



Time to Sputum Smear Conversion in Patients with Bacteriologically Confirmed Pulmonary Tuberculosis in Kiambu County, Kenya

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Abstract

Introduction: Tuberculosis (TB) remains a significant global health burden, with 8.3 million new cases and 1.25 million deaths reported in 2023. Africa accounted for 24% of these cases, with Kenya ranking among the top 30 high-burden countries, reporting 97,126 TB cases. Kiambu County is among Kenya's top 12 high-burden counties, with a case notification rate of 189 per 100,000. Consequently, this study aimed to assess the time to sputum smear conversion and identify demographic, clinical, and socio-economic factors associated with delayed conversion among TB patients in Kiambu County.

Methods: A prospective longitudinal study was conducted among 316 newly diagnosed TB patients, who were followed from treatment initiation with weekly sputum smear assessments and monthly measurements of blood sugar and weight until smear conversion. Data were analysed using R Version 4.3.4 employing descriptive statistics, Cox Proportional Hazards Models, and survival analysis.

Results: Delayed sputum conversion was significantly associated with a high initial bacillary load (hazard ratio, HR = 1.52, $p < 0.001$), diabetes (HR = 1.20, $p = 0.036$), and poor socioeconomic status (HR = 1.16, $p = 0.007$). Conversely, older age groups 35–44 years (HR = 0.61, $p = 0.037$) and 55+ years (HR = 0.73, $p = 0.032$) demonstrated faster conversion rates.

Conclusion: This study underscores the importance of addressing demographic, socioeconomic, and clinical factors, such as area of residence, employment status, baseline bacillary load, diagnosis delays, and diabetes, to optimise sputum smear conversion. The findings highlight the need for targeted interventions and tailored strategies to enhance treatment success across diverse populations.

Keywords: Tuberculosis, Sputum Smear Conversion, Comorbidities, Non-conversion rate, Socioeconomic factors

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Introduction

Tuberculosis remains one of the leading causes of morbidity and mortality worldwide, accounting for a significant share of the global infectious disease burden, with an estimated 8.3

million new cases and 1.25 million deaths reported in 2023 (1). TB remains a major challenge in low- and middle-income countries, with Africa contributing about 24% of global cases. Kenya is among the top 30 high-burden

countries, reporting 97,126 TB cases in 2023, many of which were bacteriologically confirmed pulmonary TB. (2,3). Within Kenya, Kiambu County stands out as one of the twelve high-burden counties, recording a case notification rate (CNR) of 189 per 100,000 population and 2,109 bacteriologically confirmed cases representing 57% of its TB burden (2).

The World Health Organisation (WHO) recommends a standardised six-month treatment regimen for drug-sensitive TB, comprising an initial two-month intensive phase with Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol, followed by a four-month continuation phase with Rifampicin and Isoniazid (4,5). Sputum smear conversion from positive to negative is a key indicator of treatment response in pulmonary TB, typically expected by the second month. Timely conversion reduces infectiousness and improves outcomes, while delays signal poor response, ongoing transmission, and potential drug resistance (6–8).

Recent global and regional studies have identified various predictors of delayed sputum smear conversion, with high bacillary load, poor nutrition, and comorbidities like diabetes and HIV consistently linked to delays across multiple African contexts. (9–12). In Kenya, there is limited research on predictors of delayed smear conversion, especially at sub-national levels. Furthermore, the existing facility-based studies have mainly focused on overall treatment outcomes, without specifically exploring how demographic, clinical, biological, and social factors influence time to conversion (13). Moreover, most existing studies globally have used retrospective designs or focused on isolated variables, such as HIV or diabetes, without a comprehensive multivariable approach tailored to specific population contexts (7,14).

This study addresses the limited evidence on how comorbidities, substance use, socio-demographics, and delays in care influence sputum smear conversion among TB patients in

urban and peri-urban settings. It specifically examines Kiambu County, assessing time to conversion and key predictors of delay. By highlighting the role of social determinants such as alcohol use, housing, and education, the study provides context-specific insights to guide targeted TB care, enable early identification of high-risk patients, and strengthen Kenya's TB control efforts

Material and Methods

Study design

This prospective longitudinal study aimed to determine the time to sputum smear conversion through weekly microscopy from the start of TB treatment and to identify factors linked to delayed conversion. A prospective design was used to capture key variables not routinely recorded in standard TB care.

