	117(57.6%)	203(100.0%)	

6.1.2.5. TB/HIV Co-infection among New and Re-treatment Cases

There was a marked difference in HIV positivity between new and re-treatment cases of tuberculosis patients. The total number of HIV negative tuberculosis patients was 147; of whom 141(54.9%) were new cases and 6(31.6%) were re-treatment cases. From the total of 276 tuberculosis patients tested for HIV, 129 were confirmed to have been infected with HIV and among them 116(45.1%) were new cases and 13(68.4%) were re-treatment cases. The odds ratio of HIV positivity between re-treatment and new cases was 2.63(95% CI 0.90-8.05). This indicates that re-treatment cases are 2.63 times more prone to HIV infection than new cases (Table 11).

Table 11: HIV positivity among new and re-treatment cases of tuberculosis patients, Gambella Regional State, Ethiopia, 2009(N=276).

Pt. category	HIV Positive N	HIV Negative N	Total N	Odds Ratio (95% CI)
New cases	116(45.1%)	141(54.9%)	257(93.1%)	1.00*
Retrt. cases	13(68.4%)	6(31.6%)	19(6.9%)	2.63(0.90-8.05)
Total	129(46.7%)	147(53.3%)	276(100%)	

Pt. = Patient, Retrt. = Retreatment

6.1.3. Prescribing Practice of Service Providers

The assessment of the prescribing practice of service providers (prescribers) for new and re-treatment cases both in the intensive (initial) and continuation phases of tuberculosis treatment was done by comparing the regimens that were actually being prescribed to patients with the regimen that is recommended in the recent guideline for each weight category of tuberculosis patients (FMOH, 2008).

6.1.3.1. Prescribing Practice of Service Providers for New Cases in the Intensive and Continuation Phases

A total of 823 patient treatment records were reviewed for assessing the prescribing practice of service providers of whom 783 were new cases and the remaining 40 were re-treatment cases. In both cases, the proportion of correct and incorrect prescriptions for each particular drug are specified (Table 12).

From all patient treatment records reviewed for new cases in the intensive phase, Rifampicin and Isoniazid were correctly prescribed in 641(81.9%) cases and incorrectly prescribed in 142(18.1%) cases. Similarly, Pyrazinamide was correctly and incorrectly prescribed in 657(84.0%) and 125(16.0%) cases respectively. The proportion of cases where Ethambutol was correctly prescribed was 621(88.2%). However, Streptomycin was prescribed in only two cases and the proportion of correct and incorrect prescriptions was just fifty-fifty.

In the continuation phase, Rifampicin was prescribed correctly and incorrectly in 64(50.4%) and 63(49.6%) cases respectively. Isoniazid was correctly prescribed in 571(72.9%) cases and incorrectly prescribed in 212(27.1%) cases. Similarly, Ethambutol was correctly prescribed in 558(85.1%) cases and incorrectly prescribed in 98(14.9%) cases.

More than 50% of the prescriptions (422/823) were made in the weight category of 39.5 to 54.4 kilograms. The proportion of correctly prescribed anti-TB drugs in this category was nearly 100%.

Table 12: Prescribing practice of service providers for new tuberculosis cases, Gambella Regional State, Ethiopia, 2009 (N=783)

Weight Range (kg)	Drug Regimen					
	Intensive Phase N = 783			Continuation Phase N = 783		
	Drug	Correct	Incorrect	Drug	Correct	Incorrect
≤ 7.4 kg	R	10(31.25%)	22(68.75.0%)	R	6(18.75%)	26(81.25%)
	H	10(31.25%)	22(68.75%)	H	6(18.75%)	26(81.25%)
	Z	14(43.75%)	18(56.25%)	E	1(100%)	-
	E	16(50%)	8(30.8%)			
	S	-	1(100.0%)			
7.5-9.4 kg	R	14(100%)	-	R	14(100%)	-
	H	14(100%)	-	H	12(85.7%)	2(14.3%)
	Z	12(85.7%)	2(14.3%)			
	E	14(100%)	-			
9.5-14.4 kg	R	5(13.9%)	31(86.1%)	R	24(66.7%)	12(33.3%)
	H	5(13.9%)	31(86.1%)	H	20(55.6%)	16(44.4%)
	Z	22(61.1%)	14(38.9%)			
	E	6(25.0%)	18(75.0%)			
	S	-	1(100.0%)			
14.5-19.4 kg	R	14(41.2%)	20(58.8%)	R	20(62.5%)	12(37.5%)
	H	14(41.2%)	20(58.8%)	H	19(55.9%)	15(44.1%)
	Z	12(35.3%)	22(64.7%)	*E	2(5.9%)	-
	E	15(71.4%)	6(28.6%)			
19.5-29.4 kg	R	24(77.4%)	7(22.6%)	*R	1(8.3%)	11(91.7%)
	H	24(77.4%)	7(22.6%)	H	12(38.7%)	19(61.3%)
	Z	24(77.4%)	7(22.6%)	E	12(63.2%)	7(36.8%)
	E	19(79.2%)	5(20.8%)			
29.5-39.4 kg	R	52(57.8%)	38(42.2%)	*R	-	2(100.0%)
	H	52(57.8%)	38(42.2%)	H	22(24.4%)	68(75.6%)
	Z	52(57.8%)	38(42.2%)	E	24(27.0%)	65(73.0%)
	E	43(59.7%)	28(38.9%)			
	S	1(100.0%)	-			
39.5-54.4 kg	R	422(99.5%)	2(0.5%)	H	380(89.6%)	44(10.4%)
	H	422(99.5%)	2(0.5%)	E	420(99.1%)	4(0.9%)
	Z	421(99.3%)	2(0.5%)			
	E	421(99.3%)	-			
54.5-70.4 kg	R	100(83.3%)	20(16.1%)	H	98(81.7%)	22(18.3%)
	H	100(83.3%)	20(16.1%)	E	98(81.7%)	22(18.3%)
	Z	100(83.3%)	20(16.1%)			
	E	91(73.4%)	16(12.9%)			
≥70.5 kg	R	-	2(100.0%)	H	2(100%)	-
	H	-	2(100.0%)	E	2(100%)	-
	Z	-	2(100.0%)			
	E	-	1(50.0%)			
Total	R	641(81.9%)	142(18.1%)	R	64(50.4%)	63(49.6%
	H	641(81.9%)	142(18.1%)	H	571(72.9%)	212(27.1%)
	Z	657(84.0%)	125(16%)	E	558(85.1%)	98(14.9%)
	E	621(88.3%)	82(11.7%)	-	-	-
	S	1(50.0%)	1(50%)	-	-	-

***** = indicates inappropriate use of a drug type

6.1.3.2. Incorrect Prescribing Practices in New TB Cases in the Intensive and Continuation Phases

The total number of incorrect prescriptions made in the different weight categories for each specific anti-tuberculosis drug both in the intensive and continuation phases in new tuberculosis cases were classified in to under dose and over dose prescribing errors (Table 13).

In the new tuberculosis cases, there were a total of 865 incorrect drug prescriptions made for all the five anti-tuberculosis drugs; of which 290(33.5%) were made in under doses and 575(66.5%) were in over doses.

Out of the total 865 incorrect anti-tuberculosis drug prescriptions made in the new cases, 492 were in the intensive phase and 373 were in the continuation phase. In both the intensive and continuation phases, the number of over dose prescriptions was greater than the number of under dose prescriptions for all anti-tuberculosis drugs.

