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# Evaluation of Adherence to the Guideline in Diagnosis of Tuberculosis Patients Attending Yekatit 12 Hospital Medical College, 2023

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## ABSTRACT

**Background: Tuberculosis has plagued humanity for centuries, causing significant suffering. References to the disease may even be found in the Old Testament, dating back to when the Israelites lived in Egypt, where TB was widespread. The term "tuberculosis" was first introduced by Lanneal and Bayle in the early 19th century. In 1882, Robert Koch identified the TB bacillus, marking a breakthrough in understanding the disease. Chalmette and Querin later laid the foundation for the Bacillus Calmette-Guérin (BCG) vaccine. TB chemotherapy began in 1943 with the introduction of streptomycin, followed by para-aminosalicylic acid in 1951. Short-course chemotherapy became the standard of care in the mid-1970s. Objectives: To evaluate the quality of TB diagnosis based on national tuberculosis guidelines. Methods: A retrospective study was conducted at Yekatit 12 Hospital, reviewing the records of patients of all ages treated for Tuberculosis (TB) between September 8 and October 9, 2023. Two nurses and one medical intern evaluated patient charts, sputum microscopy results, and radiographic records to assess adherence to diagnostic criteria. The collected data was checked for completeness and analyzed using SPSS software 24.1. Results: Out of the 116 patient records reviewed, 38 (32.6%) were diagnosed with smear-positive pulmonary TB (PTB), 48 (41.4%) with smear-negative PTB, and 30 (25.9%) with extrapulmonary TB (EPTB). Among those with smear-positive PTB, 24 (63.2%) were diagnosed correctly based on national guidelines. However, only 15 (31.2%) met the diagnostic criteria for smear-negative PTB cases when cases with three consecutive negative smears were excluded. Encouragingly, more than half of the patients diagnosed with lymph node TB had findings that aligned with national guidelines. Conclusion and Recommendation: Non-adherence to national TB diagnostic guidelines remains a significant challenge at Yekatit 12 Hospital. This gap in adherence underscores the need for targeted interventions to improve diagnostic practices. To enhance diagnostic accuracy and patient outcomes, it is essential to identify and implement strategies that encourage better compliance with these guidelines among clinicians. This could include regular training, closer monitoring, and more precise guidelines to ensure consistent and accurate TB diagnoses.**

**Keywords:** Tuberculosis (TB), Non-adherence, National tuberculosis guidelines, Diagnostic accuracy

## INTRODUCTION

### Background

Tuberculosis has been known since time immemorial, and it has inflicted the most misery on humanity. There are probably references to Tuberculosis in Old Testament books of the Bible dating to a time when the Israelites lived in Egypt, where TB was prevalent [1]. Lanneal and Bayle first used the name tuberculosis in the early 19th century. Robert Hock discovered the TB bacillus in 1882 AD. Chalmette and Querin laid the foundation for BCG vaccination (1). In 1943, chemotherapy began with the advent of streptomycin, followed by para-aminosalicylic acid, which was ionized in 1951. Short-course chemotherapy for TB started in the mid-1970s. Morbidity and mortality data from rich countries in the prechemotherapy era have shown that Tuberculosis declined even before specific intervention was available. This is most likely because of improved socioeconomic status. However, a decline in the rate of tuberculosis infection was observed in industrial countries due to continued socioeconomic development following the introduction of chemotherapy in 1940 [1]. Studies have shown that poorly organized tuberculosis control programs hurt tuberculosis situations by increasing the pool of infectious parents in society (chronic bacillary secretors). The experience of a few national programmers promoted and assisted by the International Union against Tuberculosis and Lung Disease during the 1990s provides the basis for today's WHO strategy for the tuberculosis control program [1].

Global efforts to control TB were strengthened in 1991 when the World Health Assembly resolutions recognized TB as a significant global public health problem. Two targets for TB control were established as part of this resolution: 70% of new smear-positive cases should be detected, and at least 85% should be treated [3]. These two targets were enabled by the DOTS strategy launched by WHO in 1994. In 2006, WHO launched the new Stop TB strategy, the core of which is DOTS [2]. In 2002, the global treatment success rate for TB reached 86%, the highest level at the time, reflecting the effectiveness of international health strategies. From 1995 to 2018, the treatment of 41 million people and the saving of 6 million lives highlight the significant progress made. However, challenges remain, particularly with multidrug-resistant TB (MDR-TB) and the need for more accessible treatment options in resource-limited areas. [3]

Ethiopia, the second most populous country in Africa, is significantly affected by Tuberculosis (TB), ranking third in Africa and seventh among the 22 high TB-burden countries globally. By 2017, the prevalence and incidence rates for all forms of TB were estimated at 261 and 359 per 100,000 people, respectively, contributing to an annual mortality rate of 64 per 100,000. According to the 2017 report from the Ethiopian Public Health Institute, the proportion of TB admissions has declined, falling from nearly 5% in 2001/02 to 1.5% in 2015/16. Additionally, TB prevalence and mortality rates have been reduced by more than 50% compared to the baseline values in 1990. This improvement can be attributed to the Federal Ministry of Health's focus on TB as a significant public health issue, integrating TB prevention and control into its key priority programs. [4, 5, 6, 7]

