Demographic, Clinical Characteristics and Diagnostic Outcome of Presumptive Pulmonary Tuberculosis Patients Attending Health Care Facilities in Soroti District

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Abstract: Background: Tuberculosis is a public health problem in Uganda. In Soroti district, there were unanswered healthcare system questions about Pulmonary Tuberculosis testing. Therefore, we conducted a cross-sectional study across six health facilities to achieve the following objectives; Describe demographic and clinical characteristics of presumptive Pulmonary Tuberculosis patients attending the health care facilities, Describe sputum texture trends across the health care facilities, and Evaluate diagnostic performance characteristics of Ziehl Neelsen smear microscopy using Gene X-pert as the gold standard.

Methods: From April to June 2023, we employed purposive and simple random techniques to recruit 150 participants aged ≥12 years across the healthcare facilities. Standardized questionnaires were used to collect respondents' demographic and clinical data. A standard operating procedure for sample collection was employed to collect sputum specimens, subsequently tested for *Mycobacterium tuberculosis* using Gene X-pert and Ziehl Neelsen smear microscopy. Data was analyzed using both descriptive and analytical statistics.

Results: The study reported more female participants (73.3%) than males (26.6%). The predominant age group was 12-21 years. Patients presented with fever, noticeable weight loss, night sweats, and cough in the hierarchical order. Most patients produced muco-salivary sputum specimens, but the purulent sputum samples tested positive for *Mycobacterium Tuberculosis*. Ziehl Neelsen smear microscopy showed an average performance in detecting Pulmonary Tuberculosis.

Conclusion: Female health-seeking behavior, teens' locality and purulent sputum texture are more likely to influence Pulmonary Tuberculosis testing services in the health care system in Soroti district. Community sensitization and quality testing are important Pulmonary Tuberculosis control strategies.

Keywords: Sputum texture, Ziehl Neelsen smear microscopy, Clinical presentation, Demography, Health care facilities

1. Introduction

Tuberculosis (TB) disease is caused by rod-shaped bacteria called *Mycobacterium tuberculosis (MTB),* which are spread when TB-infected persons discharge aerosols into the environment [1]. The disease normally affects the lungs causing Pulmonary TB (PTB) but it can also disseminate to other body organs resulting in extra-PTB [2]. PTB is a preventable and curable disease. However, the epidemic continues to burden the global healthcare system affecting over 10 million people per year [1]. According to a study by Maryam et al. (2023) [3], the time-varying reproduction number for PTB indicates that each infected person causes at least one new infection over time and the chain of

transmission is not disrupted. Crucial action is needed to end the PTB epidemic by 2030, a goal adopted by all member states of the United Nations and the World Health Organization [4, 5].

Uganda is one of the 30 high burden TB countries, which registers an estimated 91,000 new cases per year [6] and several studies have highlighted the disease burden in the Country [7, 8, 9, 10]. According to Zawedde et al. (2022), there are several patient and health system-level barriers to PTB management [23]. In Soroti district, there were healthcare system misnomers and unanswered questions about the validity of clinical characteristics associated with PTB disease. Some individuals were infected with PTB but remained asymptomatic [11] while other people presented with the clinical features and yet lacked the disease [7]. Uganda's Ministry of Health National TB and Leprosy Control Program developed standardized guidelines for routine assessment of PTB clinical signs [12]. We believed this standardization was a biased clinical assessment tool because it could not be applied in more diverse or less severely affected populations. On the other hand, demographic patterns of the patient population attending health care facilities were uncertain and yet they are known to influence health and disease [13, 14].

Despite Uganda's concerted effort of PTB control, diagnosis was still a challenge. 65% of the primary healthcare facilities routinely use Ziehl Neelsen (ZN) smear microscopy as the main PTB testing method, which misses 60% of the case findings [15]. The gap was also observed in Mbale and Soroti regions where the TB case notification rates throughout ten years (2013-2022) were very low compared to other regions in Uganda [8]. Even more challenging, macroscopic sputum examination was not being done in the primary health care facilities and yet it would be a useful diagnostic indicator of the quality of life in patients with PTB and other respiratory disorders [16, 17]. Therefore, we conducted a cross-sectional study across six health facilities in Soroti district to achieve the following objectives; (1)-Describe demographic and clinical characteristics of presumptive PTB patients attending the health care facilities (2)-Describe sputum texture trends of the patients across the health care facilities and (3)-Evaluate diagnostic performance characteristics of ZN smear microscopy using Gene X-pert as gold standard. The study provided important information for supporting PTB testing decision-making, planning, and policy formulation.

