Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Gender-Specific Determinants of Tuberculosis Treatment Interruption in an Urban High- Burden African Setting: A Retrospective Cohort Study of Males in Nairobi, Kenya (2019– 2023)

L. Nkirote Mugambi-Nyaboga

lmugambi@chskenya.org

Centre for Health Solutions-Kenya

Kevin Owuor

Centre for Health Solutions-Kenya

Maerro Lutta

Centre for Health Solutions-Kenya

Elizabeth Mueni

Ministry of Health - Nairobi County

Martin Githiomi

Ministry of Health-Division of National Tuberculosis, Leprosy and Lung Disease Program

Aiban Rono

Ministry of Health-Division of National Tuberculosis, Leprosy and Lung Disease Program

Immaculate Kathure

Ministry of Health-Division of National Tuberculosis, Leprosy and Lung Disease Program

Paul Wekesa

Centre for Health Solutions-Kenya

Research Article

Keywords: (3, 10)

Posted Date: September 3rd, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10448548/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Background

Tuberculosis remains a major global public health challenge despite the availability of effective treatment. Treatment interruption undermines tuberculosis control by increasing disease transmission, treatment failure, and mortality. In Kenya, men account for most tuberculosis cases and experience poorer treatment outcomes, yet determinants of treatment interruption among men in urban settings remain insufficiently studied. In this study we examined the association between comorbidities, therapy-related factors, and health system factors and tuberculosis treatment interruption among males in Nairobi, Kenya.

Methods

A retrospective cohort study was conducted using routinely collected tuberculosis surveillance data from Nairobi County between January 2019 and June 2023. The data included 24,794 males aged 15 years and older who were newly diagnosed with tuberculosis and notified within Nairobi. The primary outcome was treatment interruption. Variables included comorbidities (diabetes and malnutrition), therapy-related factors (adverse drug reactions), and health system engagement measured by the frequency of clinic visits for sputum monitoring and drug refills. Descriptive statistics summarized patient characteristics, and bivariate associations were assessed using chi-square tests. Multivariable logistic regression models were used to estimate adjusted odds ratios and 95% confidence intervals for factors associated with treatment interruption.

Results

Overall, 7.9% of patients experienced treatment interruption. Malnutrition was independently associated with higher odds of interruption (adjusted odds ratio 1.23, 95% confidence interval 1.12–1.35). Adverse drug reactions, though based on few recorded events, were strongly associated with interruption (adjusted odds ratio 10.62, 95% confidence interval 3.53–31.95). In contrast, consistent clinic attendance demonstrated a strong protective effect; each additional clinic visit was associated with a substantial reduction in the likelihood of treatment interruption (adjusted odds ratio 0.30, 95% confidence interval 0.28–0.31). Alcohol use and pulmonary tuberculosis were also associated with higher interruption risk.

Conclusions

Treatment interruption among men receiving tuberculosis care in Nairobi was influenced by both patient vulnerabilities and health system engagement. Integrating nutritional support, strengthening monitoring

and management of adverse drug reactions, and expanding patient-centered service delivery models that facilitate regular clinic follow-up may improve treatment continuity. Targeted interventions addressing these factors could strengthen treatment outcomes and support progress toward tuberculosis control goals in urban high-burden settings.

BACKGROUND

Tuberculosis (TB) remains one of the leading causes of mortality and morbidity globally despite being preventable and curable [1]. In 2024, an estimated 10.7 million people fell ill with tuberculosis and 1.23 million died from the disease, making TB the leading cause of death from a single infectious agent, having surpassed both HIV/AIDS and COVID-19 [1, 2]. Global efforts aim to eliminate TB as a public health threat by 2030 [3–5]. Achieving these goals requires strengthening the entire TB care cascade, particularly ensuring treatment completion among populations at highest risk of poor outcomes.

Treatment interruption, often referred to as loss to follow-up (LTFU) remains a major barrier to TB control [6, 7]. Patients who interrupt treatment remain infectious for longer periods, experience worse clinical outcomes, and face substantially higher risks of relapse, mortality, and drug-resistant TB [8–11]. Evidence from multiple settings demonstrates that treatment interruption is driven by complex and interrelated factors including socioeconomic constraints, gender, stigma, patient mobility, pill burden, adverse drug reactions, and health system barriers [10, 12–14]. In Kenya, the 2018 national TB non-adherence survey indicated that nearly 35% of TB patients did not fully adhere to treatment, with risk factors including older age, male sex, HIV-negative status, intensive treatment, and extrapulmonary TB [15]. These findings highlight persistent structural and clinical barriers that undermine treatment continuity.