Table 13: Incorrect treatment regimens in new tuberculosis cases in the intensive and continuation phases, Gambella Regional State, Ethiopia, 2009(N=783)

Weight Range(kg)	Incorrect Drug Regimen					
	Intensive Phase			Continuation Phase		
	Drug	Under dose	Over dose	Drug	Under dose	Over dose
≤ 7.4 kg	R	6(27.3 %)	16(72.7%)	R	1(3.8%)	25(96.2%)
	H	6(27.3%)	16(72.7%	H	1(3.8%)	25(96.2%)
	Z	11(50.0%)	11(50.0%)			
	E	6(75%)	2(25%)			
	S	-	1(100%)			
7.5-9.4 kg	R	-	-	R	-	-
	H	-	-	H	-	2(100%)
	Z	-	2(100%)			
9.5-14.4 kg	R	20(64.5%)	11(35.5%)	R	1(8.3%)	11(91.7%)
	H	20(64.3%)	11(35.5%)	H	1(6.25%)	15(93.75%)
	Z	2(14.3%)	12(85.7%)			
	E	15(83.3%)	3(16.7%)			
	S	-	1(100%)			
14.5-19.4kg	R	1(5%)	19(95%)	R	-	12(100%)
	H	1(5%)	19(95%)	H	-	15(100%)
	Z	1(4.5%)	21(95.5%)			
	E	-	6(100%)			
19.5-29.4kg	R	-	7(100%)	*R	10(90.9%)	1(9.1%)
	H	-	7(100%)	H	11(57.9%)	8(42.1%)
	Z	-	7(100%)	E	1(14.3%)	6(85.7%)
	E	-	5(100%)			
29.5-39.4kg	R	2(5.3%)	36(94.7%)	*R	2(100.0%)	-
	H	2(5.3%)	36(94.7%)	H	7(10.3%)	61(89.7%)
	Z	2(5.3%)	36(94.7%)	E	2(3.1%)	63(96.2%)
	E	1(3.4%)	27(96.4%)			
39.5-54.4kg	R	2(100%)	-	H	28(54.5%)	16(36.4%)
	H	2(100%)	-	E	-	4(100%)
	Z	2(100%)	-			
54.5-70.4kg	R	20(100%)	-	H	20(90.9%)	2(9.1%)
	H	20(100%)	-	E	20(90.9%)	2(9.1%)
	Z	20(100%)	-			
	E	16(100%)	-			
≥70.5 kg	R	2(100.0%)	-	H	-	-
	H	2(100.0%)	-	E	-	-
	Z	2(100.0%)	-			
	E	1(50.0%)	-			
Total	R	53(37.3%)	89(62.7%)	R	14(22.2%)	49(77.8%)
	H	53(37.3%)	89(62.7%)	H	68(32.1%)	144(67.9%)
	Z	40(32.0%)	85(68.0%)	E	23(23.5%)	75(76.5%)
	E	39(47.6%)	43(52.4%)			
	S	-	1(100.0%)			

6.1.3.3. Prescribing Practice of Service Providers for Re-treatment Cases in the Intensive and Continuation phases

The prescriptions for the different anti-TB drugs in the re-treatment case for all weight categories in the intensive and continuation phases are classified in to correct and incorrect prescriptions for each specific drug (Table 14).

In the re-treatment tuberculosis cases, there were a total of 308 prescriptions for all the anti-tuberculosis drugs. From these, 232 were correct and 76 were incorrect prescriptions. One hundred ninety three of the total drug prescriptions were made in the intensive phase and 115 were in the continuation phase.

Table 14: Prescribing practice of service providers for re-treatment TB cases in the intensive and continuation phases, Gambella Regional State, Ethiopia, 2009 (N=40)

Weight Range (kg)	Drug Regimen					
	Intensive Phase			Continuation Phase		
	Drug	Correct	Incorrect	Drug	Correct	Incorrect
9.5-14.4 kg	R	1(100.0%)	-	R	1(100.0%)	-
	H	1(100.0%)	-	H	1(100.0%)	-
	Z	1(100.0%)	-			
	E	1(100.0%)	-			
19.5-29.4 kg	R	-	1(100.0%)	R	-	1(100.0%)
	H	-	1(100.0%)	H	-	1(100.0%)
	Z	-	1(100.0%)	E	-	1(100.0%)
	E	-	1(100.0%)		-	-
	S	-	1(100.0%)		-	-
29.5-39.4 kg	R	3(60.0%)	2(40.0%)	R	-	4(100.0%)
	H	3(60.0%)	2(40.0%)	H	-	5(100.0%)
	Z	3(60.0%)	2(40.0%)	E	-	5(100.0%)
	E	3(60.0%)	2(40.0%)			
	S	-	5(100.0%)			
39.5-54.4 kg	R	24(96%)	1(4%)	R	19(76%)	6(24%)
	H	24(96%)	1(4%)	H	8(32%)	17(68%)
	Z	24(96%)	1(4%)	E	23(92%)	2(8%)
	E	24(96%)	1(4%)			
	S	17(81%)	4(19%)			
54.5-70.4 kg	R	8(100.0%)	-	R	5(100.0%)	-
	H	8(100.0%)	-	H	4(50.0%)	4(50.0%)
	Z	8(100.0%)	-	E	5(62.5%)	3(37.5%)
	E	8(100.0%)	-			
	S	7(87.5%)	1(12.5%)			
Total	R	36(90.0%)	4(10.0%)	R	25(69.4%)	11(30.6%)
	H	36(90.0%)	4(10.0%)	H	13(32.5%)	27(67.5%)
	Z	36(90.0%)	4(10.0%)	E	28(71.8%)	11(28.2%)
	E	36(90.0%)	4(10.0%)			
	S	22(66.7%)	11(33.0%)			

***** = indicates inappropriate use of a drug type

6.1.3.4. Classification of Incorrect Prescribing of Anti-TB Drugs in Re-treatment Cases in the Intensive and Continuation Phases

The prescriptions for each anti-tuberculosis drugs for all weight categories in the intensive and continuation phases are classified in to correct and incorrect prescriptions for each specific drug (Table 14).

In the re-treatment case, a total of 76 incorrect drug prescriptions were made of which; 8 were made in under doses and 68 were made in over doses. Out of the total 76 drug prescriptions, 27 were made in the intensive phase and 49 were in the continuation phase. The majority of the prescriptions errors were made in over doses.

6.2. Exit Interview with Patients

6.2.1. Socio-demographic Characteristics of TB out Patients

As shown in table 15, a total of 113 tuberculosis outpatients were interviewed from the six health facilities included in the study; of whom 68(60.2%) were males and 45(39.8%) were females. During the interview, parents or guardians were interviewed for children and for those who can not manage themselves. The mean age of the respondents was 26.4 years (SD=13.42). Eighteen (15.9%) of the out patients interviewed were aged 1 to 14 years and 88(77.9%) of the respondents were within the age range of 15-49 years. Four (3.5%) were in the age range of 50 to 64 years. The remaining 3(2.7%) were aged 65 years and above.

The majority of the respondents were never married, 49(43.4%) and currently married, 46(40.7%). Divorced and widowed both constituted 18(15.9%) of the total respondents. Forty-five (39.8%) of the respondents were Orthodox Christians; while Catholic and Protestant both constituted 48(42.5%). Muslims constituted 16(14.2%) of the total respondents.

Thirty (26.5%) of the respondents were illiterates whereas 30(26.5%) were 1 to 6 grades. Thirty-nine (34.5%) were 7 to 12 grades. There was only one respondent who could read only. Four (3.5%) respondents were able to read and write and those having college/university education constituted 9(8.0%).

Table 15: Socio demographic characteristics of exit interview TB out patients, Gambella Regional State, Ethiopia, 2009(N=113).