2. Methods and Laboratory Analyses

2.1 Study design and population setup

The cross-sectional study targeted a population of presumptive TB patients attending TB departments of six health facilities; Soroti Regional Referral Hospital (SRRH), TASO Soroti Cluster Hospital, Princess Diana Health Center (H/C) IV, Tiriri H/C IV, Soroti H/C III and Western Division H/C III in Soroti district, Uganda. Participants aged 12 years and above were allowed to take part in the study for several reasons; it is not easy to collect sputum samples from children below 12 years. These children have paucibacillary TB so it is uncommon to find smear-positive cases among them [18]. For participants below 18 years, written consent was obtained from their parents or guardians.

2.2 Data collection methods

The study employed a purposive sampling approach to select study sites and a simple random technique to select the participants. From April to June 2023, a total of 150 respondents from the six healthcare facilities were recruited into the study.

2.2.1. Demographic and clinical data collection

Pre-tested and standardized questionnaires were used to collect respondents' demographic and clinical data. A standard operating procedure (SOP) for sample collection was used to guide acquisition of participant sputum specimens for subsequent *MTB* testing by ZN smear microscopy and Gene X-pert assay. All the project field activities were carried out according to the Ministry of Health and the National TB and Leprosy Program guidelines and Ethical standards [19].

2.2.2. Sputum collection and preservation

During sputum collection, safety precautions were observed and all specimens were treated as potentially infectious. Respondents were instructed on how to collect sputum specimens after rinsing their mouths thoroughly with clean water. Following this step, participants coughed deeply to loosen the sputum and then collected 5mls of phlegm into the falcon tubes. Each tube was tagged with a unique number for sample tracking and identification. After collection, smears for ZN microscopy were prepared immediately before liquefaction took place. The remaining sputum samples were also instantly processed for Gene X-pert assay or stored between 2°C to 6°C for up to 7 days.

2.3 Laboratory analyses

2.3.1. Sputum macroscopic examination

Each freshly collected sputum specimen was visually inspected and manually evaluated for textural properties.

2.3.2. ZN smear microscopy

ZN smear preparation and staining was done following the procedure by Bayot, Mirza, and Sharma, (2023) [20]. Transferred 15ul of a mucoid or purulent portion of sputum sample onto the center of a clean glass slide and made a smear of size; 2cm X 3cm. Air-dried the prepared smear for 10 minutes and then fixed with gentle heat. Covered the smear with 5mls of 10% carbolfuchsin dye and applied heat underneath the slide until steam appeared. Allowed the preparation to stain for 5 minutes and washed off the dye with clean water. Decolorized the smear with 50% acid alcohol for 2 minutes and washed it off with clean water. Counterstained the smear with methylene blue for 1 minute and then washed off the stain with clean water. Thereafter, placed the stained slide vertically on the drying rack and allowed it to air-dry at room temperature. The smear batches were examined for acid-fast bacilli using Zeiss Fluorescence microscope (Primo star model), in line with sputum examination technical guidelines for direct TB microscopy by the International Union against TB and Lung Disease [21].

2.2.3. Gene X-pert assay

Gene X-pert *MTB* assay by Kohli et al. (2021) (22) was performed as follows; 1ml of sputum sample was mixed with 2mls of Gene X-pert sample reagent, shaken several times, and incubated for 15 minutes at room temperature. The mixture was transferred into the Gene X-pert cartridge and inserted into the Gene X-pert machine. Cycle thresholds of 5 rpoB gene probes automatically reported the presence of *MTB* using Gene X-pert Dx software, version 2.1. Gene X-pert pert assay semi-quantitatively estimated the concentration of bacilli as defined by the cycle threshold range. Specimens containing *MTB* DNA were reported as POSITIVE while specimens lacking *MTB* DNA were reported as NEGATIVE.