Kenya remains among the 30 high TB and TB/HIV burden countries globally, which together account for nearly 80% of the global TB burden [16]. In 2021, there were an estimated 32,000 TB deaths in Kenya, making it one of the country's leading causes of mortality [17]. The 2016 Kenya TB Prevalence Survey revealed marked gender disparities. TB prevalence among men was more than twice that of women (809 versus 359 per 100,000 population), and men accounted for the majority of undiagnosed infectious cases [18, 19]. Nearly 40% of TB cases remained undiagnosed in the community, with men disproportionately represented among these "missing people with TB." [20, 21]. These disparities suggest that gender-specific barriers influence both TB care engagement and treatment outcomes.

Men accounted for more than 65% of TB notifications in Kenya, with the highest burden among young adults aged 25–34 years and older men aged 65 years and above, particularly in urban settings [18, 19, 22]. Compared with women, men have been more likely to experience delayed diagnosis, poorer engagement with TB services, advanced disease at presentation, and treatment interruption. These patterns are influenced by gendered health-seeking behaviours, occupational mobility, higher alcohol and tobacco use, economic pressures, stigma, reliance on informal healthcare care [23–27]. Despite the

central role of men in TB transmission dynamics, TB programs in Kenya and similar high burden settings remain largely gender-neutral and often fail to address barriers that uniquely affect men [28]

Studies from Sub-Saharan Africa and other high-burden settings have identified stigma, food insecurity, long distances to health facilities, pill burden, and treatment fatigue as key contributors to TB treatment interruption [23–27]. In Kenya, alcohol use, HIV status, low education, and treatment phase have been identified as predictors of non-adherence and treatment interruption [29–32]. However, important knowledge gaps remain. Comorbidities such as diabetes and malnutrition; both increasingly recognized as contributors to poor TB outcomes, have not been adequately examined in relation to treatment interruption among men in Kenya. Additionally, adverse drug reactions (ADRs), widely documented as drivers of treatment interruption globally [13], have received limited attention in the Kenyan context [23–25]. Health system engagement, particularly the frequency of clinic visits for sputum monitoring and drug refills, has also been understudied despite evidence that patient-provider contact supports adherence [33].

Urban settings introduce additional complexities. Nairobi City County, Kenya's capital and largest metropolis, is characterized by dense informal settlements, high population mobility and heterogeneous health-seeking behaviours [34, 35]. Although Nairobi has relatively strong health infrastructure compared with rural counties, treatment interruption remains common particularly among men[1]. Understanding how clinical comorbidities, therapy-related factors, and health system characteristics interact to influence treatment continuity in such settings is therefore critical for designing effective interventions.

Guided by the WHO adherence conceptual framework domains [36], we aimed to examine how comorbidities (diabetes and malnutrition), therapy-related factors (adverse drug reactions), and health system factors (frequency of clinic visits for sputum monitoring and drug refills), influence tuberculosis treatment interruption among males aged 15 years and older receiving TB treatment in the urban City of Nairobi, Kenya.

METHODS

Study Design and Setting

We employed a retrospective cohort design using secondary analysis of routinely collected TB surveillance data from Nairobi City County, Kenya. Patients reviewed included those initiated on treatment from January 2019 to June 2023. These patients were followed until treatment interruption or completion, according to national TB program definitions. This study is reported in accordance with the STROBE guideline for observational studies (Additional file 1).

Nairobi County is Kenya's most populous and densely populated urban city county, comprising twelve sub-counties with marked socioeconomic heterogeneity [34]. Nairobi contributes approximately 13.6% of all TB notifications nationally [37] and TB care is delivered through an integrated public–private network [35]. All health facilities report patient-level data to the National TB Program's electronic surveillance

system (TIBU). Urban TB prevalence is markedly higher than in rural areas (760 vs. 453 per 100,000 population) [19], driven by dense informal settlements, overcrowded housing, high population mobility, and socioeconomic inequalities that sustain transmission hotspots. Despite relatively strong health infrastructure; including 267 public and 738 private health facilities, and geographic access to care for over 99% of residents within one hour [35], Nairobi paradoxically reports a lower TB treatment success rate than the national average (82.5% vs. 84.3%) [37]. Treatment interruption remains a persistent challenge, particularly among men. Against this backdrop, we examined whether comorbidities, therapy-related, and health system factors were associated with TB treatment interruption among males in this complex urban setting.