### Statement of the Problem

Mycobacterium tuberculosis has penetrated all the societies in the world, resulting in 1/3rd of the world's population being infected [3]. Worldwide wide, in 2009, there were 9.4 million TB cases, including 1.1 million cases among people with HIV, and 1.7 million people died from TB, including 380,000 people with HIV [2]. This death compromises 25% of avoidable deaths in

developing countries (2). Globally, in 2005, the annual incidence of TB, expressed as the number of new TB cases, was about 8.8 million people, and 7.4 million of these were in Asia and Africa. The annual number of deaths due to TB was 1.6 million, including 195,000 patients infected with HIV. It is estimated that one million (11%) of the total TB cases are children < 15 years of age [3]. Twenty-two high-burden countries (HBC) account for approximately 80% of the estimated number of new TB cases (all forms) arising worldwide. Ethiopia stands 7th in the list of HBCUs for TB (3). The estimated global incidence rate fell to 137 cases per 100,000 in 2009 after peaking in 2004 at 142 cases per 100,000 populations [2].

According to the MOH hospital statistics data, Tuberculosis is the leading cause of morbidity, the 3rd cause of hospital admission and the 2nd cause of death in Ethiopia. According to the 2007 WHO estimation, the incidence of TB in all forms and smear-positive TB stand at 341 and 154 per 100,000 population, respectively, in Ethiopia, and the prevalence and mortality of Tuberculosis of all forms are estimated to be 546 and 73 per 100,000 population, respectively. In 2006/07, Ethiopia registered 129,743 cases of TB [3]. Seroprevalence of HIV among TB patients is 40% according to the WHO Report 2008, and 31% according to more recent national data from 1999 E.C [3]. The WHO has declared TB as a global emergency since 1993. However, the problem is still out of control in many parts of the world. Efforts to tackle the issues so far have not been fruitful, at least in some areas. The main reasons for the failure include an inadequate political commitment from the government, a poor national TB control program, a high rate of population growth and HIV/AIDS epidemiology [2].

Currently, diagnosis and treatment are not standardized in Ethiopia (5). The disorganized and haphazard effort to diagnose and treat Tuberculosis, coupled with the lack of adequate essential resources, is the primary reason for failure [17]. So, it is vital that all health workers in the country strictly adhere to the guidelines to control TB [17]. In Ethiopia, reports show that a great majority of patients in big Hospitals and TB demonstration centers were started on anti-TB without proper diagnosis [9]. In one look at the TB control activities in rural Ethiopia, amid meager recourses, there has yet to be any attempt to systematically identify the pattern of diagnosis and social impact of Tuberculosis on the rural communities, for example, according to research done in 2020 at Agaro Health Center, most tuberculosis diagnoses needed to be deliberate and performed with confirmation [16].

The limited available diagnostic facilities and, therefore, unreliability in making firm diagnoses could negatively affect the tuberculosis control program with overdiagnosis or underdiagnosis. In recent years, the role of laboratory-based diagnostic methods has been enhanced by the impact of AIDS: overdiagnosis of sputum smear-negative PTB (due to difficulties in diagnosis) and underdiagnosis of sputum smear positive PTB (due to excess laboratory workload) [10).

Accurate diagnosis of active Tuberculosis is essential for controlling this disease in both high- and low-incidence regions and for the welfare of individuals [3]. For this reason, WHO sets standard diagnostic criteria to be followed before initiating anti-TB treatment, and currently, Ethiopia has accepted a national guideline for diagnosing Tuberculosis. Besides the above risks of poor diagnostic modalities and techniques, the absence of properly conducted studies in the country will contribute to further deterioration of the habit of adherence to the guideline; therefore, the importance of this study is unquestionable.

### Significance of the Study

The study evaluates the evidence supporting the initiation of anti-TB medication at Yekatite 12 Hospital and assesses whether the WHO standard diagnostic criteria are being applied. It is a reference for future large-scale studies, with findings that can inform subsequent recommendations and improvements in TB treatment practices.

## LITERATURE REVIEW

Tuberculosis was named to indicate the formation of firm nodules. It is a necrotizing bacterial infection that commonly affects the lungs. Still, lesions can also occur in other organs, such as the kidney, bones, lymph nodes or meanings, or they may be disseminated throughout the body [10].

The primary target of the DOTS strategy is to detect at least 70% of smear-positive PTB cases, the significant sources of tuberculosis transmission. Accurate diagnosis of pulmonary Tuberculosis is a cornerstone of tuberculosis control. Low detection of smear-positive and overdiagnosis of smear-negative pulmonary Tuberculosis has been a relentless problem over the years in Ethiopia [20].