2.4 Statistical analysis

Data was analyzed using both descriptive and analytical statistics and presented in the form of tables and line graph

3. Results

The study health facilities consisted of two hospitals, two H/C IVs and two H/C IIIs. A total of 150 participants were recruited for the study and all respondents were able to produce sputum samples. Of the 150 respondents; 40 (26.7%), 27 (18%), 28 (18.7%), 10 (6.6%), 9 (6%), and 36 (24%) were from Tiriri H/C IV, Soroti H/C III, Western Division H/C III, Princess Diana H/C IV, TASO Soroti Cluster Hospital and SRRH respectively. 3 out of the 150 participants tested positive for *MTB,* representing PTB prevalence of 2%.

3.1. Demographic and clinical characteristics of presumptive PTB patients attending healthcare facilities

Out of the 150 participants, 110 (73.3%) were females while 40 (26.6%) were males. Of the female participants; 33 (30%), 20 (18.1%), 21 (19.1%), 6 (5.1%), 7 (6.4%) and 23 (20.9%) were from Tiriri H/C IV, Soroti H/C III, Western Division H/C III, Princess Diana H/C IV, TASO Soroti Cluster Hospital and SRRH respectively. For the male respondents; 13 (32.5%), 7 (17.5%), 7 (17.5%), 7 (17.5%), 4 (10%) and 2 (5%) were from SRRH, Tiriri

H/C IV, Soroti H/C III, Western Division H/C III, Princess Diana H/C IV, and TASO Soroti Cluster Hospital respectively *(Table 1*.

Based on age group; 55 (36.6%), 24 (16%), 16 (10.7%), 19 (12.7%), 12 (8%) and 24 (16%) of the participants were under 12-21years, 22-31 years, 32-41 years, 42-51 years, 52-61 years and ≥ 62 years respectively. 12-21 age group had the highest number of participants of which 34.5% (19 out of 55 respondents) came from Soroti H/C III, 30.9 % (17 out of 55 respondents) were from Tiriri H/C IV, 16.4% (9 out of 55 respondents) were from SRRH, 14.5% (8 out of 55 respondents) were from Western Division H/C III, while 1.8% (1 out of 55 respondents) were coincidentally from Princess Diana H/C IV and TASO Soroti Cluster Hospital. In addition, all patients who tested positive for PTB were in the 12-21 years age bracket. By chance, both 22-31 and ≥ 62 years' age groups registered the second highest number of participants who were mostly from Tiriri H/C IV, Western Division H/C III, and SRRH. 52-61 age group registered the least number of participants, especially from Princess Diana H/C IV and TASO Soroti Cluster Hospital (*Table 1*).

Among the 150 patients, 86 (57.3%) had persistent fevers for two weeks, 73 (48.7%) had noticeable weight loss, 70 (46.7%) had night sweats, 46 (30.7%) had cough for more than two weeks and 5 (3.3%) had chest pain. 48.7% of the participants from all the health facilities had fevers and at least any other three symptoms (cough, noticeable weight loss and night sweats). 95% (38 out of 40), 85% (34 out of 40), and 65% (26 out of 40) of the patients from Tiriri H/C IV had fevers, noticeable weight loss and night sweats respectively. While 60.7% (17 out of 28) and 57.1% (16 out of 28) of the patients from Soroti H/C III had fevers and night sweats respectively. Participants from Western Division H/C III, Princess Diana H/C IV, TASO Soroti Cluster Hospital, and SRRH also had coughs, fevers, night sweats, and noticeable weight loss but at a proportion less than 50%. Chest pain was observed in 22.2% (2 out of 9), 10% (1 out of 10), and 5.9% (2 out of 34) of the patients from TASO Soroti Cluster Hospital, Princess Diana H/C IV and SRRH respectively (*Table1*).