Study Population

The study population consisted of all males aged 15 years and older who were newly diagnosed with TB within the study period and notified within Nairobi County. Of the 41,839 individuals diagnosed with TB during these years, 26,973 were male. After excluding females and patients diagnosed outside Nairobi County, 24,794 males met the inclusion criteria, of whom 1,969 (7.9%) were recorded as having interrupted treatment and 22,825 (92.1%) successfully continued care without interruption (Fig. 1). Patients with missing treatment outcomes, those transferred out to facilities outside Nairobi County, and records with incomplete key variables required for analysis were excluded. Treatment interruption was defined programmatically as any episode recorded as loss to follow-up, non-adherence, or default. This binary outcome reflected standard definitions used in TB control programs and previous literature [6].

Data Sources and Data collection

De-identified patient-level data were extracted from the National Tuberculosis Program's electronic surveillance system (TIBU) following authorization from the Division of National TB, Leprosy and Lung Disease Program.

Study Variables

The primary outcome (dependent variable) was tuberculosis treatment interruption, defined programmatically as loss to follow-up during treatment according to national TB program definitions. The primary exposures of interest (independent variables) included comorbidities (diabetes and malnutrition), therapy-related factors (adverse drug reactions, or ADRs), and health system factors (frequency of clinic visits for sputum follow-up tests and drug refills). Diabetes was recorded as present or absent based on clinician documentation. Malnutrition was measured using body mass index (BMI), classified per WHO and USAID guidelines, with BMI < 18.5 kg/m^2 categorized as malnutrition. ADRs reflected any unintended harmful reaction to TB medication, documented by clinicians. The number of completed sputum test visits and drug-refill visits, ranging from zero to four, was used as an ordinal

measure and as a proxy for treatment adherence and engagement with care. Because visit count and treatment interruption are temporally linked, this measure was analyzed only among bacteriologically confirmed cases with scheduled monitoring and is interpreted as engagement with care rather than a causal effect. Covariates were selected a priori based on theoretical relevance. These included age, alcohol use, HIV co-infection, type of TB (pulmonary or extrapulmonary), bacteriologic confirmation, presence of a treatment supporter, year of TB diagnosis, and sub-county of residence. These covariates reflect known determinants of TB treatment outcomes and potential confounders of the exposure-outcome relationships under investigation. All covariates were measured at baseline at the time of TB treatment initiation.

Statistical Analysis

The conceptual framework guided the selection of exposure variables and covariates included in the regression models. The data cleaning process involved validating age distributions, reviewing comorbidity entries for accuracy, and addressing implausible values. Missing data accounted for only 8.6% of the dataset. Missing data mechanisms were assessed using Little's test, and a complete-case analysis was used, with records missing key analytic variables excluded; Little's test was consistent with data missing completely at random. The final dataset contained demographic, clinical, and TB treatment-monitoring variables. Because we analyzed the complete cohort of eligible TB patients recorded during the study period, a formal sample size calculation was not required.

Descriptive statistics, including means, standard deviations, frequencies, and proportions, were used to characterize patient demographics and clinical profiles. Bivariate analyses using Pearson's chi-square test evaluated associations between treatment interruption and individual patient characteristics. To address the three research questions, unadjusted and adjusted binary logistic regression models were constructed. The models were used to estimate odds ratios (ORs) and adjusted odds ratios (AORs) with corresponding 95% confidence intervals to determine the magnitude and direction of associations. Statistical significance was defined as $p < 0.05$ with associations that remained significant at a more conservative threshold of $p < 0.01$ considered robust. Model development was guided by both theoretical considerations and empirical associations observed in bivariate analyses. All analyses were conducted using SPSS version 20. Multicollinearity among independent variables was assessed using variance inflation factors (VIFs) to ensure that predictor variables included in the regression models were not highly correlated. Model fit for the final multivariable logistic regression models was evaluated using the Hosmer–Lemeshow goodness-of-fit test.