Study setting

This study was conducted in Kiambu County, Kenya, a high TB-burden area in the Mount Kenya Region. Bordered by six counties, Kiambu experiences high population migration, diverse economic activities, and a poverty rate of about 25% (15). Additionally, it comprises both urban and peri-urban populations with varying healthcare access and includes twelve sub-counties, each with at least 15 treatment sites and 5 diagnostic sites.

Study participants

Adults aged 18 years and older with bacteriologically confirmed, drug-sensitive pulmonary tuberculosis, diagnosed and initiated on first-line treatment between December 2023 and June 2024 in any of the selected facilities, were recruited in the study. Enrollment was consecutive, based on informed consent. Patients with drug-resistant TB at baseline, those clinically diagnosed, or individuals with unverified adherence or a high likelihood of loss to follow-up were excluded.

Sample size determination

The sample size was determined using the standard formula for comparing two

proportions, based on the expected reduction in smear positivity from baseline to the end of the intensive phase. The baseline smear positivity rate was estimated at 60%, with an anticipated decline to 15% after the intensive phase (4). The calculation assumed a 95% confidence level, 80% power, and a design effect of 1.05 to account for clustering, with an intraclass correlation coefficient of 0.05. To further accommodate an anticipated 25% dropout rate, the sample size was adjusted upward. This yielded an estimated requirement of approximately 13 participants per facility, and with 24 facilities included, the total sample size was 316 participants (16).

Sampling methods

The County is divided into 12 administrative Sub-Counties, from which two high-volume health facilities were purposively selected per Sub-County. Eligible patients were consecutively enrolled until the required sample size was achieved. Clustering was applied at both the Sub-County and facility levels.

Data collection tools and procedures

This study integrated routine TB care with enhanced diagnostic and clinical monitoring. Patients were enrolled at the time of diagnosis, before treatment initiation. To complement the initial diagnostic method, additional sputum samples were collected: cases diagnosed by GeneXpert/Truenat/LAMP underwent microscopy to determine bacillary load, while those diagnosed by microscopy were tested with GeneXpert/Truenat to assess rifampicin resistance.

Baseline assessments included random blood sugar (RBS), HIV testing, haemoglobin, and anthropometric measurements. Nutritional support was provided for patients with malnutrition.

During follow-up, patients received weekly sputum smears and monthly weight checks with treatment dosage adjustment. RBS was monitored monthly, and alcohol and smoking were assessed as binary variables. Patients with

abnormal RBS underwent HbA1c testing and were referred to the medical outpatient clinic (MOPC). HIV-positive patients were linked to the comprehensive care clinic (CCC), and anaemia was managed according to severity.

Data collection tools were pilot-tested on 15% of the sample (n=47) at Wangige Sub-County Hospital, with results excluded from the final analysis. The questionnaire showed good reliability (Cronbach's $\alpha = 0.82$). Pilot findings informed refinements to question wording, skip patterns, response options, and the abstraction sheet, enhancing clarity, validity, and ease of use.

Data management and analysis

Data were initially entered into Google Sheets and subsequently cleaned in Excel to address duplicates, assess completeness, and ensure accuracy. Analysis was conducted using R version 4.3.4. Outliers were evaluated, with valid outliers retained and errors either corrected or excluded. A correlation matrix was used to assess multicollinearity and inform feature selection. Descriptive statistics were used to summarise key variables, followed by survival analysis using the Cox proportional hazards model to identify factors influencing time to sputum smear conversion. The dataset was structured in a person-time format, capturing weekly observations for each participant until conversion or censoring due to death, loss to follow-up, transfer out, or development of drug resistance, resulting in more observations than individual participants. Results were reported using hazard ratios (HR), p-values, and 95% confidence intervals (CI), and were visually presented through tables, box plots, and graphs to aid interpretation and inform recommendations.

Ethical consideration

Ethical clearance was granted by the KEMRI Scientific and Ethics Review Unit (SERU), KEMRI/SERU/CRDR/090/4752, and a research permit was obtained from NACOSTI (License No: NACOSTI/P/23/31848). Informed consent was secured from all participants,

ensuring compliance with Good Clinical Practice guidelines and the Declaration of Helsinki. Participant well-being was prioritised, especially for those with delayed conversion or treatment failures. Confidentiality was maintained by using participant study numbers, and participation was voluntary.