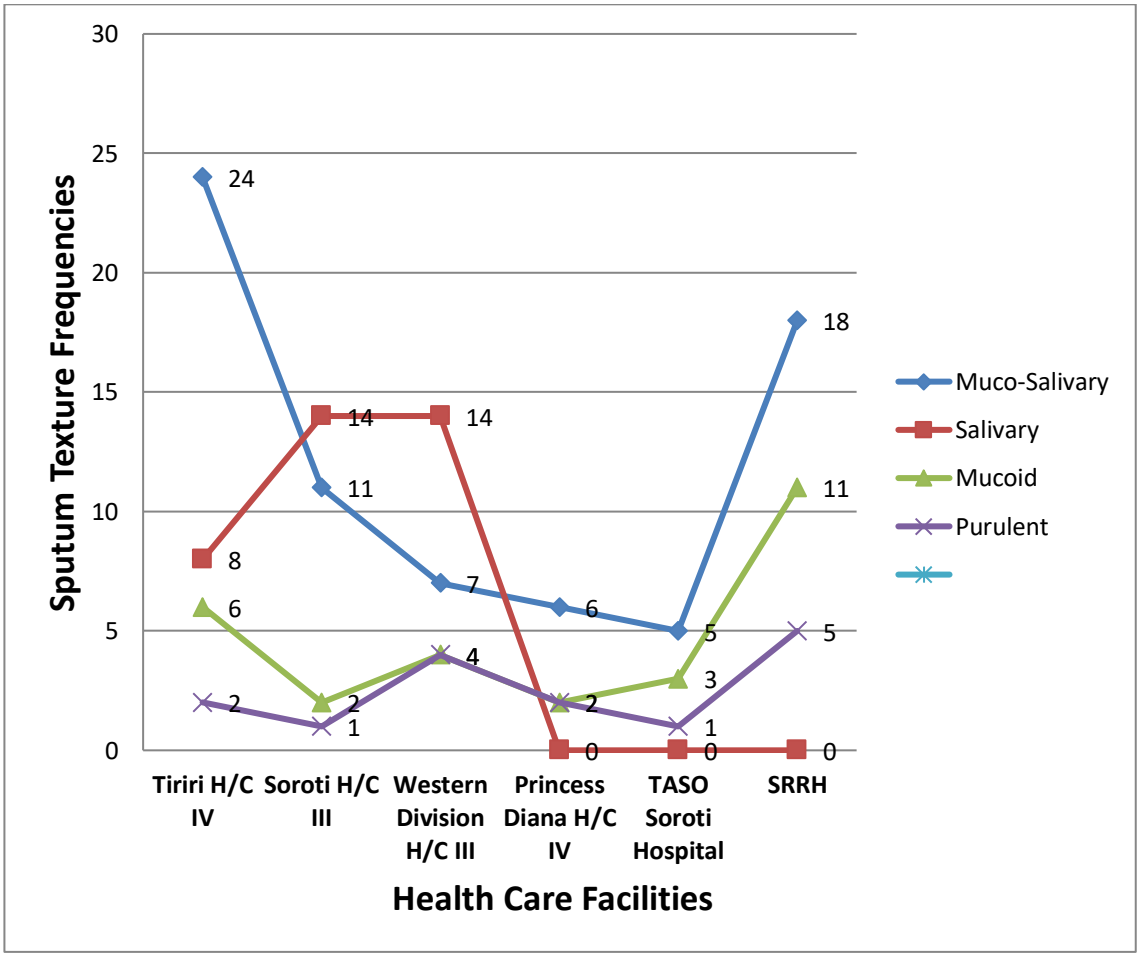
Table1: Shows demographic and clinical characteristics of the participants across the health care facilities

Characteristic	Total Number Enrolled	Tiriri H/C IV	Soroti H/C III	Western Division H/C III	Princess Diana H/C IV	TASO Soroti Cluster Hospital	SRRH
Sex: n (%)							
Male	**40(26.6)**	7 (17.5)	7(17.5)	7(17.5)	4(10)	2 (5)	13(32.5)
Female	**110 (73.3)**	33(30)	20 (18.1)	21(19.1)	6(5.1)	7(6.4)	23 (20.9)
Age in years n (%)							
12-21	**55 (36.6)**	17(30.9)	19(34.5)	8(14.5)	1(1.8)	1(1.8)	9(16.4)
22-31	**24 (16)**	4(16.6)	4(16.6)	7(29.2)	1(4.2)	2(8.3)	6(25)
32-41	**16 (10.7)**	3(18.8)	2(12.5)	4(25)	0(0.0)	2(12.5)	5(31.3)
42-51	**19 (12.7)**	6(31.6)	0(0.0)	4(21.1)	2(10.5)	2(10.5)	5(26.3)
52-61	**12 (8)**	2(16.7)	4(33.3)	3(25)	0(0.0)	1(8.3)	2(16.7)
≥ 62	**24 (16)**	8(33.3)	0(0.0)	2(8.3)	6(25)	1(4.2)	7(29.2)
Clinical presentation n (%)							
Cough							
Yes	**46 (30.7)**	12 (30)	13 (46.4)	10 (34.5)	1 (10)	2 (22.2)	8 (23.5)
No	**104 (69.3)**	28 (70)	15 (53.6)	19 (65.5)	9 (90)	7 (77.8)	26 (76.5)
Fever							