Ethical considerations

Ethical approval

for this study was obtained from the Walden University Institutional Review Board (Approval Number 10-02-24-0990091). The Kenya National TB Program subsequently granted permission to access anonymized, de-identified programmatic data. All procedures were conducted in adherence to the Kenya

Data Protection Act (2021). Because only anonymized secondary data were used, informed consent was not required. Risks associated with analysis of potentially stigmatizing conditions such as TB, malnutrition, alcohol use, and HIV co-infection were minimized by aggregating results and presenting findings at a population level.

RESULTS

Study Participant Characteristics

Between January 2019 and June 2023, a total of 24,794 eligible adult males (15+ years diagnosed with TB in Nairobi County) were included in the analysis. The mean age was 36 years (standard deviation 12). Nutritional assessments showed that 42.3% (10,496) of patients were underweight, 47.1% (11,679) had normal BMI, and 6.9% (1,713) were overweight or obese as shown in Table 1. The majority of patients had pulmonary TB, accounting for 83.8% (20,783) of all cases, and 60.8% (15,086) were bacteriologically confirmed at diagnosis. Nearly all patients, 99.6% (24,696), had a documented treatment supporter, and 3.5% (861) reported alcohol use at baseline. Diabetes was rare, affecting 0.8% (188) of patients, while adverse drug reactions (ADRs) were reported in 0.1% (13) of cases (Table 2). Clinic attendance patterns showed that only 29.4% (4,433) of bacteriologically confirmed patients completed all four recommended sputum tests and drug-refill visits during treatment. Overall, 7.9% (1,969/24,794) of male TB patients experienced treatment interruption during the study period.

Bivariate Analysis

Bivariate analyses showed substantial variation in treatment interruption across patient characteristics as shown in Table 3. Underweight patients experienced interruption at 9.2% (964), compared with 7.2% (839) among those with normal BMI and lower proportions among the overweight and obese groups. Patients with bacteriologically confirmed TB had interruption rates of 8.6% (1,291) compared with 7.0% (678) among those without confirmation. Pulmonary TB was associated with greater interruption, with 8.5% (1,771) interrupting treatment compared with 4.9% (198) among patients with extrapulmonary TB. Alcohol use was strongly associated with interruption, with 13.8% (119) of alcohol users interrupting treatment compared with 7.7% (1,850) among non-users. Interruption rates varied across sub-counties, exceeding 10% in Roysambu 11.5% (125) and Embakasi 10.2% (555). Yearly fluctuations were modest but peaked in 2021 at 8.8% (457).

Comorbidities and therapy-related characteristics also displayed clear contrasts. Malnutrition was associated with higher interruption, with 9.2% (964) of malnourished patients interrupting care compared with 7.0% (1,005) among non-malnourished patients. Diabetes did not demonstrate meaningful differences in interruption rates, with 7.4% (14) of diabetic patients interrupting compared with 7.9% (1,955) among non-diabetic patients. ADRs were strongly associated with interruption; 46.2% (6) of patients with an ADR interrupted treatment compared with 7.9% (1,963) of those without an ADR. Clinic attendance showed the strongest gradient: patients who completed all four recommended visits had extremely low interruption rates of 0.6% (27), while those attending zero sputum visits had an

interruption rate of 25.0% (363), and those attending only one visit had the highest interruption at a rate of 35.0% (538), as shown in Table 4.

Multivariable Regression Analyses

Multivariable analysis (Table 5) addressing the first research question showed that malnutrition was significantly associated with increased odds of treatment interruption. In unadjusted analysis, malnourished patients had 33.8% higher odds of treatment interruption (OR = 1.338, 95% CI 1.220 - 1.467, p<0.001). Further, after adjusting for age, alcohol use, HIV co-infection, bacteriologic confirmation, type of TB, treatment supporter, sub-county, and year of diagnosis, Malnourished patients had 23% higher odds of treatment interruption compared with patients with normal nutritional status (AOR = 1.23, (95% CI 1.120 - 1.353, p<0.001). Diabetes, however, showed no significant association with treatment interruption in either unadjusted or adjusted models. In the fully adjusted model, several covariates were independently associated with treatment interruption, including alcohol use, pulmonary TB, and residence in sub-counties such as Dagoretti, Mathare, and Ruaraka. HIV status, age, presence of a treatment supporter, and bacteriologic confirmation were not significant predictors.