A study from August 2001 to January 2002 in districts of Tigry shows that smear-positive pulmonary tuberculosis patients diagnosed per the diagnostic criteria represent 13.9% of all tuberculosis patients and 24.6% of pulmonary tuberculosis cases [20]. Among patients diagnosed as smear-positive, only 78.8% were diagnosed correctly (2 or more sputum smear-positive for AFB). 19% were diagnosed without any documented evidence, while one patient was put on anti-TB drugs after a trial of treatment with broad-spectrum antibiotics [20]. The detection of smear-positive PTB among two forms of new TB was twice lower than the proportion reported for Ethiopia in 2002 [24].

On the other hand, the proportion of patients with smear-negative pulmonary tuberculosis diagnosis was found to be disproportionally higher than the report from elsewhere [23]. Patients with presumed sputum smear-negative diagnoses accounted for 42.6% of all forms of TB and 70.6% of pulmonary TB diagnoses. These findings indicate that the chance of tuberculosis transmission could be high because of the sub-optimal defection of sputum smear-positive cases.

The increases in smear-negative pulmonary tuberculosis diagnosis in Ethiopia could be attributed to several factors: non-adherence to the diagnostic algorithm, poor quality of sputum microscopy and HIV- TB co-infections [20]. In this study, they found that non-adherence to the national diagnostic algorithm is a common problem in hospitals and other health institutions; of the (42.6%) of smear-negative pulmonary tuberculosis patients, only 2.9% were diagnosed as per the national diagnostic criteria, three initial negative smears for AFB followed by a trial of treatment with broad spec from antibiotics and 3 repeated negative smears and CXR findings consistent with pulmonary tuberculosis diseases) for 27.7% of smear-negative patients, the review team also considered the diagnosis correct. In 22.2% of patients, smear-negative pulmonary diagnosis was made based on three initial negative smears and CXR features, while 7.9% were diagnosed based on three initial negative smears for AFB. Only CXR evidence was used in 6.9% of patients, while 5.9% were put on TB treatment without any documented

evidence to substantiate their diagnosis. Two patients with three initial smears positive for AFB were put on anti-TB drugs as smear-negative PTB [20].

Regarding the investigation and procedures used to reach smear-negative PTB diagnosis, of 40.6% of patients presumed smear-negative PTB diagnosis, three initial smears were not made in 24.2%, 43.3% were not tried on broad-spectrum antibiotics, only 5% had repeat sputum smear, 32.3% had no CXR evidence, and no investigation was made in 6% of patients [20]. Thus, misdiagnosis is highly likely to occur among patients in whom the diagnosis of PTB was made without sputum smear examination because of the low diagnostic specificity of clinical signs and radiographic findings, particularly in HIV burden countries like Ethiopia [22]. A similar study in Malawi documented a relatively higher case defection rate (59%) among PTB suspects with three sputum smear examinations [11].

The quality of the EPTB diagnosis was assessed based on whether patients had consistent signs and symptoms of Tuberculosis and a lack of clinical response to treatment with broad-spectrum antibiotics. Of the EPTB patients who were on treatment, 67% were diagnosed with lymph node TB, and the remaining 23% were diagnosed with other anatomical sites. All patients diagnosed with lymph node TB have no documented evidence [20]. Of the 94 EPTB patients, 53.2% were treated with broad-spectrum antibiotics, while 44.7% were not. Of the lymph node TB, 50.8% worsening or the absence of clinical response to broad-spectrum antibiotics treatment was documented. At the same time, the reaming was put on anti-TB drugs without trial of therapy. Thirteen patients with involvement of organs other than lymph nodes were placed on anti-TB drugs without a trial of treatment with broad-spectrum antibiotics, and 50.1% had worsening or no clinical response to broad-spectrum antibiotics treatment [20]. Another study was done in 2000 at Agaro Health Center; most cases were started in DOTS without any confirmation of the diagnostics [16]. WHO diagnostic criteria were fulfilled only in 36.5% of cases; that is, 26.6% of patients had smears positive > 2 x for AFB, 5.3% of patients had fine needle aspiration of the lymph node consistent with Tuberculosis, and 3.7% of patients had chest X-ray consistent with Tuberculosis [16].

In the rest, 64.4% of patients were initiated anti-TB therapy without fulfilling the WHO diagnostic criteria (12). For instance, 37.1% of patients were diagnosed by symptoms and signs only and evaluated erythrocyte sedimentation rate (> 15/hr) [16]. In recent years, the role of laboratory-based diagnostic methods has been enhanced by the impact of AIDS (1). The accurate diagnosis of active Tuberculosis is essential for the welfare of the individuals [3].

The upsurge of HIV infection that changed the pattern of the disease in patients makes the diagnosis based on clinical observation less reliable [1].

## OBJECTIVE

### General Objective

To evaluate the quality of Tuberculosis (TB) diagnosis based on the national tuberculosis guidelines at Yekatite 12 Hospital.

### Specific Objectives

- To determine the socio-demographic characteristics of TB cases.

- To identify the types of Tuberculosis based on the sites of involvement.
- To assess the clinical findings in TB cases.
- To evaluate the investigations performed before the initiation of anti-TB treatment.