Characteristics	N (%)
Sex	
Male	68(60.2)
Female	45(39.8)
Age	
1-14	18(15.9)
15-49	88(77.9)
50-64	4(3.5)
≥65	3(2.7)
Marital status	
Never married	49(43.4)
Currently married	46(40.7)
Divorced/separated	10(8.9)
Widowed	8(7.1)
Religion	
Orthodox	45(39.8)
Other Christian	48(42.5)
Muslim	16(14.2)
Others*	4(3.6)
Education	
Illiterate	30(26.5)
Read only	1(0.9)
Read and write	4(3.5)
1-6 grade	30(26.5)
7-12	39(34.5)
College education/graduate	9(8.0)
Occupation	
Farmer	33(29.2)
Civil servant	16(14.2)
Student	28(24.8)
House wife	11(9.7)
Merchant	4(3.5)
Daily labourer	6(5.3)
No job	10(8.8)
Others**	5(4.4)

Others* = No religion, Others** = Priests + Employees in private organizations and NGOs

6.2.2. Patient's Knowledge about TB Treatment

Out of the total 113 TB out patients interviewed, 54(47.8%) reported that they were directly observed by tuberculosis care providers while taking their drugs in the first two months of their treatment (intensive phase). There was a marked difference in the proportion of new and re-treatment tuberculosis cases who were directly observed by tuberculosis care providers during the first two months of their treatment, 50.6% versus 39.3%, respectively. But there was only a slight difference in the proportion of male and female tuberculosis patients who reported that they were directly observed in the first two months of their treatment, 48.1% versus 46.7%, respectively (Table 16).

Only 38(33.6%) of the respondents confirmed that they come to health facilities daily to collect and take their drugs under the direct supervision of tuberculosis care givers in the first two months of their treatment. There was a certain difference in the proportion of new and re-treatment tuberculosis out patients who visited health facilities daily to collect and take their drugs, 23.5% versus 28.6%, respectively. The proportion of male tuberculosis patients who visited health facilities daily to take their drugs during DOTS was higher than those among females, 26.5% and 22.2%, respectively.

The majority of respondents, 79(70.5%) reported that they were told about the duration of their treatment by health care providers. There was a slight difference in the proportion of new and re-treatment cases of tuberculosis patients who reported that they were informed about the duration of their treatment, 69% versus 75%, respectively.

Sixty-five (57.5%) of the interviewees said that they were provided with information about the side effects of anti-tuberculosis drugs. The proportion of informed re-treatment cases about side effects was higher than new cases (67.9% versus 54.1%). The proportion of male and female tuberculosis patients who reported that they were provided with information about the side effects of anti-tuberculosis drugs was 54.4% and 60% respectively.

Regarding the opinion of respondents on what would happen if they do not take their medication as prescribed by health care providers, 56(49.6%) of the respondents said that the disease would relapse and 53(46.9%) of the respondents reported that death would ensue. Forty-four (51.8%) of new cases and 12(42.9%) of re-treatment cases reported that the disease

would relapse as a result of not taking the drugs as prescribed. Thirty-eight (44.7%) of new cases and 14(50%) of re-treatment cases of tuberculosis out patients interviewed reported that they would die of tuberculosis if they do not take the anti-TB drugs as prescribed.

From the total 113 out patients interviewed, no patient was able to mention the names of the anti-tuberculosis drugs that he/she was taking. But all patients were able to indicate correctly the number of tablets of anti-tuberculosis drugs they were taking.

Table 16: Patient's knowledge on the practice of treatment provision in the health facilities, Gamblella Regional State, Ethiopia, 2009 (N=113).

	Total	Retrt.	New	Male	Female
Characteristics	N (%)	N (%)	N (%)	N (%)	N (%)
Medical staff observe during drug intake(1st 2 months)	54(47.8)	11(39.3)	43(50.6)	34(48.1)	21(46.7)
Interval of facility visit to take drugs					
Monthly	46(40.7)	9(32.1)	37(43.5)	27(37.7)	19(42.2)
Three times a month	25(22.1)	8(28.6)	17(20)	15(22)	10(22.2)
Weekly	14(12.4)	3(10.3)	11(12.9)	8(11.8)	6(13.3)
Daily	38(33.6)	8(28.6)	20(23.5)	18(26.5)	10(22.2)
Duration of treatment told	79(70.5)	21(75)	58(69)	46(68.7)	33(73.3)
Information given about side effects	65(57.5)	19(67.9)	46(54.1)	37(54.4)	27(60)
Opinion on consequences of not taking drugs as prescribed					
Nothing happens	2(1.8)	---	2(2.4)	2(2.9)	---
Disease relapses	56(49.6)	12(42.9)	44(51.8)	36(52.9)	20(44.4)
Death	53(46.9)	14(50)	38(44.7)	29(42.6)	24(53.3)
Others*	2(1.8)	1(3.6)	1(3.6)	1(1.5)	1(2.2)
Number of tablets being taken	113(100)	28(100)	85(100)	68(100)	45(100)
Interruption of treatment	2(1.8)	---	2(2.6)	2(2.9)	-

Retrt. = Re-treatment Others* = Disease reaches sever stage + No idea

6.3. Results from Observation Check List

This particular instrument assessed the storage condition of anti-TB drugs in the store and dispensary of the health facilities, the practice of personnel working in tuberculosis clinics, availability of facilities in support of TB care and anti-TB drug stock position.

6.3.1. Storage Condition of Anti-TB Drugs

The storage condition of anti-TB drugs was assessed with regard to adequacy of drug storage condition as an indicator of drug quality. Adequacy of drug storage condition by itself is determined by how many of the indicators stated for an ideal drug storage condition were met by the store and dispensary of the respective health facilities. The storage condition in the store and dispensary of the health facilities was rated as poor (0-3), not adequate (4-5), moderately adequate (6-7), adequate (8-10) and more than adequate (11). The numbers in parentheses indicate the number of storage condition indicators that must be met in order for the store to be classified in that particular rating.

The only hospital in the region which is part of the health facilities included in the study scored six out of the eleven indicators and two health centres scored seven out of eleven. This indicates that the storage condition in the store and dispensary of these three health facilities was within the range 6-7 which is moderately adequate and the drug quality is acceptable.

One health centre scored two out of eleven and another health centre scored three out of eleven indicating that the storage condition in the store and dispensary of the two health centres fell within the range 0-3 which is poor and quality of anti-TB drugs may be poor.

The last health centre scored nine out eleven indicators indicating that the storage condition in the store and dispensary of this health centre fell within the range 8-11 which is adequate and the quality of anti-TB drugs is acceptable.

The regional store was also assessed with respect to all the indicators used to assess the storage condition of anti-TB drugs in the store and dispensary of the health facilities except one indicator which is separation of store and dispensary since there was no dispensary in the regional store. Out of the ten indicators, the regional store scored five.

6.3.2. Personnel Working in Tuberculosis Clinic

All the health facilities included in the study had one nurse each assigned in the tuberculosis clinic for tuberculosis and leprosy control activities. The nurses in charge of TB care in all health facilities reported to have taken at least one additional training on tuberculosis prevention and control. However, except in the hospital and one health centre, the nurses in the tuberculosis clinics had additional assignments elsewhere in the health facility.

In all health facilities, the personnel working in the tuberculosis clinic knew well the cardinal signs of tuberculosis, the anti-TB treatment categories and the disease classification. They check the weights of patients at recommended intervals. They also check the nutritional status of tuberculosis patients (they ask the patients) and advise their patients about the types of food they should take.

6.3.3. Availability of Facilities in Support of TB Care

In all the health facilities excluding the hospital, the recent version of Tuberculosis, Leprosy and TB/HIV Control Programme manual was present. But tuberculosis and leprosy unit registers were available in all health facilities. Drug and laboratory reagents request form was available only in three health centres.

Inadequate (stock outs) supply of Acid Fast Bacilli (AFB) reagent was observed in three health centres. An adequate supply of slides and sputum cups was observed in four health facilities. However, inadequate supply (stock outs) of slides and sputum cups was observed in two health centres and hence slides were being re-used.