Results

Social demographic characteristics of the participants

The final analysis included 310 participants; six were excluded due to incomplete data. This group comprised 99 females (32%) and 211 males (68%). The median age was 28 years (IQR: 20–38) for females and 38 years (IQR: 30–50) for males. Overall, 66% lived in formal settlements, more so among males (69%) than females (60%). Secondary education was the most common education achieved (52%), with more females (62%) than males (48%) having attained it. Casual labour was the prevalent

employment status among males (38%), while 44% of females were unemployed. During weekly sputum follow-up, 92% submitted all samples, 6% missed some but converted, and 2% died or were lost to follow-up.

Clinical characteristics of the participants

Table 2 compares clinical characteristics by sex, showing that undernutrition (BMI <18.5) was more common in males (62%) than females (29%), while HIV positivity was higher in females (21% vs. 9%). Most participants had multiple symptoms, with 97% of females presenting with ≥ 3 symptoms compared to 87% of males. Diagnostic delay was slightly longer in females (median 6 weeks) than in males (5 weeks).

As shown in Figure 1, the median conversion was ~5 weeks for both sexes, but females had a wider interquartile range, and males had more outliers beyond 10 weeks.

Table 1

Social Demographic Characteristics of the Participants - Kiambu County, 2024

Characteristic		Female, n = 99	Male, n = 211	Overall, n = 310
Age Group, Years	15-24	40 (40%)	26 (12%)	66 (21%)
	25-34	22 (22%)	58 (27%)	80 (26%)
	35-44	24 (24%)	53 (25%)	77 (25%)
	45-54	12 (12%)	55 (26%)	67 (22%)
	55+	1 (1%)	19 (9%)	20 (7%)
	Median Age [IQR], years	28 [20, 38]	38 [30, 50]	36 [26, 47]
Settlement	Formal Settlement	59 (60%)	145 (69%)	204 (66%)
	Informal Settlement	40 (40%)	66 (31%)	106 (34%)
Highest Education Level	None	0 (0%)	1 (0.5%)	1 (0.3%)
	Primary	20 (20%)	71 (34%)	91 (29%)
	Secondary	61 (62%)	101 (48%)	162 (52%)
	Tertiary	18 (18%)	38 (18%)	56 (18%)
Occupation	Casual Laborer	11 (11%)	81 (38%)	92 (30%)
	Employed	22 (22%)	45 (21%)	67 (22%)
	Not Employed	44 (44%)	27 (13%)	71 (23%)
	Self-employed	22 (22%)	58 (27%)	80 (25%)
Marital Status	Married	47 (47%)	74 (35%)	121 (39%)
	Separated/Divorced	13 (13%)	59 (28%)	72 (23%)
	Single	39 (39%)	74 (35%)	113 (36%)
	Widow/Widower	0 (0%)	4 (2%)	4 (1%)

Most participants converted within 3–6 weeks, with higher conversion among males (79%) than females (71%). Conversely, 29% of females did not convert, compared to 21% of males.

Side effects were similar across sexes, though females reported more multiple side effects. Comorbidities such as alcoholism (53% in males vs. 15% in females) and smoking (27% vs. 5%) were higher among males. Diabetes prevalence was similar. Males had a greater overall comorbidity burden, with only 36% reporting none, compared to 72% of females. Bacillary load and RBS levels were comparable, though males had slightly higher median RBS.

Outcome measures (Cox Proportional Hazards Model)

The Cox proportional hazards model in Figure 2 identified key predictors of delayed sputum smear conversion. Participants aged 35–44 and those 55+ had significantly lower hazards of non-conversion compared to those aged 15–24 (HR = 0.81, $p = 0.037$ and HR = 0.72, $p = 0.032$,

respectively). Living in informal settlements was linked to a higher risk of non-conversion (HR = 1.16, $p = 0.007$). Although males had a slightly higher hazard than females, the difference was not significant (HR = 1.07, $p = 0.366$). Education level had no significant effect. Employment status mattered: casual labourers (HR = 1.19, $p = 0.04$), employed (HR = 1.22, $p = 0.026$), and self-employed (HR = 1.20, $p = 0.04$) participants had a higher risk of non-conversion than the unemployed.