## METHODOLOGY

### Study Area and Period

The study was conducted at Yekatit 12 Hospital and Medical College. Yekatit 12 Hospital was established in 11923G. Until the Ethiopian revolution of the 11970s, it was known as Haile Selassie I Hospital, named after Emperor Haile Selassie I. In addition, Yekatit 12 Hospital Medical College maintains electronic medical record systems, which streamline the process of collecting data for this study. These records contain detailed information on patient demographics, medical history, investigation results, diagnoses and disease progress over time. The Hospital serves over 5 million people in its central 5 Departments in the catchment area. Addis Ababa was chosen as the study setting due to its diverse population, representing various socioeconomic backgrounds and cultural contexts. The city is known for its well-established healthcare infrastructure, making it a suitable location to access many emergency patients. An institutional-based cross-sectional study will be carried out in Yekatit 12 hospital medical colleges from September 8 to October 9, 2023

### Study Design

An institutional-based retrospective chart review was conducted to evaluate the guidelines for diagnosing Tuberculosis at Yekatit 12 Hospital.

### Population

**Source Population:**

All tuberculosis patients are visiting Yekatit 12 Hospital.

**Study Population:**

This includes all patients attending the TB follow-up clinic at Yekatit 12 Hospital from September 8, 2023, to October 9, 2023.

### Data Collection Process

**Instruments:**

A structured checklist was used to collect data, which included the following variables: sex, age, marital status, occupation, the signs and symptoms associated with TB, contact with individuals having a chronic cough, BCG vaccination status, investigations performed for each patient, the initiation of broad-spectrum antibiotics before anti-TB medication, the working diagnosis of the patient, response to treatment, the anti-TB regimen the patient is receiving, and the patient's clinical case details.

### Variables:

***Dependent Variables:***

Adherence to the diagnostic guideline for Tuberculosis

***Independent Variables:***

- Socio-demography includes sex, age, and marital status.

- Symptoms and signs of Tuberculosis
- Investigations performed like ESR, chest X-ray, FNA or biopsy and AFB stain
- Treatment response (improving, deteriorating)
- Who decides on the initiation of anti- TB medication (Nurse, HO, doctor, unknown)
- Type of TB case on sites of involvement.

***Data Collectors and Supervisors:***

- Two nurses participated in data collection alongside the principal investigator.
- Training on the data collection checklist and methods was provided to the data collectors.
- The principal investigator reviewed each completed questionnaire daily to identify any missed or improperly filled sections. Any discrepancies were corrected the following day.

**Data Analysis**

This study examined how well Tuberculosis (TB) diagnoses at Yekatit 12 Hospital Medical College in 2023 aligned with national guidelines. A total of 116 patient records were reviewed, classifying cases into smear-positive pulmonary TB (PTB), smear-negative PTB, and extrapulmonary TB (EPTB). The collected data was checked for completeness and analyzed using SPSS software 24.1.

**Operational Definition**

**New Case**: A patient who never had treatment for TB or has been on previous anti-TB treatment for less than four weeks [3].

**Relapse:** A patient declared cured or treatment completed of any form of TB in the past but who reports back to the health service and is newly found to be AFB smear-positive or culture-positive [3].

**Treatment Failure**: A patient who, while on treatment, is smear positive at the end of the fifth month or later after commencing. Treatment failure also includes a patient who was initially sputum smear-negative but becomes smear-positive during treatment [3].

**Defaulter**: A patient who has been on treatment for at least 4 weeks and where treatment was interrupted for eight or more consecutive weeks [3]

**Return after Default**: A patient previously recorded as defaulted from treatment and returns to the health facility with smear-positive sputum [3].

**Transfer Out**: A patient who started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of treatment results [3].

**Treatment Completed**: A patient who completed treatment but for whom smear results are not available in the 7th month or one month before the completion of therapy [3].

**Cured:** an initially smear-positive patient who is sputum smear-negative at, or one month before, the completion of treatment and on at least one previous occasion (usually at the end of the 2nd or 5th month) [3].

**Treatment Success**: The sum of patients two are declared "cured\' and those who have "completed" treatment [3].

**Chronic Case:** A TB patient who remains smear-positive after completing a treatment regimen [3].

**Suspect Case PTB**: The patient is suspected when presenting with symptoms and signs suggestive of Tuberculosis, in particular, cough, for two weeks or more [3].

**Positive AFB Stain**
**Pulmonary TB** is diagnosed when there are at least two acid-fact bacilli (AFB) positive results of sputum [6].

**Raised ESR**: When ESR > 15 mm/first hour in the Westergeen method.

**Adherence**
**For Adults**: When the following criteria are met [6].

- TB can be diagnosed when any of the following criteria are met.
- Bacteriological examination of the sputum's positive sputum examination (+ve- AFB stain> 2) or one AFB + ve + radiological abnormalities consistent with active pulmonary TB.

**For Children**: Two criteria must be met to show adherence in well-nourished children, and two should be met in malnourished children (2).