Yes	**86 (57.3)**	38 (95)	17(60.7)	13 (44.8)	2 (20)	3 (33.3)	13 (38.2)
No	**64 (42.7)**	2 (5)	11 (39.3)	16 (55.2)	8 (80)	6 (66.7)	21 (61.8)
Night sweats							
Yes	**70 (46.7)**	26 (65)	16 (57.1)	12 (41.4)	3 (30)	2 (22.2)	11 (32.4)
No	**80 (53.3)**	14 (35)	12 (42.9)	17 (58.6)	7 (70)	7 (77.8)	23 (67.6)
Weight loss							
Yes	**73 (48.7)**	34 (85)	13 (46.4)	10 (34.5)	2 (20)	3 (33.3)	11 (32.4)
No	**77 (51.3)**	6 (15)	15 (53.6)	19 (65.5)	8 (80)	6 (66.7)	23 (67.6)
Chest pain							
Yes	**5 (3.3)**	0 (0)	0 (0)	0 (0)	1 (10)	2 (22.2)	2 (5.9)
No	**145 (96.7)**	40 (100)	28 (100)	29 (100)	9 (90)	7 (77.8)	32 (94.1)

3.2 Sputum texture trends of the patients across the health care facilities

Out of the 150 sputum specimens collected from the patients, 71 were muco-salivary, 36 were salivary, 28 were mucoid and 15 were purulent. Most muco-salivary sputum specimens were collected from Tiriri H/C IV followed by SRRH, Soroti H/C III, Western Division H/C III, Princess Diana H/C IV, and TASO Soroti Cluster Hospital. Salivary sputum samples were obtained from Soroti H/C III Western Division H/C III and Tiriri H/C IV. Furthermore, the highest numbers of mucoid and purulent samples were obtained from SRRH followed by Tiriri H/C IV and Western Division H/C III. All the sputum specimens that tested positive for *MTB* were purulent. There was no significant relationship between MTB and sputum texture (p=0.21) *(Graph 1)*



Graph 1: Shows sputum texture trends of 150 patients across the six healthcare facilities

3.3 Diagnostic performance characteristics of ZN smear microscopy using Gene X-pert as the gold standard

The diagnostic performance of ZN smear microscopy was obtained using Gene X-pert as the gold standard. The performance characteristics were expressed as Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV). Sensitivity was 66.6%, Specificity was 97.5%, PPV was 50% and NPV was 98% (*Table 2).*

Table 2: Shows performance of ZN smear microscopy using Gene X-pert as the gold standard

Performance characteristic	Result
Sensitivity	66.6%
Specificity	97.5%
PPV	50%
NPV	98%

Number of sputum samples (N) = 150

4. Discussion

PTB is a highly infectious disease and a public health concern that inequitably impacts the most vulnerable populations worldwide. The Stop TB Strategy outlines ways for controlling TB and, beyond, towards the long-term goal of eliminating the disease as a global health problem by 2050 [24]. In this study, we enlightened on the patient and healthcare level aspects that influence PTB testing in the Soroti district. The H/C IIIs and H/C IVs had three main TB testing gaps (laboratory under staffing, poor specimen collection and high result turnaround time) and this affect quality of patient care in the district. Apart from the referral hospital (SRRH), the health facilities (Tiriri H/C IV, Soroti H/C III, and Western Division H/C III) located miles away from Soroti city had the highest number of respondents and were more likely to play a big role in PTB testing and management. Three participants tested positive for *MTB,* representing a study PTB prevalence of 2%. These patients were enrolled into care and followed up with a full treatment course.