Among clinical factors, multiple side effects were significantly associated with delayed conversion (HR = 1.31, $p = 0.004$), while HIV status and undernutrition were not. Alcoholism and smoking showed no significant impact, despite being more common in males. However, diabetes significantly increased the hazard of non-conversion (HR = 1.20, $p = 0.036$). Higher baseline bacillary load significantly predicted delayed conversion: 3+ (HR = 1.52, $p < 0.001$) and 2+ (HR = 1.29, $p = 0.035$).

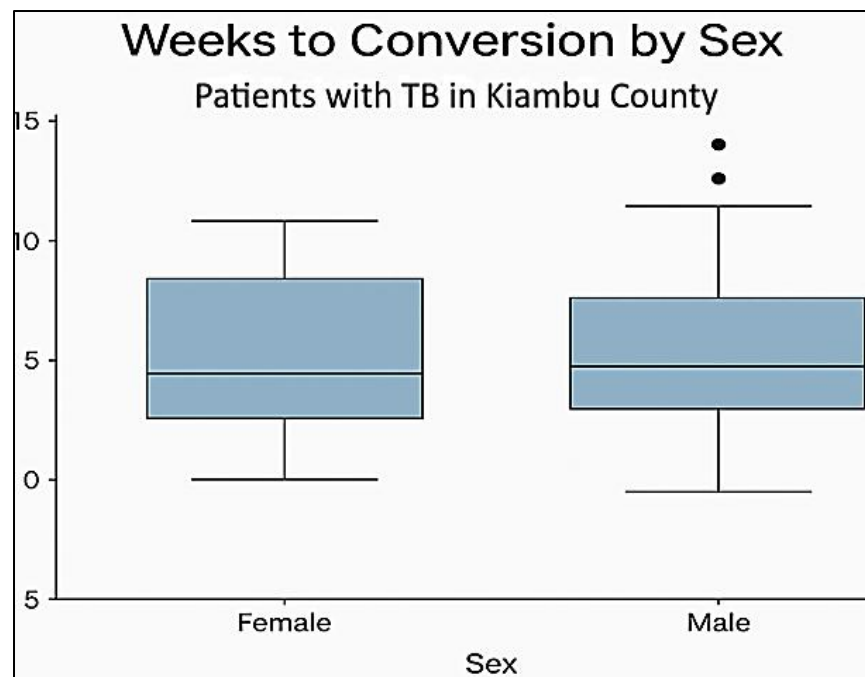


Figure 1
Weeks to Conversion by Gender – Kiambu County, 2024

Survival analysis

Delay in Diagnosis and Conversion: The Kaplan-Meier curve (Figure 3) shows how diagnostic delays influence the time to sputum smear conversion. Patients diagnosed within ≤ 4 weeks converted more quickly (median 5.0 weeks), while those with delays

of 9–12 weeks (median 6.0 weeks) and ≥ 13 weeks (median 7.0 weeks) experienced slower conversion. The shaded areas represent confidence intervals, highlighting the variability of results. These findings indicate that longer delays in diagnosis were associated with prolonged infectiousness and delayed treatment response.