Out of all the six health facilities, DOTS (Directly Observed Therapy Short course) was being implemented in two health centres only. Even in those health facilities that implement DOTS, there was no water to be used by patients in the intensive phase. Patients were supposed to come with their own water in plastic bottles.

In all health facilities, adequate supply of disposable syringes for administration of streptomycin was observed. Even though the Fixed Dose Combination (FDC) drugs were

available in blister form, total unavailability of paper and plastic bags for dispensing anti-TB drugs was observed in two health centres

6.3.4. Anti-TB Drugs Stock Position

It was observed that EH, RH and RHZE were out of stock in certain health facilities. In one health centre, EH and RH were out of stock for a month. In another health centre, RHZE was out of stock for a minimum of one week and a maximum of three weeks in the past one year.

Overstocking of anti-TB drugs was also observed in two health centres. In one health centre, Ethambutol and Isoniazid were overstocked, in another health centre; RHZE and RH were overstocked and expiring.

Five of the six health facilities included in the study were observed to have expired anti-TB drugs. In the only hospital in the region, it was observed that there were substantial quantities of expired RHZE, RHE, EH and Streptomycin. In one health centre, certain quantity of RHZE, RHE, EH and Streptomycin were found expired. In another health facility, expired pyrazinamide was observed. Still in another health facility, it was observed that certain quantity of Isoniazid and EH were found expired. A certain number of vials of streptomycin were also observed to have expired in one health facility. In the last health centre, a substantial quantity of expired anti-TB drugs were reported to have been hoarded in a separate store, but the store man (administrator of the health centre) was not willing to provide us the key for that particular store to determine the exact quantity.

In all of the health facilities, there was not any properly functioning stock record. It was only in one health facility that even the stock cards themselves were available. But even in this health facility, there was a discrepancy between stock records and stock counts. The rest health facilities did not have any stock record system.

6.4. Practice of Pharmacy Personnel Related to Anti-TB Drugs

Store personnel of four of the health facilities were non-pharmacy professionals. The work experience of personnel working in the store and dispensary of the health facilities and the regional store ranged from one year to three years.

Except the hospital, no health facility had Pharmacy and Therapeutics Committee (PTC). All health facilities had no culture of discussion forum on anti-TB drug management. Except the personnel working in the regional store and two other store personnel working in two health facilities, no training was given to store managers on stock management.

Four health facilities reported that they determine their drug needs using consumption method of quantification. The regional store and one health centre used morbidity method for quantifying their drug needs. The store personnel in one health facility said that he had never performed any sort of quantification because drugs and medical supplies are quantified by the regional health bureau i.e. the regional health bureau does not provide them with all drugs and medical supplies that they request rather gives them what it believes is enough.

With regard to drug collection intervals, one health facility and the regional store reported that they collect their drug needs from higher levels annually. Three health facilities reported that they collect their drug needs quarterly. The store personnel from one health facility said that he collect drugs biannually. Still the store personnel in another health facility said that he did not have any fixed interval for drug collection i.e. drug collection is made when the need arises.

Concerning inventory control or flow of stocks, First-In/First-Out (FIFO) and First-Expiry/First-Out (FEFO) principles were being utilised in all health facilities and the regional store. Five of the health facilities reported that they report anti-TB drug consumption to the respective health bureaux quarterly and one health facility reported anti-TB drug consumption monthly.

7. DISCUSSION

This study generated important information regarding TB/HIV co-infection level, prescribing practice of service providers (prescribers), knowledge of tuberculosis out patients about their treatment and adequacy of the information provided to patients by service providers. It also described the quality of anti-TB drug management in health facilities and availability of facilities in TB care.

This study revealed that the proportion of male (55.8%) study participants in the record review was greater than females (44.2%). This may reflect differences in either disease risk or access to care between female and male tuberculosis patients.

The majority of tuberculosis patients co-infected with HIV (61.3%) were within the age range of 20-39 years which is in agreement with a study conducted in other part of Ethiopia, Arsi zone (Wajisso, 2003). One probable justification for this finding could be individuals in this age category are sexually active with the possibility of having multiple sexual partners and hence increased chance of contracting HIV.

The total HIV prevalence among tuberculosis patients in the selected health facilities in the region was 46.7% which is significantly higher than what was documented by previous researches (Askar, 2008; Datiko et al., 2008; Wajisso, 2003; FMOH, 2008; van der Werf et al., 2007). But it is significantly lower than the figure indicated in a study conducted in Israel (Bendayam et al, 2007). The higher co-infection level might be attributable to low level of awareness about HIV in the community in general and among tuberculosis patients in particular.

The proportion of male tuberculosis patients co-infected with HIV was almost equal to that among females. This is in consistence with the findings of other studies conducted in Somaliland and Ethiopia (Askar, 2008; Wajisso, 2003). This may indicate male and female tuberculosis patients might have been equally exposed to the risks factors to HIV/AIDS.

This study also described that the proportion of TB/HIV co-infection in patients from the hospital in the region was higher than the other health facilities. One possible difference between the hospital and the health centres could be the difference in the degree of

urbanization of the areas where they are located. This is substantiated by previous studies conducted in Eritrea, Southern, Nations, Nationalities and Peoples Region and Oromiya Regional State (Datiko et al., 2008; van der Werf et al., 2007; Wajisso, 2003). The possible explanation for this could be the increased chance of exposure to risk factors to HIV infection in the community served by the hospital compared to those who get treatment service in the health facilities in the small towns where the degree of urbanization is less.

Previous studies documented high prevalence of HIV among extra pulmonary tuberculosis patients. The risk of extra pulmonary tuberculosis increases with concurrent AIDS and tuberculosis. Extra pulmonary tuberculosis constitutes about 15% to 20% in immunocompetent tuberculosis patients and accounts for more than 50% of tuberculosis cases in HIV-positive individuals (Mohan and Sharma, 2004; Golden and Vikram, 2005). This study also revealed that the level of TB/HIV co-infection among extra pulmonary tuberculosis patients was significantly higher than that among pulmonary cases. This is in contrast to other studies conducted in Ethiopia, Oromiya and Southern, Nations, Nationalities and Peoples Region (Wajisso, 2003; Yassin et al., 2004).

In the present study, re-treatment tuberculosis cases were found to be more significantly associated with HIV positivity than new cases. The discrepancy in co-infection level might have arisen from the low tuberculosis cure rate in the region (39.2%) which in turn is influenced by high prevalence of HIV among tuberculosis patients. This substantiates the hypothesis that high level of TB/HIV co-infection in the region could be among the factors contributing to the low tuberculosis cure rate.

This study revealed that there was a significant number of prescribing errors (over doses and under doses where both cases are malpractices) in both new and re-treatment cases in the intensive and continuation phases of tuberculosis treatment. This may seriously jeopardise the objective of the national tuberculosis prevention and control programme in general and the degree of desired tuberculosis treatment outcomes such as tuberculosis cure rate and tuberculosis treatment success rate in particular.

This study also showed that there was a significant difference in the proportion of under dose anti-tuberculosis drug prescription in new and re-treatment tuberculosis cases. This means that prescribers make more under dose prescribing errors than over dose prescribing errors in

new cases than re-treatment cases. This may indicate the difference in curiosity of service providers (prescribers) in treating new and re-treatment tuberculosis cases. A possible justification for this could be re-treatment cases are left with only one chance of treatment using the first line anti-tuberculosis drugs and hence, prescribers might pay more attention while prescribing anti-tuberculosis drugs to re-treatment cases than to new cases.