In examining therapy-related factors for the second research question, ADRs emerged as one of the most potent predictors of treatment interruption. Patients experiencing ADRs had nearly tenfold higher odds of interruption in unadjusted analysis (OR = 9.963, 95% CI 3.345 - 29.676, p<0.001). After adjusting for covariates, patients who experienced ADRs had more than tenfold higher odds of treatment interruption compared with those without ADRs (AOR = 10.62, 95% CI 3.527–31.948, p < 0.001). The adjusted model again showed significant contributions from alcohol use, pulmonary TB, and several sub-counties. HIV co-infection, age, and treatment supporters were not significantly associated with interruption.

Analysis of health system factors was restricted to bacteriologically confirmed cases with complete sputum monitoring records (n = 15,086). The third research question was used to evaluate health system-related factors, specifically the frequency of clinic visits for sputum monitoring and drug refills. Clinic attendance demonstrated a strong protective effect. In unadjusted analysis, each additional visit reduced the odds of interruption by approximately 62% (OR = 0.382, 95% CI 0.364 -0.401, p<0.001). After adjustment, this effect increased in magnitude; each additional visit was associated with a 70.5% reduction in odds of interruption (AOR = 0.295, 95% CI 0.278 - 0.312, p<0.001). Patients who completed all four visits had interruption rates near zero, whereas those who made minimal visits faced substantially higher risk. The adjusted model similarly identified alcohol use, pulmonary TB, and residence in Embakasi, Kamukunji, Mathare, and Roysambu as significant predictors of interruption, while HIV co-infection, age, and treatment supporters did not demonstrate statistically significant effects. Among the predictors examined, adverse drug reactions showed the strongest positive association with treatment interruption, while consistent clinic attendance demonstrated the strongest protective effect.

DISCUSSION

We examined the association between comorbidities, therapy-related factors, and health system factors with TB treatment interruption among males in Nairobi County using a large retrospective cohort of nearly 25,000 patients. Three key findings emerged: (i) malnutrition was independently associated with increased odds of treatment interruption, (ii) adverse drug reactions (ADRs), although rare, were associated with a ten-fold increase in the likelihood of interruption, and (iii) consistent clinic attendance strongly protected against interruption, with each additional visit reducing the odds by approximately 70%. These findings highlight the interplay between clinical vulnerability and health system engagement in shaping treatment continuity in a high-burden urban setting.

Malnutrition was significantly associated with treatment interruption even after adjusting for demographic and clinical characteristics. Undernutrition compromises physical strength, tolerance to TB medicines, and the ability to attend clinic visits. Malnourished patients may experience appetite loss or gastrointestinal discomfort, which could contribute to missed doses or treatment discontinuation [23, 24]. In Kenya, nearly half of TB patients are undernourished, reflecting the country's high TB–malnutrition comorbidity burden [38]. These findings reinforce the role of nutrition not only in TB incidence but also in continuity of care. Integrating nutritional support within TB programs may therefore help reduce treatment interruption among vulnerable patients.

In contrast, diabetes was not associated with treatment interruption in this cohort. This finding differs from studies conducted in Ethiopia, Brazil, and Asia, where diabetes was reported as a predictor of non-adherence and loss to follow-up, often attributed to polypharmacy, treatment complexity or side effects [39–42]. Several factors may explain this lack of association. The recorded prevalence of diabetes in this cohort was extremely low (0.8%), suggesting possible underdiagnosis within routine program data. Limited statistical power may also have contributed to the finding.

The most pronounced association with treatment interruption was observed among patients experiencing ADRs. Individuals reporting ADRs had more than tenfold higher odds of interrupting treatment compared with those without ADRs. This finding aligns with previous studies showing that medication side effects including nausea, neuropathy, hepatotoxicity, and hypersensitivity reactions were important drivers of treatment discontinuation [13, 43]. Although ADRs were infrequently documented in this dataset (0.1%), the magnitude of their association suggests that reactions may be underreported in routine clinical practice. The wide confidence interval reflects the few recorded ADR events, so this association warrants cautious interpretation. In many resource-limited settings, ADR monitoring is often limited by time constraints, insufficient pharmacovigilance systems, and competing clinical priorities. For working-age men managing long treatment regimens alongside employment responsibilities, even mild side effects may discourage continued treatment unless promptly recognized and managed. Strengthening ADR monitoring, patient counselling, and early clinical management, particularly during the intensive phase, may reduce treatment interruption.