Table 2

Clinical Characteristics of the participants - Kiambu County, 2024

Characteristic		Female, n = 99	Male, n = 211	Overall, n = 310
BMI, kg/m ²	<16 (SAM)	9 (9%)	38 (18%)	47 (15%)
	16 – 18.49 (MAM)	20 (20%)	93 (44%)	113 (36%)
	18.5 – 24.99 (Normal)	60 (61%)	73 (35%)	133 (43%)
	25 – 29.9 (Overweight/ Obese)	10 (10%)	7 (3%)	17 (6%)
HIV status	Negative	78 (79%)	192 (91%)	270 (87%)
	Positive	21 (21%)	19 (9%)	40 (13%)
Symptoms	One symptom	0 (0%)	3 (1.4%)	3 (1%)
	Two symptoms	3 (3%)	24 (11%)	27 (9%)
	Three or more symptoms	96 (97%)	184 (87%)	280 (90%)
	Median delay in diagnosis [IQR], weeks [†]	6 [3, 9]	5 [2, 9]	5 [2, 9]
Weeks to sputum smear conversion	Weeks 1–2	5 (5%)	15 (7%)	20 (7%)
	Weeks 3–4	27 (28%)	50 (24%)	77 (25%)
	Weeks 5–6	32 (33%)	77 (37%)	109 (36%)
	Weeks 7–8	6 (6%)	26 (13%)	32 (11%)
	Week 9 and beyond	23 (24%)	38 (18%)	61 (20%)
Conversion/ non-conversion	Non-Conversion	29 (29%)	45 (21%)	74 (24%)
	Conversion	70 (71%)	166 (79%)	236 (76%)
Anti-TB Side Effects	No. side effects	64 (65%)	150 (71%)	214 (69%)
	One side effect	4 (4%)	14 (7%)	18 (6%)
	Two side effects	21 (21%)	35 (17%)	56 (18%)
	Three or more side effects	10 (10%)	12 (6%)	22 (7%)
Comorbidities	Alcoholism	15 (15%)	112 (53%)	127 (41%)
	Diabetes	11 (11%)	21 (10%)	32 (10%)
	Smoking	5 (5%)	57 (27%)	62 (20%)
No. of comorbidities *	No. comorbidities	71 (72%)	76 (36%)	147 (47%)
	One comorbidity	22 (22%)	78 (37%)	100 (32%)
	Two comorbidities	4 (4%)	50 (24%)	54 (17%)
	Three or more comorbidities	2 (2%)	7 (3%)	9 (3%)
Baseline Bacillary Quantification	0-9AFB/field (Actual Numbers)	6 (6%)	22 (10%)	28 (9%)
	1+	9 (9%)	22 (10%)	31 (10%)
	2+	38 (38%)	77 (37%)	115 (37%)
	3+	46 (47%)	90 (43%)	136 (44%)
	Median RBS [IQR], mMol/L	5.8 [5.2, 6.9]	6.0 [5.1, 7.9]	5.9 [5.1, 7.6]
	Diabetic RBS levels at baseline	11 (11%)	32 (15%)	43 (14%)
	*Comorbidities assessed- Anaemia, malnutrition, alcoholism, smoking, HIV, diabetes.			
*BMI- SAM - Severe Acute Malnutrition, MAM - Moderate Acute Malnutrition				