In the present study, out of the total 823 patient treatment records assessed, more than half (449) of the prescriptions were made to patients in the weight category of 39.5 to 54.4 kilograms. Among these, 424(94.4%) were new cases and 25(5.6%) were re-treatment cases. The proportion of prescriptions containing incorrect doses of anti-TB drugs in the new cases in this category (39.5 to 54.4 kilograms) was very small (0.5%) compared to the two adjacent weight categories (29.5 to 39.4 kilograms and 54.5 to 70.4 kilograms). This could possibly be because prescribers try to approximate initial weight of tuberculosis patients from above (54.5 to 70.4 kilograms) and from below (29.5 to 39.4 kilograms) to this weight category (39.5 to 54.4) since most of the patients (54.6%) are from this weight range. This may be substantiated by observing the proportion of incorrect prescriptions in the two adjacent weight categories where almost all of the prescribing errors in the intensive phase in the weight category of 29.5 to 39.4 kilograms were over doses and those in the 54.5 to 70.4 kilograms were all under doses.

In the continuation phase of the two adjacent weight categories (39.4 to 54.4 and 54.5 to 70.4 kilograms), over dose prescriptions of anti-TB drugs outweighs under dose prescriptions in the 29.5 to 39.4 kilogram weight range whereas greater than 90% of prescription errors in the 54.5 to 70.4 kilogram weight category were under doses. This again substantiates the condition in the intensive phase where prescribers incline more in approximating the initial weight of patients to the 39.5 to 54.4 kilogram weigh category.

The possible reason for these incorrect prescriptions could be because prescribers do not stick to the recent TB, Leprosy and TB/HIV Control Programme Manual 2008. One probable explanation for this could be prescribers used to use the 2004 treatment guideline where there are certain discrepancies in weight cut-off and age consideration with the above mentioned recent manual in prescribing anti-TB drugs. Another possible justification could be lack of awareness/curiosity of prescribers on the possible consequences which may be substantiated

by the significant proportion of under dose prescriptions in new tuberculosis cases than re-treatment cases.

The misuse manifested in prescribing the anti-TB drugs has its own consequences on patient adherence to treatment and susceptibility of mycobacterium micro organisms to the first line and even to the second line chemotherapeutic agents. Hence, prescribing in under doses may directly lead to the emergence of resistant strains of mycobacterium which can cause either multi-drug resistant or extensively multi-drug resistant tuberculosis. This could lead to low tuberculosis cure rate among patients who have completed their anti-TB treatment regimen properly. Similarly, over dose prescribing may lead to the occurrence of increased side effects and drug-related toxicities which may compromise patient adherence to treatment. This may again contribute its own share to the low tuberculosis cure rate in the region.

Directly Observed Therapy (DOT) improves the desired treatment outcomes (success and cure rates) of tuberculosis by making patients more adherent/compliant to their treatment. Out of the total 113 patients interviewed in this study, 47.8% reported that they were directly observed by health care providers while taking their drugs during the first two months of their treatment. This is by far better than a study conducted in East Showa zone, Oromiya, Ethiopia (Kura, 2007). The proportion of directly observed respondents was higher among new cases than re-treatment cases. The possible explanation for this could be re-treatment cases may be considered by health care providers to be more knowledgeable about their treatment from the previous exposure and leave them to take their drugs on their own. Direct observation was slightly higher in males than females which is in agreement with a study conducted in Sudan (Mohammed, 2007).

Making patients know about the duration of their treatment from the very beginning helps dedicate themselves to the six or eight month treatment period. This is because patients will convince themselves to adjust their life style in such a way that it will not affect their treatment. This is because the patient will be going to health facilities every day during the intensive phase which may not enable him/her to carry out all the activities that a normal person can do in his farm land or other work areas. The patient will also be entertaining the side effects of the anti-TB drugs he/she is taking through out the duration of his/her treatment which may compromise the individual's day-to-day activities. In this study, 70% of the

respondents reported that they were informed about the duration of their treatment which is by far better than a study conducted in Oromiya, Ethiopia (Kura, 2007).

Providing patients with information about the side effects of anti-TB drugs that they are taking helps them to be aware about these side effects beforehand and reduces the chance of treatment discontinuation and other related problems. In the present study, 57.5% of the respondents confirmed that they were provided with information about side effects of anti-TB drugs. This is very low compared to another study conducted in Vietnam (Hoa et al., 2009). This low level of information provision to patients may indicate that the nurses in the health facilities included in the study had additional assignments in the wards and hence may not have sufficient time to spare to discuss all the necessary pieces of information with patients. This may compromise the therapeutic outcome expected to be achieved at the end of treatment.

Appropriate storage condition for drugs and medical supplies in general and anti-TB drugs in particular in stores and dispensary units of the health facilities enables the distribution of drugs having the right quality to patients. Failing to provide the storage conditions specified by the manufacturer may lead to deteriorated drugs being dispensed to patients. Regarding the anti-TB drugs storage condition, Isoniazid, Streptomycin, Ethambutol and Pyrazinamide should be stored at room temperature while Rifampicin may be stored up to $40^{O}C$ (DACA[1], 2004). But since the anti-TB drug preparations are now available in fixed-dose combinations, they should be stored at room temperature.

From the six health facilities, the drug storage condition in the stores and dispensaries of the health facilities was moderately adequate in three health facilities and adequate in one health facility. In both cases, the quality of the anti-TB drugs that may be stored is acceptable. But the storage condition in the regional store and one health facility was not adequate (drug quality may be adequate) and poor (drug quality may be poor) respectively. In both cases, the condition may result in low drug quality and hence low TB cure rate and drug resistance.

In places like Gambella where the temperature is very high throughout the year, the most important indicator in drug storage condition is the presence or absence of ventilator in each store and dispensary units of the health facilities. The drug stores in all health facilities had no ventilator to regulate the temperature of the room in which drugs are stored. This is critical

because in all health facilities except one, the average temperature throughout the year is very high. This may facilitate premature deterioration of anti-TB drugs in the stores and dispensaries of the health facilities. Patients being prescribed deteriorated drugs will not get cured from tuberculosis, even if, they complete their drugs properly. This might have contributed to the low tuberculosis cure rate in the region.

In each of the health facilities assessed, one nurse is assigned for tuberculosis care activities. Except in two health facilities, the personnel in charge of tuberculosis care had additional assignments in the wards. This may compromise the quality of service rendered to TB patients since they will be busy discharging the additional activities they are assigned to do. All the TB personnel reported that they had taken at least one additional training on TB care. Training can help TB personnel to update their knowledge on current developments in the field and improve the efficiency of the services they deliver.

The other important point observed in this study was that the tuberculosis personnel check the weights of tuberculosis patients at recommended intervals. They also check the nutritional status of patients and encourage them to take nutrious food staffs while they are on anti-TB drugs. This may increase patient compliance to treatment and hence, tuberculosis cure rate. Checking the weights of patients could help the tuberculosis personnel to adjust doses of drugs in the continuation phase which is important to avoid under dose prescribing.

TB, Leprosy and TB/HIV Prevention and Control Programme Manual recent version (2008), drug and laboratory reagent request form, AFB reagents, slides and sputum cups and availability of water in the TB clinic are important in tuberculosis control. This is because prescribers need this manual in order to avoid over dose and under dose prescribing. The present study revealed that TBL and TB/HIV manual recent version (2008) was not available in one of the health facilities studied; this might have negative impact on tuberculosis cure rate. This is substantiated by the significant proportion of incorrect (under dose and over dose) anti-tuberculosis drug prescriptions investigated in this study.

Drug and laboratory reagent request form was not available in three health facilities. This may make proper stock management difficult and possibly leads to stock outs or overstocking of drugs and reagents. Inadequate supply of sputum cups and slides and re-use of slides was

reported in three health facilities. Reuse of slides may contaminate the sample to be taken from the patient and hence leads to false results.