- The Mantoux test is an area of indurations of 10mm or more 48-78 after injection of the Mantoux in non-BCG vaccinated children.
- Radiological finding compatible with TB.
- Strong history of household (close) contact with proven or highly suggestive cases of TB.
- Strongly suggest TB symptom complex (13).

**Sputum Culture**
AFB stain can be used in cases of pulmonary TB, producing few bacilli to be detected. It is also mainly used for drug sensitivity testing. It detects 20 to 25% more cases among TB-symptomatic patients than smear examination, but two or more AFB stains could close that of a single culture. It takes several weeks to yield results and is a complex and sophisticated diagnostic tool, so it is not feasible in developing countries as a diagnostic tool.

**Radiological Examination**
Chest X-rays are sensitive but less specific. They're helpful for differential diagnosis of pulmonary disease among patients with negative sputum smears, military TB, and childhood TB [3].

**Chest X-rays** should be read by a radiologist or an experienced physician [3]. No shadow is typical for TB, and 40% of patients diagnosed as having TB disease by chest X-ray have another disease.

**Upper lobe infiltration and cavitary** lesions are the most frequent pulmonary TB in both HIV-infected and noninfected adults (3). However, atypical chest X-ray findings are common in HIV-infected patients [3].

### Histo Pathological Examination

In developing countries, where mycobacterium TB infection is frequent, HIV-infected individuals have primary and secondary mycobacterium tuberculosis infection with the usual well-formed granuloma composed of epitheloid cells, Langerhans giant cells and lymphocytes with central cases necrosis. In these lesions, acid-fast mycobacteria are few and often challenging to find [11].

### The Diagnosis of Tuberculosis in Children

There is always difficulty in children since TB is rarely smear-positive and thus depends on other clinical evidence. Gastric aspirate has yielded positive results of direct stain in 30-40% of cases if done by an experienced hand [13]. TB can be diagnosed when three of the following are present, but in PEM or immunocompromised children, it is diagnosed when two are present [3, 13].

- The Mantoux test is an area of indurations of 10mm or more 48-78 after injection of the Mantoux in non-BCG vaccinated children.
- Radiological finding compatible with TB.
- Strong history of household (close) contact with proven or highly suggestive cases of TB.
- Strongly suggest TB symptom complex. Besides, the diagnosis of active TB should be presumed when any of the following conditions are met [13].
- Positive manteaux reaction in non-BCG vaccinated children < 5 years of age.
- Radiologic picture of the milliary pattern.
- Pathologic findings compatible with TB from biopsy or surgically removed lesions.
- Isolation of the organism by AFB (in sputum or gastric aspirate). The treatment of TB becomes more difficult in the presence of malnutrition or other causes of immune compromise, like HIV/AIDS, because the month-out reaction on purified protein derivative (PPD) becomes negative [13].

### Ethical Consideration

A formal approval letter was obtained from the Ethical Review Committee of the Yekatit 12 Hospital Public Health Department. All study participants gave informed consent. All patient information was kept confidential and used exclusively for the study. Participants had the right to withdraw from the study during data collection if they chose not to continue. To ensure privacy, the questionnaire did not include personal information, including patient names.

### Problems Encountered

There is a lack of adequately conducted similar studies to compare the results. The recording system was incomplete and poorly maintained, which may have affected data accuracy and consistency.

## RESULTS

The diagnostic audit was done on 116 patients of all ages in the continuous phase of tuberculosis treatment. Most of them (92.2%) were diagnosed in Hospital (table 6). 62(53.5%) were male and 54(46.6%) were female, 39(29.3%) were farmer and 22(19%) were house wife (table 1).

Of the total patients assessed, 38 (32.6%) were diagnosed with smear-positive pulmonary Tuberculosis, 48(41.4%) were diagnosed with smear-negative pulmonary Tuberculosis, 21(18.1%) were EPTB, and 9(7.6%) were diagnosed with diss TB (Table 2).

Of 38 smear-positive pulmonary TB patients, 24(63.2%) had at least two or more initial smears positive AFB. In contrast, 4(10.5%) patients have one smear-positive plus CXR and prior trial of broad-spectrum antibiotics, 3(7.9%) patients have only CXR, 1(2.6%) patients have one smear and 6(15.8%) patients were put on anti-TB without any documented evidence that potentiates their diagnosis as smear-positive pulmonary TB. Among patients diagnosed as smear-positive PTB, 24(63.2%) were correctly diagnosed (2 or more sputum smears positive for AFB in the rest, the diagnosis was incorrect according to tuberculosis guideline diagnosis. The diagnosis of the smear-negative PTB was considered correct in 15(31.2%) patients based on the national tuberculosis diagnostic guideline (3 initial negative smears for AFB followed by a trial of treatment with broad-spectrum antibiotics and CXR evidence consistent with pulmonary tuberculosis diseases 6(12.5%) patients have three initial smears negative for AFB and CXR evidence, 5(10.4%) patients have three initial smears negative for AFB and trial broad-spectrum antibiotics, three smears negative for AFB, one patient have 2 AFB negative and CXR evidence, three patients have smear-negative plus CXR evidence 7(14.6%) patients have CXR and trial of broad-spectrum antibiotics and two patients have only CXR evidence for their diagnosis (table 5).