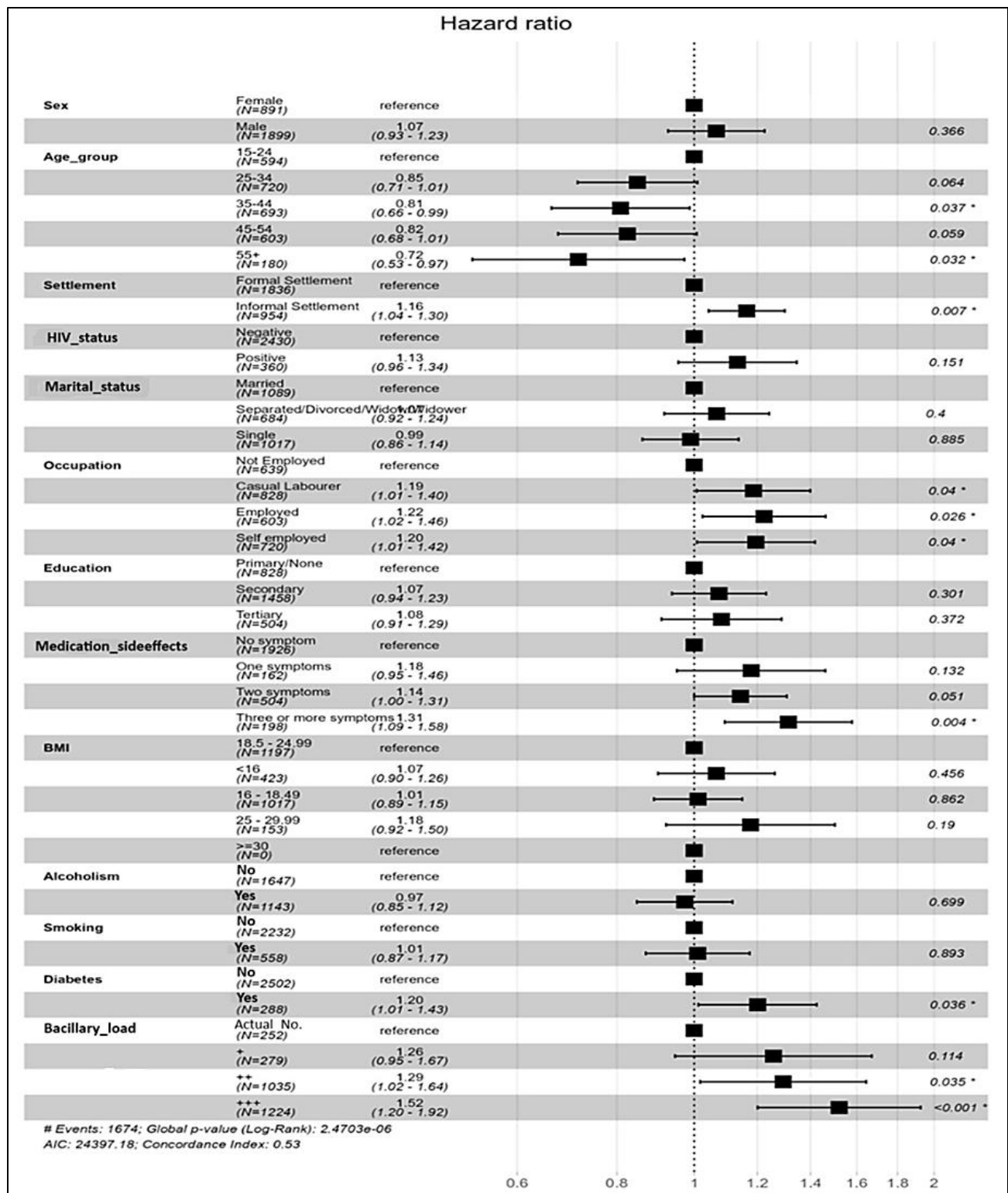


Figure 2
Multivariable Cox Regression Analysis of Predictors of Time to Sputum Smear Conversion - Kiambu County, 2024

Discussion

In this study, clinical factors exerted a greater impact on delayed sputum smear conversion among pulmonary TB patients than demographic characteristics. Delayed conversion was significantly linked to residence in informal settlements, engagement in casual labour, multiple drug-related side effects, diabetes, and high baseline bacillary load. These findings highlight the importance of targeted interventions that address both social determinants and clinical drivers to enhance treatment response and improve TB outcomes.

Time to sputum smear conversion

The non-conversion rate of 24% observed in this study contrasts with findings from other studies, which were 35% in Kenya, 15.7% in Uganda, 17% in Kandahar City,

Afghanistan, and 19.5% in Karachi, Pakistan (6,13,17–19). These discrepancies could be due to differences in study populations, treatment protocols, or healthcare infrastructure. Furthermore, Weekly conversion rates steadily increased, with a median conversion time of 5 weeks. This finding is consistent with studies showing similar median conversion time (6).

Demographic characteristics

Age significantly impacted conversion, with participants aged 35 and above showing better sputum conversion rates 35–44 (HR = 0.61, $p = 0.037$) and 55+ (HR = 0.73, $p = 0.032$). This finding contrasts with other studies that suggest younger individuals often exhibit better treatment outcomes due to stronger immune responses (20). However, adherence issues common in older adults might counterintuitively support faster conversion observed in this age group (21).