Directly Observed Therapy improves the desired treatment outcomes (success and cure rates) of tuberculosis by making patients more adherent to their treatment (Obiri-Danso et al., 2009; Gopi et al., 2006). DOTS was being practiced only in two health facilities but even in these health facilities, there was no water in the TB clinic to be used by patients to swallow their drugs during the intensive phase. Rather, patients were made to bring their own water in plastic bottles. But this has its own problems since it may force TB care providers to dispense anti-TB drugs for which they are not sure about the compliance of patients. In addition, the plastic bottles themselves are not convenient for patients because there were even instances during the data collection that the tablets escape from the mouth of the patient in to the bottle while trying to swallow them. Therefore, it would be more appropriate to avail water in the TB clinics and to use cups instead of plastic bottles.

Serious management problems of anti-TB drugs were observed in all health facilities. A stock out of RHZE, EH and RH was observed in different health facilities. RHZE, RH, H and Z were over stocked in two health facilities. Significant quantities of RHZE, RHZ, EH, H and Z were found expired in different health facilities. Stock out of anti-TB drugs in the health facilities may lead to interruption of treatment of TB patients who have already started their treatment which in turn may lead to progression of the disease. In addition, this might also lead to emergence of resistant strains of mycobacterium which contributes to low tuberculosis cure rate. Expiration of anti-TB drugs is wastage of the merger resource in the health system. In addition, it needs additional expenditure for its safe disposal.

In this study, it was clearly observed that there were no stock records in five of the health facilities and not updated in one health facility. Stock records are important source of information to see how effectively the distribution system is being managed. They provide detailed information on how products flow through the system and can be used to identify where problems are occurring so that corrective actions can be taken (MSH, 1997).

There was no supervision by higher levels to the store of three of the six health facilities. But the stores of the other three health facilities received supervision from the regional health bureau once in the last one year. However, the feedbacks given were only verbal which may

not be sufficient to appropriately transfer the desired information to the store personnel. Feedback helps to take corrective actions for weak performance of the store personnel i.e. it is an important instrument for promoting rational use of drugs in general and anti-TB drugs in particular. It is also one of the most powerful tools for motivating staff.

Store personnel of four health facilities were non-pharmacy professionals (nurses). This indicates that there was a problem in assigning staffs in their appropriate position which may have its own negative impact on proper management of drugs and medical supplies. Basically, since they are drug experts, pharmacy professionals should be assigned in the store and dispensary units in order to harvest maximum benefit from drugs and medical supplies.

With the exception of the hospital, all health facilities did not have Pharmacy and Therapeutics Committee (PTC). PTC facilitates the line of communication between the medical staff and the pharmacy staff. The committee also reviews and approves all matters pertaining to the use of medications (Kura, 2007; Bender, 1983). Absence of PTC may hinder the health facilities from making maximum benefit of anti-TB drugs and providing quality services to tuberculosis patients.

8. CONCLUSION AND RECOMMENDATIONS

From this study it can be concluded that TB/HIV co-infection level in Gambella Regional State is high. This might have contributed to the low tuberculosis cure rate in the region. In addition, there was a significant level of prescription errors, improper DOTS implementation and poor patient knowledge about tuberculosis. The drug management in store and dispensary of the respective health facilities were improper which might have contributed to low tuberculosis cure rate.

Based on the findings of this study, the following recommendations were forwarded for consideration and implementation by all concerned bodies.

- Training on mechanisms to improve the behaviour of prescribers to stick to the guide lines and consequences of prescribing over and under doses of anti-TB drugs should be arranged to tuberculosis service providers.
- The Regional Health Bureau should be able to staff the TB clinics of its health institutions with at least one full time health worker for TB care.
- TB care providers should be trained on the benefits of information provision to patients.
- The Regional Health Bureau and other concerned bodies should critically assess the drug storage conditions in the health facilities and take corrective measures promptly.
- The Regional Health Bureau should be able to establish a culture of inter-health facility transfer of anti-TB drugs on the verge of their expiry to prevent wastage, morbidity and mortality.
- The Federal Ministry of Health and the Regional Health Bureau should be able to provide health facilities with all the drugs and medical supplies that they need by maintaining appropriate storage conditions until they are distributed.
- The Regional Health Bureau should make supportive supervision and follow up the implementation of DOTS in the health facilities in the region.
- The regional Health Bureau should be able to assign appropriate personnel in the store and dispensary units of the health facilities.

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Annex I: English version informed consent form

My name is _____. I am working with Addis Ababa University research team on "Assessment of tuberculosis treatment and quality of Anti-TB drug management in health facilities in Gambella Regional State". The objective of this study is to make valuable contribution in TB management at individual, family, health facility, regional and national levels. For this reason I am going to ask you certain questions which may take approximately 20 minutes. The information you give will be kept secret and your name and address will not be recorded on the questionnaire. Participation in this interview depends on your full consent. You do not have to answer any or even all of the questions that you do not want to answer. But since your sincere suggestion or response is very crucial, I hope that you are going to participate in the study.

Would you participate in the study?

Yes ☐ No ☐

Name of interviewer _____ Signature_____

Name of supervisor _____ Signature_____

Date _____

Annex II: Amharic version informed consent form

በጋምቤላ ክልል በሚገኙ የሳንባ ነቀርሳ ህክምና አገልግሎት የሚሰጡ ጤና ማእከላት በሳንባ ነቀርሳና ተያያዥ ጉዳዮች በተመለከተ ለሚደረግ ቃለ መጠይቅ የስምምነት ማረጋገጫ

ስሜ _____ እባላለሁኝ፡፡ የምሰራው ከአዲስ አበባ ዩኒቨርስቲ የጥናት ቡዱን ጋር «ስለ ሳንባ ነቀርሳና ተያያዥ ጉዳዮች» ነው፡፡ የዚህ ጥናት ዓላማ ደግሞ በሽተኛው ላይ ያተኮረ ተግባራዊ ለውጥ በግለሰብ፣በቤተሰብ፣በጤና ማዕከሉ፣በክልሉና በአገር አቀፍ ደረጃ ከፍተኛ አስተዋፅኦ ለማበርከት ነው፡፡ ለዚህ ጥናት ይረዳ ዘንድ 20 ደቂቃ ገደማ የሚወስዱ ጥያቄዎችን ልጠይቅዎት እፈልጋላለሁኝ፡፡ የሚሰጡት መልስ በሚስጢር የሚጠበቅ ሲሆን ስምዎንም ሆነ አድራሻዎ በመጠይቁ ላይ አይሰፍርም፡፡ በዚህ ጥናት ላይ መሳተፍ በእርስዎ ሙሉ ፍቃደኝነት ላይ የተመሰረተ ሲሆን የተወሰኑት ወይም ሁሉንም ጥያቄዎች አለመመለስ ይችላሉ፡፡ ነገር ግን የርስዎ አስተያየት ወይም መልስ በጣም ጠቃሚ ስለሆነ በጥናቱ ላይ ይሳተፉሉ ብዬ ተስፋ አደርጋለሁ፡፡

በቃለ መጠየቅ ለመሳተፍ ፍቃደኛ ነዎት?

አዎ☐ አይደለሁም ☐

የመረጃ ሰብሳቢ ስም _____ ፊርማ.....

የተቆጠጣሪ ስም _____ ፊርማ.....

Annex III: Amharic version exit interview form

የተመላላሽ በሽተኛ የቃለ መጠየቅ ቅፅ

የጤና ማዕከሉ ስምና ደረጃ.....

የመጠየቁ መለያ ቁጥር.....

ቃለ መጠይቅ የተደረገበት ቀን.....