Demographic patterns are a topic of much interest because of their influence on TB burden and importance in the healthcare and treatment of patients. In our study, we found out that females dominated the study. Moreover, all patients who tested positive for PTB were ladies. Women have good health seeking habits [25], they routinely visit the health centers even for minor sicknesses. This behavior could have contributed to their large numbers. Notably, most of the female patients were recruited from Tiriri H/C IV and SSRH. Unlike SRRH, Tiriri H/C IV is located about 29 kilometers away from the heart of Soroti city. This health facility serves a huge rural female population and we believe it plays an important role in the routine management of PTB disease in Soroti district. On other hand, highest male attendances were observed at SRRH and we linked this trend to the referral nature of the facility and the presence of specialized TB services. Males have busy lifestyles characterized by more frequent movements, social and economic activities than females [26, 27]. They hardly find time to routinely seek health care services unless they fall seriously sick or get referred for specialized management. Therefore, females have better health-seeking behaviors than males and are more likely to receive PTB services, especially from rural-based healthcare facilities.

Most of the study participants were teens of age bracket; 12 to 21 years. This age group comprises adolescents who are always under strict movement rules by either their household families or schools. Most of the teen participants were from Soroti H/C III and Tiriri H/C IV, which are located near schools and miles away from the center of Soroti city. This arrangement enables the adolescents to easily access health facilities and seek TB services. In addition, all PTB cases registered were teens and we believe the trend was influenced by the high number of participants in the said age category. The study also observed similar numbers of youthful (22-31 years) and elderly

(≥ 62 years) participants but with variable trends across the health facilities. There was no clear explanation for this pattern and we do recommend more demographic studies with bigger sample sizes to obtain more insight into the matter. The least number of participants observed under the advanced age bracket (52-61) and the urban-based health facilities was probably due to low patient turn up. It is possible that the community was not aware of the age-related risk of TB disease and this impacted routine hospital attendance. According to the WHO TB report (2019), elderly people have an increased risk of developing TB disease [21]. A study done by Samuel et al. (2022) also reported a high prevalence of PTB among people in the advanced age group (≥ 50 years) [7]. Our study recommends routine community sensitization about age-associated risk of TB disease by the health care facilities. In conclusion, teens are a restrictive age group whose access to PTB services is at the mercy of the health care facilities location.

The patients presented with multiple clinical signs, but the fever was more predominant followed by noticeable weight loss, night sweats, and cough. Fever has been recognized as one of the hallmarks of clinical disease since ancient times. Exogenous stimuli spur the release of endogenous pyrogens (interleukin-1, tumor necrosis factor and interferon α) which act on the thermoregulatory hypothalamus hence causing fever (28). As the body responds to the circulating tumor necrosis factor, the hypothalamus resets body temperature to a higher level for a while. Later, body temperature returns to normal and the extra heat is lost by sweating [28]. Noticeable weight loss is a clinical indicator of circulating proinflammatory mediators and cytokines that stimulate anorexia [29]. Furthermore, fever, night sweats, and noticeable weight loss were more pronounced in patients from the rural-based health facilities (Tiriri H/C IV and Soroti H/C III) while cough varied in participants across all the health facilities. Among the patients with multiple signs (fever, noticeable weight loss, night sweats, and cough) across the health facilities, only 3 tested positives for PTB disease. This implies that most of the patients had clinical characteristics but tested negative for PTB and were therefore associated with other disease states. In comparison with a similar Ugandan study carried out by Samuel et al. (2022), participants were found to have noticeable weight loss, night sweats, fever, and cough in hierarchical order [7]. Samuel's study was carried out in Western Uganda and had a large sample size compared to our study. This could explain variations in the clinical presentation of the patients between the two studies. Chest pain was the least recorded clinical sign and was observed only amongst patients from the urban-based health facilities (SRRH, TASO Soroti Cluster Hospital, and Princess Diana H/C IV). Moreover, none of the participants with chest pain tested positive for PTB, hence a less probable indicator of the disease. Although fever, noticeable weight loss, night sweats, and cough may be sometimes dubious, they still remain useful clinical indicators of PTB disease.