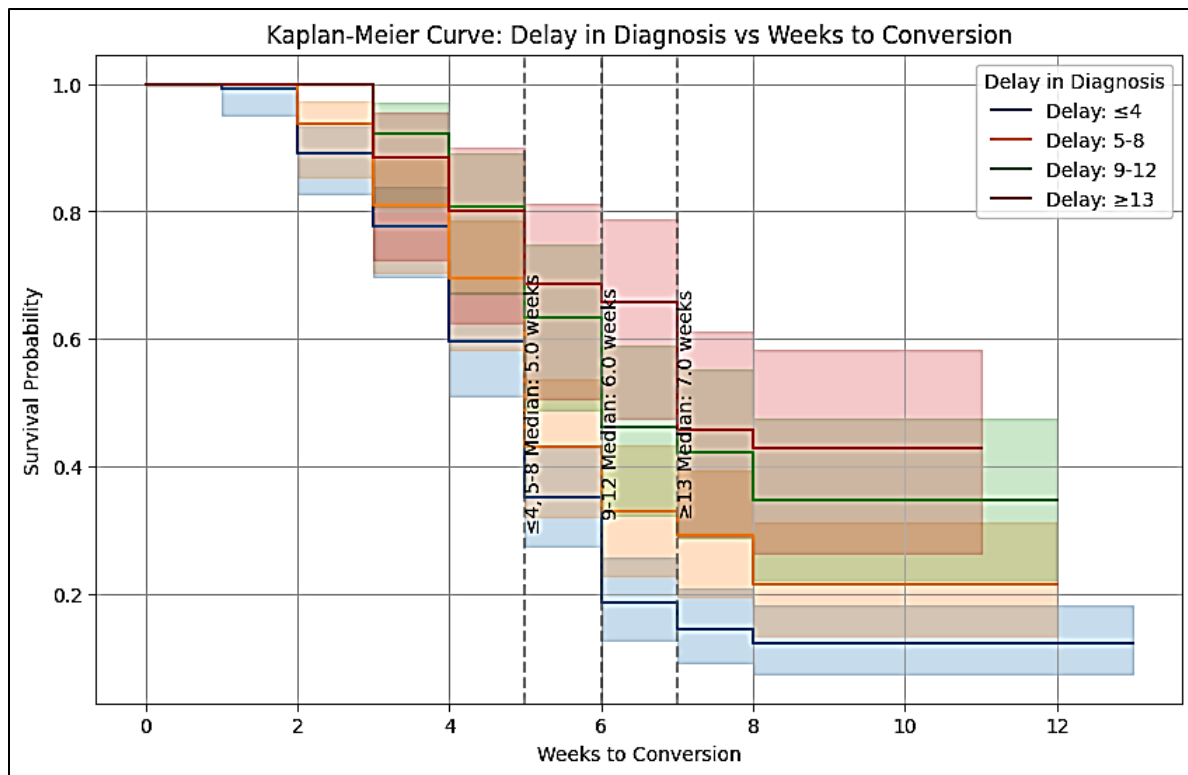


Figure 3

Kaplan-Meier Survival Curve Showing Time to Sputum Conversion by Delay in Diagnosis Categories - Kiambu County, 2024

Socioeconomic characteristics

In the current study, socioeconomic factors, particularly residence settlement type, significantly influenced smear conversion. Participants from informal settlements had a higher risk of non-conversion (HR = 1.16, $p = 0.007$), reflecting how poor living conditions contribute to delayed conversion, consistent with existing literature on the impact of overcrowding, limited healthcare access, and low socioeconomic status (22,23).

Employment status also emerged as an important predictor of non-conversion, particularly employed (HR = 1.22, $p = 0.026$). This supports studies identifying employment-related challenges as barriers to TB adherence (23,24). However, it contrasts with some research that suggests socioeconomic status, including employment, does not consistently impact conversion (25). These discrepancies highlight the complexity of socioeconomic influences on TB outcomes and the need for further research.

Clinical characteristics

Clinical characteristics showed notable gender-based differences influencing smear conversion. However, HIV co-infection did not significantly affect conversion in this cohort, contrasting with wider literature that associates HIV with poorer TB treatment outcomes. (26,27). The lower impact observed may indicate effective integrated TB and HIV care in the region, consistent with findings from sub-Saharan Africa (26). Higher baseline bacillary load was strongly associated with slower smear conversion 3+ (HR = 1.52, $p < 0.001$) and 2+ (HR = 1.29, $p = 0.035$), consistent with other studies (7,24). This indicates that the severity of infection at baseline, as measured by bacillary load, may be a key predictor of treatment success.

Although malnutrition was common, it did not significantly impact non-conversion, likely due to timely nutritional support. Nevertheless, given its known link to delayed conversion, this emphasises the need for

continued nutritional interventions for patients with low BMI. (19,28). Adjusting doses by weight might have minimised the impact of weight gain on conversion, agreeing with retrospective findings where weight gain was linked to faster conversion (29).

The study identified diabetes as a key comorbidity negatively impacting TB treatment success, increasing the hazard of non-conversion (HR = 1.20, $p = 0.036$). This supports existing literature showing that diabetes could impair immune response and reduce treatment effectiveness in TB management (30,31). In contrast, alcoholism and smoking did not show a significant association with non-conversion in this study, differing from previous research linking these factors to delayed sputum conversion (32).