Out of EBTB 21(18.1%), 14 patients were diagnosed as gland TB, out of which 9(42.9%) were diagnosed correctly with FNA evidence plus a prior trial of broad-spectrum antibiotics and 4(19.1%) have only FNA evidence for their diagnosis, 1(4.8%) patients have only clinical evidence for their diagnosis. Out of EPTB, other than in, only 3(42.9%) were tried on prior broad-spectrum antibiotics regarding diss. TB out of 9(7.8%) patients, only 4(44.4%) patients were diagnosed based on clinically signed symptoms and prior antibiotics use, and 5(55.6%) have only clinical signs and symptoms.

Out of 116 patients, 82(74.5%) had a chronic cough for more than 3 weeks, and 98(84.6%) had a sign and symptoms complex of TB. 61(55.4%) of patients had contact with chronically coughing patients. Other clinical findings included abnormal chest findings in 53 (48.1%), lymphadenopathy in 24(21.8%), hepatomegaly in 11 (10), splenomegaly in 9(8.1%) and joint swelling in 1(0.9%) of patients (Table 3). The performed investigation were ESR in 84(76.3%) patients, AFB stain in 68(61.8%) CXR in 81(73.6%) of patients and FNA in 23(20.9%) cases of glandular TB (Table 4).

When the response to treatment was evaluated, 21(18.1%) of patients were cured, 21(18.1%) of patients were completed, and the majority of patients, 55(47.4%), were transferred cases (Table 7). Generally, among 116 tuberculosis patients of all forms registered in Yekatit 12

Hospital's tuberculosis center, 64(55.2%) wholly followed diagnostic criteria, and the rest, 52(44.8%), initiated anti-TB without fully following the WHO diagnostic guideline (Table 6).

**Table 1: Frequency distribution of socio-demographic characteristics of cases of TB. Yekatit 12 Hospital March 2023**

| Characteristics | Number(n) | Percentage (%) |
|---|---|---|
| **Age(year)** | | |
| 0-14 | 21 | 19.1% |
| 15-24 | 28 | 24.1% |
| 25-34 | 33 | 30.0% |
| 35-44 | 18 | 16.3% |
| 45-54 | 9 | 7.8% |
| 55 | 6 | 4.0% |
| **Sex** | | |
| Male | 62 | 53.5% |
| Female | 54 | 46.6% |
| **Occupation** | | |
| Housewife | 22 | 20.0% |
| Merchant | 15 | 13.6% |
| Farmer | 34 | 29.3% |
| Government employee | 15 | 12.9% |
| Others | 30 | 25.9% |

**Table 2: Frequency distribution of working diagnosis of patients in the TB clinic of Yekatit 12 Hospital, March 2023**

| Diagnosis Type | Number(n) | Percentage (%) |
|---|---|---|
| Pulmonary TB (total) | 86 | 74.1% |
| Smear-positive PTB | 38 | 32.7% |
| Smear-negative PTB | 48 | 41.4% |
| Extrapulmonary TB(EPTB) | 21 | 18.1% |
| Glands | 14 | 121% |
| Spine | 2 | 1.7% |
| Joints | 1 | 0.8% |
| Meningitis | 1 | 0.8% |
| Abdomen | 3 | 2.5% |
| Disseminated TB (diss. TB) | 9 | 7.8% |
| Lung +liver | 2 | 1.7% |
| Lung +liver +spleen | 2 | 1.7% |
| Lung +pleura | 2 | 1.7% |
| Lung +pericardium | 3 | 2.5% |

**Table 3: Frequency distribution of clinical findings of Tuberculosis, yeast 12 Hospital March 2023**

| Clinical findings | Number(n) | Percentage (%) |
|---|---|---|
| Chronic Cough(>3weeks) | 82 | 74.5% |
| Chronic cough(<3weeks) | 14 | 12.7% |
| Fever | 100 | 99.9% |
| Nights sweats | 103 | 93.6% |

| | | |
|---|---|---|
| Chest pain | 80 | 72.7% |
| Hemoptysis (blood in cough) | 32 | 29.1% |
| Weakness of limbs | 20 | 18.1% |
| Back pain/swelling | 32 | 29.1% |
| Contact with a chronic cougher | 61 | 55.4% |
| Prior antibiotic use | 55 | 50.0% |
| Abnormal chest findings | 53 | 48.1% |
| Lymphadenopathy | 24 | 21.8% |
| Hepatomegaly | 11 | 10.0% |
| Splenomegaly | 9 | 8.1% |
| Joint swelling | 1 | 0.9% |
| Meningeal signs | 1 | 0.9% |
| Weight loss | 94 | 85.4% |