የጤና ማእከሉ ልዩ ኣከባቢ..... እ

ክፍል አንድ፡ የታማሚው ሶሽዮ-ዲሞግራፊክ ባህርያት

ተ.ቁ.	ጥያቄዎች	ታማሚው ሊሰጣቸው የሚችል መልሶች
1	ፆታ	1. ወንድ 2. ሴት
2	ዕድሜ	.....
3	የትምህርት ደረጃ	1. ማንበብና መፃፍ የማይችል 2. ማንበብ ብቻ የሚችል 3. ማንበብና መፃፍ የሚችል 4. አንደኛ ደረጃ (1-6) 5. ሁለተኛ ደረጃ (7-12) 6. ኮሌጅ/ዩኒቨርሲቲ
4	የስራ ሁኔታ	1. ገበሬ 6. ጡረተኛ 2. የመንግስት ሰራተኛ 7. ስራ የሌለው 3. ተማሪ 8. የቤት እመቤት 4. ነጋዴ 9. ሌላ ካለ..... 5. የቀን ሰራተኛ
5	የጋብቻ ሁኔታ	1. ያገባ/ች/ 2. ያገባ/ች/ና ከትዳር ጓደኛው/ዋ/ ጋር አብሮ/ራ/ የሚኖር/የምትኖር/ 3. ያገባ/ች/እና ከትርዳር ጓደኛው/ዋ/ጋር አብሮ/ራ/ የማይኖር/የማትኖር/ 4. በህጋዊ መንገድ የፈታ/ች/ 5. የትዳር ጓደኛው የሞተች/ባት/
6	የትዳር ጋደኛው ከሞተች/ባት/	1. በሳንባ ነቀርሳ ምክንያት 2. በሌላ ምክንያት
7	ስንት ልጆች አልዎት	.....
8	የሚከተሉት ሃይማኖት ቢገልፁሉኝ	1. ኦርቶዶክስ ክርስቲያን 2. ሌላ ክርስቲያን 4. ሌላ 3. ሙስሊም

ክፍል ሁለት፡ ታማሚው ስለ ሳንባ ነቀርሳ እና ህክምናው ያለው/ያላት እውቀትና የጤና ማእከል ለመድረስ የሚጓዘው/የምትጓዘው ርቀት

ተ.ቁ.	ጥያቄዎች	ታማሚው ሊሰጣቸው የሚችል መልሶች
1	ከአሁን በፊት የሳንባ ነቀረሳ መድሃኒቶችን ለወር ወይም ከዛ በላይ ወስደው ያቃሉ?	1. አዎ 2. ወስጀ አላውቅም
2	የሳንባ ነቀርሳ መድሃኒት መውሰድ ከጀመሩ ምን ያህል ይሆንዎታል? /በክፍት ቦታው ይገለፅ/	……..
3	መድሃኒቱን መውሰድ ከጀመሩ እስከ ሁለት ወር ድረስ መድሃኒቱን ሲውጡ የሚያይ□ት የጤና ባለሞያ አለ?	1. አዎ 2. የሚያየኝ የለም
4	መድሃኒትዎን ለመውሰድ በሳምንት/በወር ስንት ግዜ ወደ ጤና ማእከሉ ይመጣሉ?	……
5	ዶክተሩ ህክናዎትን ምን ያህል ግዜ እንደሚወስድ ነግረዎታል?	1. አዎ 2. አልነገረኝም/ችኝም 3. አላስታውስም
6	ህክምናዎ ከመጨርስዎ በፊት መድሃኒቱን ለምን ያህል ግዜ እንደሚወስዱ ዶክቶሩ ነገረዎታል?	1. ለ 6 ወር 2. ለ 7 ወር 3. ለ 8 ወር 4. ሌላ ካለ/ይገለፅ/ ……
7	መድሃኒቱን ሲወስዱ የመድሃኒቱ የጎንዮች ስሜቶች/ሳይድኢፌክት ቢከሰት ሐኪሙ ወደ ጤና ማእከሉ እንዲመለሱ ነግረዎታል?	1. አዎ 2. አልነገረኝም/ችኝም
8	መድሃኒትዎን ሐኪም ባዘዘው መሰረት ባይወሰዱ ምን የሚከሰት ይመስልዎታል?	1. ምንም አይከሰትም 2. ህመሙ ያገረሻል 3. ሞት 4. ሌላ ነገር/ይገለፅ/ ……
9	የሚወስድዋቸውን የሳንባ ነቀርሳ መድሃኒቶች ስም ቢጠቅስሉኝ?	1. …… 4. …… 2. …… 5. …… 3. ……
10	ከቤትዎ ወደ ጤና ማእከሉ ያለው ርቀት ምን ያህል ይሆናል?እ	1.ከ10ኪ.ሜ.በላይ/ከ2 ሰኣት በላይ መንገድ 2.ከ10ኪ.ሜ. በታች/ከ2ሰኣት በታች መንገድ
11	ከያአንድዳንዱ የሳንባ ነቀርሳ መድሃኒት በቀን ምን ያህል ይወስዳሉ;	1……4…… 2……5…… 3……
12	መድሃኒትዎ መውሰድ አቋርጠው ያውቃሉ?	1. አዎ 2. አቋርጬ አላውቅም
13	ለ12ኛው ጥያቄ መልሰዎ አዎ ከሆነ ለምን (በክፍት ቦታው ግለፅ)	……

ጥያቄዬን ጨርሼአለሁ፣ ለትብብርዎ አመሰግናለሁ።

Annex IV: English version Exit Interview form

Exit interview N^{O}_____

Name and level of the health facility_____

Location_____

Date of interview_____

Part one: Socio-demographic characteristics of the patients

No	**Questions**	**Suggested options for the questions**
1	What is the sex of the respondent?	1. Male _____ 2. Female _____
2	How old are you? (enter in the space)	_____years
3	What is the highest-level of schooling you have attended? (enter in the space)	1. Illiterate_____ 2. Read only _____ 3. Read and write only_____ 4. Elementary (1-6) _____ 5. Senior secondary (7-12)____ 6. College/university education (graduate)___
4	What is your current occupation?	1. Farmer _____ 5. Daily laborer_____ 2. Civil servant_____6. Pensioner_____ 3. Student_____ 7. Unemployed_____ 4. Merchant_____ 8. House wife_____ 9. Others (specify) _____
5	What is your marital status?	1. Never married 2. Currently married 3. Divorced/separated 4. Widowed 5. No response
6	If widowed	1. Due to tuberculosis 2. Other cause.
7	How many children do you have? (enter in the space)	_____ Child/ Children
8	Which religion do you follow?	1. Orthodox Christian 2. Other Christianity (specify) _____ 3. Muslim 4. Other (specify) _____

Part two: Knowledge about tuberculosis and its treatment and distance patients travel to health frailties.

No	Questions	Suggested options for the questions
1	Have you had previously taken Anti-TB drugs for a month or more?	1. Yes 2. No
2	How long have you been taking your medicines ?(enter in the space)	_____ days/months
3	Does anybody among the medical staff or caregiver look at you when you take your medicine during DOTS? (1st two months)	1. Yes 2. No
4	How many days in a week or in a month do you come to take your medicines?	_____days
5	Did the doctor/care giver tell you the duration of your treatment?	1. Yes 2. No 3. I do not remember
6	For how long did the doctor/care giver tell you that you have to take your medicine before you complete your treatment?	1. 6 months 2. 7 months 3. 8 months 4. Other.
7	Did the doctor tell you to return to the clinic or health facility if any sign of side effects such as yellow eyes, fainting or renal problems occur?	1. Yes 2. No
8	What will happen if you do not take your medicines as prescribed?	1. Nothing happens 2. The disease will relapse 3. Death 4. Others(specify)_____
9	Do you know the names of the TB drugs you are taking? (enter in the space).	1. _____ 4. _____ 2. _____ 5. _____ 3. _____
10	How much distance do you travel from home to this treatment centre?	1. > 10 km /> 2 hrs walk/ 2. < 10 km /< 2 hrs walk/
11	How many tablets of each drug must you swallow per day?	1. _____ 3. _____5. _____ 2. _____ 4. _____
12	Have you ever interrupted (discontinued) your treatment?	1. Yes 2. No
13	If your answer to question N^{o}"12" is yes, why?	_____