Limitations/Strengths of the study

This prospective longitudinal study, embedded in routine TB care, incorporated nutrition, weight-based dosing, and management of comorbidities. Strengths were offset by limitations, such as limited power to detect small effects, restricted causal inference from its observational design, and potential selection bias from facility-based recruitment in Kiambu County. Weekly sputum microscopy enabled close monitoring but could not differentiate live from dead bacilli.

Conclusion

This study identified key factors influencing sputum smear conversion among TB patients, with a non-conversion rate of 24% and an average conversion time of 5 weeks, aligning with other studies. High baseline bacillary load, diagnostic delay, and diabetes were major predictors of poor outcomes, highlighting the importance of early detection and integrated care. Malnutrition and HIV had minimal impact, likely due to timely interventions.

Recommendations

Public health interventions should focus on vulnerable groups, especially younger

individuals and those in informal settlements, to enhance adherence and outcomes. Integrating TB and diabetes care with routine blood sugar screening is vital, while community awareness campaigns can reduce diagnostic delays. High-risk patients, such as those with diabetes or high bacillary load, require close monitoring and support. Future research should include broader populations, use advanced diagnostics like culture, and assess long-term outcomes such as relapse and post-treatment quality of life.

Definition of Terms

- **Bacillary Load:** Quantity of *Mycobacterium tuberculosis* bacteria in a patient's sputum.
- **Bacteriologically Diagnosed TB:** Tuberculosis confirmed via smear microscopy, Molecular diagnostics tests, or culture.
- **Cavitary TB:** TB where normal lung tissue is replaced by cavities.
- **Censoring (Survival Analysis):** When the event of interest is not observed due to loss to follow-up, transfer, drug resistance, or study end.
- **Comorbidities:** Presence of additional diseases alongside TB.
- **Confidence Interval (CI):** Range of values likely containing the true population parameter (95%).
- **Continuation Phase (TB Treatment):** The four-month phase following intensive TB treatment.
- **Cox Proportional Hazards Model:** Statistical model assessing the effect of multiple factors on time to an event.
- **Delayed Sputum Conversion:** Failure to achieve smear negativity after two months of intensive TB treatment.
- **Drug-Resistant TB:** TB caused by bacteria resistant to at least one first-line anti-TB drug.
- **Drug-Sensitive TB:** TB caused by bacteria susceptible to all standard first-line anti-TB drugs.
- **Gene Xpert/Truenat/LAMP:** Molecular diagnostics for rapid detection of TB and sometimes Rifampicin resistance.
- **Hazard Ratio (HR):** Relative risk of an event between groups.
- **Informal Settlement:** Residential area with poor housing and lack of legal tenure.
- **Intensive Phase (TB Treatment):** First two months of standard TB treatment.
- **Kaplan-Meier Curve:** Graph estimating the probability of an event over time.
- **p-value:** Statistical measure of significance (0.05).
- **Predictors (Covariates):** Study variables such as age, gender, marital status, education, and religion.
- **Prospective Longitudinal Study:** Research design observing participants over time with repeated measurements.
- **Rifampicin Resistance:** TB bacteria not effectively killed by Rifampicin.
- **Smear Conversion:** Change from *Mycobacterium tuberculosis* positive to negative on smear microscopy.
- **Statistical Significance:** Indicates an effect is unlikely due to chance.
- **Survival:** Continued existence after TB diagnosis.
- **Survival Time:** Duration from treatment initiation to negative test result.
- **TB Case Notification:** Number of new and relapse TB cases reported per 100,000 population per year.
- **Undernutrition / Severe/Moderate Acute Malnutrition (SAM/MAM):** Nutritional status based on BMI; SAM <16, MAM 16–18.49, undernutrition <18.5.

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Authors' contributions

- Annfreschia Wangari Maina – Principal investigator; conceptualized the study, designed the protocol, oversaw data collection, analysed data, and drafted the manuscript.
- Dr. Jane Ongango – Guided methodology, protocol development, and manuscript review.
- Dr. Magoma Kwasa – Facilitated County approvals and supported protocol development.
- Richard Kiplimo – Supported statistical analyses and data interpretation.
- Simon Njuguna – Digitised and cleaned data, assisted with analysis.
- Dr. Moses Ndiritu – Supported County approvals and manuscript review.
- Dr. Moses Njire – Advised on study design and manuscript preparation.

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