**Table 4: Frequency distribution of investigations performed at Yekatit 12 Hospital March 2023**

| Investigation | Result | Number(n) | Percentage (%) |
|---|---|---|---|
| ESR | Normal | 4 | 3.6% |
| | Raised | 80 | 72.7% |
| | Not done | 8 | 7.2% |
| AFB Stain | Positive | 28 | 25.4% |
| | Negative | 40 | 36.3% |
| | Not done | 39 | 35.4% |
| Fine needle aspiration (FNA) | Consistent with TB | 18 | 16.3% |
| | Not Consistent | 5 | 4.5% |
| Chest X-ray | Suggestive of TB | 50 | 45.4% |
| | Not suggestive | 31 | 28.1% |
| | Not done | 29 | 26.3% |
| PPD Test | Not done | 116 | 100% |
| Culture | Not done | 116 | 100% |

**Table 5: Minimum diagnosis criteria met or not versus types of Tuberculosis diagnosed Yekatit 12 Hospital March 2023**

| Diagnosis | Minimum diagnostics criteria met | Minimum diagnostics criteria not met | Total(n) | Percentage (%) |
|---|---|---|---|---|
| Smear-positive pulmonary TB | 24(63.2%) | 14(36.8%) | 38 | 100% |
| Smear-negative pulmonary TB | 15(31.2%) | 33(68.8%) | 48 | 100% |
| Extrapulmonary (EPTB) | 17(81.0%) | 4(19.0%) | 21 | 100% |
| Disseminated TB (Diss. TB) | 4(44.4) | 5(55.6%) | 9 | 100% |
| Total | 64(55.2%) | 52(44.8%) | 116 | 100% |

**Table 6: Frequency distribution of place where the diagnosis of TB is established Yekatit 12 Hospital, March 2023**

| Place of diagnosis | Number(n) | Percentage (%) |
|---|---|---|

| | | |
|---|---|---|
| Yekatit 12 hospital | 107 | 92.2% |
| Private clinics | 9 | 7.8% |
| Others | 0 | 0.0% |
| Total | 116 | 100% |

**Table 7: Minimum diagnostic criteria met or not versus response to of patient to anti-TB Yekatit 12 Hospital, March 2023**

| Response to anti-TB treatment | Criteria met | Criteria not met | Total(n) | Percentage (%) |
|---|---|---|---|---|
| Cured | 15(71.4%) | 628.6%) | 21 | 18.1% |
| Completed treatment | 10(47.6%) | 11(52.4%) | 21 | 18.1% |
| Transferred out | 37(67.3%) | 18(32.7%) | 55 | 47.4% |
| Died | 1(33.3%) | 2(66.7%) | 3 | 2.6% |
| Status unknown | 5(31.3%) | 11(68.8%) | 16 | 13.8% |
| Total | 68(58.6%) | 48(41.4%) | 116 | 100% |

**Table 8: Frequency distribution of cases of Tuberculosis by age group and sex, yeast 12 Hospital March 2023**

| Diagnosis | <14 | 15-24 | 25-34 | 35-44 | 45-54 | 55 | Total(n) | Percentage (%) |
|---|---|---|---|---|---|---|---|---|
| | M | F | M | F | M | F | M | F |
| Pulmonary TB | 3 | 3 | 11 | 8 | 22 | 12 | 6 | 8 |
| Extrapulmonary TB(EPTB) | 4 | 3 | 3 | 3 | 1 | 3 | 1 | 2 |
| Disseminated TB (Diss. TB) | 3 | 3 | 0 | 0 | 0 | 0 | 1 | 0 |
| Total | 10 | 9 | 14 | 11 | 23 | 15 | 8 | 10 |

## DISCUSSION

The primary target of DOTS strategies is to detect at least 70% of smear-positive PTB cases that are significant sources of tuberculosis transmission. Accurate diagnosis of pulmonary Tuberculosis is a cornerstone of tuberculosis control. Low detection of smear-positive and overdiagnosis of smear-negative PTB has been a relentless problem over the years in Ethiopia. In this study smear, positive pulmonary patients diagnosed as per the diagnostic criteria represent 20.7% of all forms of tuberculosis patients and 27.9% of pulmonary tuberculosis cases. The detection of smear-positive PTB among forms of new TB was lower than the proportion reported for Ethiopia in 2002(20). But it's a bit higher than one reported from districts of the Tigray region of northern Ethiopia in 2002 [20].