Annex V: Questionnaire to assess the practice of pharmacy personnel related to anti-TB drugs

Questionnaire number: _____

Health facility name: _____

No	Questions	Suggested options for the questions
1	Job title (enter in the space)	_____
2	Year of graduation of basic training (enter in the space)	_____
3	Which department are you currently assigned?	1. In patient 2. Out patient 3. Store 4. Other (specify)_____
4	Did any of the personnel in the store receive training on stock management?	1. Yes 2. No
5	Is there Pharmacy and Therapeutics Committee in the health facility?	2. Yes 3. I do not know. 2. No
6	Has there been any discussion forum on Anti-TB drug management?	1. Yes 2. No
7	How do you quantify your drug need? (for pharmacy head/ store manager)	1. Using morbidity method 2. Using consumption method 3. Others (specify) _____
8	How often do you collect drugs from the next higher level? (for pharmacy head and stock manager)	1. Monthly 2. Quarterly 3. Biannually 4. Annually 5. Other (specify) _____
9	Are FIFO / FEFO methods practiced during drug delivery from store?	1. Yes 2. No
10	Do you summit Anti-TB drugs consumption report? (for pharmacy head/ stock manger)	1. Yes 2. No
11	If the answer to question number “10" is yes, how often?	1. Monthly 2. Quarterly 3. Biannually 4. Annually 5. Other (specify) _____

Location: _____

Annex VI: Check list to assess the status of Anti-TB drug storage and dispensary units and availability of facilities in TB care

Check list No _____

Facility Name _____

Location _____

I. General observation

No	**Questions**	**Suggested options for the questions**
1	Cleanliness (absence of litter and dust)	1.Clean 2. Not clean
2	Signs of pests	1. Absent 2. Present
3	Roof ceiling	1. Secured 2. Not secured
4	Presence of vents	1. Available 2. Not available
5	Protection from direct sunlight	1. Protected 2. Not protected.
6	Protection from moisture	1. Protected 2. Not protected
7	Absence of stock on the floor	1. Absent 2. Present
8	Separation of storage and dispensing area	1. Separated 2. Not separated
9	Availability of functional thermometer	1.Availbe 2.Not available
10	Are stock cards in use?	1. Yes 2. No
11	If stock cards are in use, do records correspond to counts	1.Yes 2.No

II. Tuberculosis specific

No	Questions	Suggested options for the questions
1	Is one or more health worker assigned for TBL activity?	1.Yes 2.No
2	Does the health worker at the TB Clinic work full time in TBL control?	1.Yes 2.No
3	Does the health worker at the TBL clinic/unit have additional trainings in TBL control?	1.Yes 2.No
4	Is the health worker in charge of the TBL control work at the time of the visit?	1.Yes 2.No
5	If yes, to question No " 4" does he/she know the cardinal signs of TB	1.Yes 2. No
6	Does he/she know the anti-TB treatment categories?	1.Yes 2.No
7	Does he/she know the disease (TB) classification?	1.Yes 2.No
8	Does the health worker check the weights of patients at recommended intervals and encourage them?	1. Yes 2. No
9	Does the health worker check the nutritional status of patients?	1. Yes 2. No
10	Is the patient information complete on TB unit register?	1.Yes 2.No
11	Are initial smear exam. results recorded correctly and completely?	1.Yes 2.No
12	Are categories of patents filled in correctly and completely?	1.Yes 2.No
13	Are intensive phase attendances recorded correctly and completely?	1.Yes 2.No
14	Do patients have follow up examination at recommended intervals?	1.Yes 2.No
15	For each patient, is the information complete to determine treatment outcome?	1.Yes 2.No
16	Is the TB and leprosy control program manual present in the facility?	1.Yes 2.No
17	Are TB and leprosy unit registers present (recent version)	1.Yes 2.No
18	Are AFB reagents in adequate supply?	1.Yes 2.No
	Drug and lab. Reagents request form	1.Yes

19		2.No
20	Are slides and sputum cups in adequate supply?	1.Yes 2.No
21	Does the laboratory re-use slides for AFB?	1.Yes 2. No
22	Arrangement of TB-examination room	1. Ventilated and allows entrance of direct sun light 2. Not ventilated and does not allow entrance of direct sun light
23	Availability of water in dispensing unit) to be used by patients under DOT	1. Available 2. Not available
23	Are paper and plastic bags available for dispensing anti–TB drugs?	1. Yes, adequate 2. Yes, inadequate 3. No
24	Are disposable syringes and needles available for patients taking streptomycin?	1. Yes, adequate 2. Yes, inadequate 3. No
25	Is the treatment directly observed?	1.Yes, adequate 2.Yes, inadequate 3.No
26	Amount of anti-TB drugs in the store	1. RH _____ 2. RHZ_____ 3. RHZE _____ 1. EH_____ 2. Streptomycin_____
27	Are there stock outs (shortage) of anti-TB drugs?	1. Yes 2. No
28	If response to question number “27” is yes, duration of stock out during the last 12 month	1. RH: Shortest_____ longest _____ 2. RHZ: Shortest_____ longest _____ 3. RHZE: Shortest_____ longest _____ 4. EH: Shortest_____longest _____ 5. Streptomycin_____ longest _____
29	Are there over stocked anti-TB drugs?	1.Yes 2.No
30	If response to question No "29" is yes: List of over stocked anti- TB drugs	1._____ 2._____ 3._____ 4._____ 5._____
31	Are there expired Anti-TB drugs	1.Yes 2. No
32	If response to question No “ 31” is yes, list of expired anti- TB drugs.	1._____ 2._____ 3._____ 4._____ 5._____

33	Amount of expired Anti-TB drugs	1. RH: _____ 5.Streptomycin_____ 2. RHZ:_____ 3. RHZE:_____ 4. EH_____
34	Has there been supervision to the pharmacy store?	1.Yes 2.No
35	If response to question No " 34" is yes	1. When? _____ 2. By whom? _____
36	Was feedback given?	1. Yes 2. No
37	If feedback was given, what type?	1. Verbal 2. Written 3. Oral and written

Annex VII: **Data abstraction format for TB/HIV co-infection and prescribing practice of service providers**

Name and level of the health facility _____

Location _____

Date of abstraction_____

1. Code number:_____

3. Sex: Male ☐ Female ☐

4. Initial date of diagnosis: _____

5. Patient's age: _____

6. Initial patient's weight: _____

7. Patient category: New ☐ Re-treatment ☐

8. Smear result:

Pulmonary positive ☐ Pulmonary negative ☐ Extra pulmonary ☐

9. HIV test result: Positive ☐ Negative ☐ Untested ☐ No service ☐

10. If positive, enrolled in HIV care: Yes ☐ No ☐

11. Prescribing practice of service providers

11.1. Treatment regimen for new cases

Regimen							
Initial/Intensive phase				Continuation phase			
Drug	Dose	# of tablets	Duration	Drug	Dose	# of tablets	Duration
1.____	____mg	_____	_____	1.____	____mg	_____	_____
2.____	____mg	_____	_____	2.____	____mg	_____	_____
3.____	____mg	_____	_____	3.____	____mg	_____	_____
4.____	____mg	_____	_____	4.____	____mg	_____	_____

11.2. Treatment regimen for re-treatment cases

Regimen							
Initial/Intensive phase				**Continuation phase**			
Drug	Dose	# of tablets	Duration	Drug	Dose	# of tablets	Duration
1.____	____mg	_____	_____	1.____	____mg	_____	_____
2.____	____mg	_____	_____	2.____	____mg	_____	_____
3.____	____mg	_____	_____	3.____	____mg	_____	_____
4.____	____mg	_____	_____	4.____	____mg	_____	_____
5.____	____mg	_____	_____	5.____	____mg	_____	_____