Most sputum specimens produced were muco-salivary, majorly obtained from health facilities that had a high number of study participants (Tiriri H/C IV and SRRH). Muco-salivary sputum specimens originate from the oral cavity, often have high concentrations of mucins and enzymes [30], and are therefore good for oral health assessment. Salivary samples were more marked in patients from the lower health facilities (Western Division H/C III and Soroti H/C III). Apart from Tiriri H/C IV, the higher-level health facilities did not register any salivary sputum specimens. In contrast with muco-salivary specimens, salivary samples contain respiratory secretions and are suitable for the diagnosis of respiratory diseases. A similar trend of mucoid and purulent sputum specimens was observed across the health facilities, with SRRH recording the highest number of these sample types. Patients who produce mucoid and purulent sputum forms have serious respiratory infections, allergic or inflammatory disorders that need specialized treatment. We do believe that high numbers of these specimen types at SRRH were influenced by the referral of severely ill patients from the lower health facilities for specialized respiratory disease management. Additionally, all sputum specimens that tested positive for *MTB* were purulent and were obtained from patients attending SRRH. We do propose that purulent sputum specimens are useful in PTB testing and are vital in specialized management of severe respiratory diseases.

The study examined the Sensitivity, Specificity, PPV, and NPV of ZN smear microscopy in PTB testing using Gene X-pert as the gold standard. According to Trevethan (2017) [31], decisions about desirable PPVs and NPVs can be approached from two related and complementary, but different, directions. One approach involves the extent to which true positive and true negative results are desirable on a screening test. The other approach involves the extent to which false positive and false negative results are tolerable or even acceptable. ZN smear microscopy yielded average Sensitivity and is capable of identifying 66.6% of patients with PTB as positive. The PPV was also average, showing only a 50% probability of positive-yielding patients as having PTB disease *(Table 2)*. Average PPV also shows that false positive outcomes cannot be minimized if only ZN smear microscopy is used in the

routine diagnosis of the disease. On the other hand, Specificity and NPV were desirable *(table 2),* which translate into minimal false negatives. This means, very few cases of PTB are left undetected by ZN smear microscopy which is a yes for the health care system and the community. Therefore, ZN smear microscopy has a desirable performance in detecting the absence of PTB and an average performance in detecting the disease presence. There is a need for a complementary microscopy method to supplement routine testing of PTB disease in health facilities.

5. Conclusion

In soroti district, we found out that the rural-based healthcare facilities have operational challenges but are more likely to play an important role in PTB testing and management. Females have better health-seeking behaviors than males and are more likely to receive PTB services, especially from rural-based healthcare facilities. Teens are a restrictive age group whose access to PTB services is at the mercy of the health care facilities location. Although fever, noticeable weight loss, night sweats, and cough may be sometimes dubious, they still remain useful clinical indicators of PTB disease. Purulent sputum specimens are useful in PTB testing and are vital in specialized management of severe respiratory diseases. ZN smear microscopy has a desirable performance in detecting the absence of PTB and an average performance in detecting the disease presence.

Recommendations

The study recommends the following; (1)-Routine community sensitization about age-associated risk of TB disease by the health care facilities. (2)-Inclusion of a complementary microscopy method to supplement routine testing of PTB disease in the health care facilities.

Compliance with ethical standards

Ethics approval and consent to participate

Ethical clearance was sought from the Research Ethics Committee of Mbale Regional Referral

Hospital and was approved under Reference: MRRH-2023-282. Written permission was obtained from all the study health care facilities before implementing the study. Written consent was also sought from all the respondents before participating in the study. For patients below 18 years, written assent was obtained from the parents or guardians. All information got from the patient was kept confidential.

Consent for publication

Both informed and written consent for publication was obtained from all the study participants.

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Authors' contributions

The main author wishes to thank all the co-authors for the academic contribution towards this work. SM participated in developing the study protocol, ethical clearance, microscopical analysis of sputum specimens, overseeing project activities and manuscript writing. LM participated in protocol writing, Gene X-pert analysis of sputum samples and manuscript writing. DA carried out project logistics, administration and manuscript writing. SN carried out field data collection, transportation and manuscript writing; SA participated in feasibility and pilot studies and manuscript writing. CB participated in project quality control, risk identification and management. JO participated in field data collection and manuscript writing. FT participated in protocol development, data analysis, monitoring and evaluation and manuscript writing.

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Competing interests

Authors declare no conflicts of interest.

Availability of data and materials

The authors declare availability of study data and materials that can provided upon request.

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