WHO diagnostic criteria were met in the majority of smear-positive pulmonary TB and EPTB of the gland, while in the majority, 33(68.7%) of smear-negative pulmonary TB and 5(55.6%) of diss. TB was initiated on anti-TB without fulfilling the diagnostic criteria, and there is a statistically significant association between the type of Tuberculosis and whether criteria were met (with X2 =36.241 of P. value =0.02 (<0.05). This could be attributed to several factors: non-adherence to the diagnostic algorithm, poor quality of sputum microscopy and HIV TB co-infection. This study treated 9 of 48 patients (18.8%) as smear-negative PTB without AFB microscopic examination. Thus, misdiagnosis is highly likely to occur among patients in whom the diagnosis of PTB was made without sputum smear examination because of the low diagnostic specificity of clinical signs and radiographic findings, particularly in HIV burden countries like Ethiopia [22]. A similar study in Malawi documented a relatively higher case detection rate (59%) among PTB suspects with three sputum smear examinations [11]. In

countries with a high burden of HIV, an increase in smear-negative PTB diagnosis was attributed to HIV co-infection. Other HIV-related pulmonary diseases that clinically resemble PTB were found to increase the diagnosis of smear-negative in resource-poor countries like Ethiopia [26] and other African countries where other diagnostic facilities are unavailable; over-diagnosis of smear-negative PTB in this study can not only be explained by the high occurrence of HIV co-infection although the proportion of smear-negative patients is more significant among HIV infected than HIV negative tuberculosis patients [27].

In EPTB, in more than half of patients with enlarged lymph nodes, the national diagnostic algorithm was adhered to by clinicians, and their decision to treat depended on clinical judgment, trial of broad-spectrum antibiotics, and FNA results. In this study, EPTB other than lymph nodes were diagnosed based on their clinical judgment and the clinician's decision to treat with TB treatment. The common extrapulmonary site of involvement was typical of HIV high-burden countries [21]. Because of the scarcity of diagnostic criteria to compare with it, it wasn't easy to comment on the quality of diagnosis in those cases. However, in the absence of diagnostic facilities, it is apparent that some of those patients could be misdiagnosed.

Proper documentation of TB health information that would enable the evaluation of detection and treatment outcomes of tuberculosis patients is essential [28]. However, 6 of 116 patients (52%) were put on treatment without any documented evidence of potential diagnosis. These problems could be attributed to the poor supervision of district TB leprosy officers.

The diagnostic algorithm used for PTB screening in Ethiopia was reported to be less sensitive and specific among HIV-infected suspects, and the inclusion of patients' HIV status as part of the diagnostic workup was recommended [13]. In this study, 14(12.1%) of 116 patients were seropositive for HIV infection. For the majority of patients 55(47.4%) who started on anti-TB medication, their progress, i.e., their response or deterioration, adverse effects of the drug on the patients and the like, were unknown because they were transferred as transferred cases to other TB follow-up clinics.

## CONCLUSION AND RECOMMENDATION

### Conclusions

The evaluation of TB diagnosis at Yekatit 12 Hospital reveals a significant adherence to national guidelines regarding patient age distribution, with most patients falling within the 20-34 age group. However, the majority of cases were smear-negative pulmonary TB, which highlights the need for alternative diagnostic approaches. Cough lasting more than three weeks emerged as the most common symptom, aligning with the typical presentation of TB. Regarding diagnostic investigations, AFB smear and ESR were the most frequently conducted tests, indicating the focus on standard diagnostic methods. Despite the adherence to some aspects of the guidelines, there are areas for improvement in aligning with best practices and ensuring comprehensive diagnostic approaches to enhance treatment outcomes.

### Recommendations

- **Strengthen Diagnostic Methods:** It is recommended to incorporate more advanced diagnostic techniques, such as molecular testing (e.g., GeneXpert), to improve the detection of smear-negative TB cases and to ensure timely and accurate diagnosis.

- **Improve Training for Healthcare Providers:** To enhance adherence to national TB guidelines, healthcare providers should receive regular training and continuous education on the latest TB diagnostic guidelines and protocols.
- **Enhance Record Keeping and Data Management:** Efforts should be made to improve the patient recording system to ensure accurate and comprehensive documentation, supporting better tracking of TB cases and treatment outcomes.
- **Promote Patient Education and Awareness:** Patients should be educated on the importance of seeking early care for symptoms such as persistent cough, as this could help in early detection and treatment, preventing further transmission.
- **Increase Access to Comprehensive TB Investigations:** To ensure more thorough diagnostic evaluations, a broader range of investigations should be routinely conducted, including chest X-rays and sputum cultures, alongside AFB and ESR tests.
- **Monitor and Evaluate Program Implementation:** Continuous monitoring and evaluation of the TB diagnostic process should be implemented to identify gaps in adherence to guidelines and provide targeted interventions where needed.
- **Strengthen TB Control Policies:** The Federal Ministry of Health should regularly revise or update national TB diagnostic and treatment guidelines to incorporate new research findings and technological advancements in TB care.

## List of Abbreviations

- AFB - Acid-Fast Bacilli
- ESR - Erythrocyte Sedimentation Rate
- TB - Tuberculosis
- MDR-TB - Multi-Drug Resistant Tuberculosis
- BCG - Bacillus Calmette–Guérin (vaccine)
- DOTS - Directly Observed Treatment, Short-course
- WHO - World Health Organization
- ESR - Erythrocyte Sedimentation Rate
- TB-HIV - Tuberculosis and Human Immunodeficiency Virus (Co-infection)
- Xpert MTB/RIF - GeneXpert MTB/RIF (a molecular diagnostic test for TB)

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