Health system engagement emerged as the most actionable determinant of treatment continuity. Completing all four recommended clinic visits for sputum monitoring and drug refills was associated with extremely low levels of treatment interruption, supporting the WHO adherence framework which highlights the importance of continuous patient-provider interaction. Conversely, patients who attended none or only one clinic visit had interruption rates of 25–35%, suggesting early disengagement from care. Similar patterns have been observed in Kenyan studies demonstrating that treatment interruption often occurs during the early phases of treatment [15, 30, 31]. Structural barriers, including travel distance, opportunity costs, and clinic congestion, may contribute to missed visits in urban low-income settings [15, 33]. For Nairobi's predominantly working-age male population, rigid clinic schedules may further exacerbate attrition. Differentiated service delivery approaches, including flexible clinic hours, workplace-based directly observed therapy (DOT), community drug refills, and digital adherence technologies, may improve retention in care.

Several covariates were also associated with treatment interruption. Alcohol use significantly increased the likelihood of interruption, consistent with evidence linking alcohol consumption with impaired adherence and disrupted routines [29, 31]. Pulmonary TB was also associated with higher interruption, potentially reflecting greater symptom burden, more intensive monitoring requirements, or perceived clinical improvement leading to premature discontinuation of therapy [10]. Geographic variation in treatment interruption was observed across several Nairobi sub-counties including Mathare, Kibra, Kamukunji, Embakasi, and Roysambu, mirroring evidence that socioeconomic deprivation, informal settlements, and barriers to healthcare access influence TB outcomes [19].

Some factors commonly associated with treatment interruption were not significant in this analysis. HIV co-infection was not associated with treatment interruption, differing from studies in Kiambu and Western Kenya where HIV was linked to higher attrition [30, 31]. This difference may reflect improvements in Kenya's integrated TB-HIV care model. Similarly, age and treatment supporter status were not significant predictors. The extremely high prevalence of treatment supporters in this cohort (99.6%), as documented in national TB program reports [15], may have limited variability in this variable and reduced its predictive value.

Study Strengths and Limitations

This study has several strengths. We analyzed a large cohort of TB patients using multi-year surveillance data, providing strong statistical power to detect associations. The use of routine program data enhances real-world relevance and reflects programmatic conditions within Kenya's TB control system. However, several limitations should be considered. The retrospective design limits causal inference, and misclassification may have occurred due to underreporting of conditions such as diabetes, ADRs, or alcohol use. Although missing data were relatively low, residual confounding may persist. In addition, because monitoring visits accrue over time, patients who interrupted early necessarily recorded fewer visits, so the strong protective association partly reflects this temporal relationship and is not interpreted as fully causal. In addition, the TIBU surveillance system does not capture socioeconomic and behavioral

factors known to influence adherence, including income, stigma, migration, and mental health. Finally, findings may not be fully generalizable beyond urban high-burden settings such as Nairobi.

Implications for Policy and Programming

These findings have important implications for TB control programs in Kenya and other urban high-burden settings. Integrating nutrition assessment and food support into TB care could address a key patient-level vulnerability identified in this study. Strengthening ADR monitoring systems and patient education may further improve treatment continuity. Finally, expanding differentiated and patient-centered service delivery models, particularly those accommodating the schedules and mobility patterns of working-age men, may substantially reduce treatment interruption. Targeted interventions in high-burden sub-counties may further address localized structural barriers to TB care.

CONCLUSION

Among nearly 25,000 males with TB in Nairobi County, treatment interruption was associated with malnutrition, adverse drug reactions, and poor clinic attendance. While malnutrition modestly increased the likelihood of interruption, ADRs had a substantial effect despite their low recorded frequency. In contrast, consistent clinic attendance strongly protected against interruption, highlighting the importance of sustained patient–provider engagement during treatment. These findings underscore the need for integrated nutritional support, strengthened monitoring and management of adverse drug reactions, and patient-centered service delivery models to improve treatment continuity for men. Targeted interventions in high-burden urban settings, particularly for men with additional risk factors such as alcohol use, may further strengthen treatment outcomes and reduce preventable interruptions in TB care. Strengthening these patient-and system-level interventions will be critical for improving treatment completion and accelerating progress toward national and global TB control targets.

Abbreviations

ADR Adverse drug reaction

AOR Adjusted odds ratio

BMI Body mass index

CI Confidence interval

COVID-19 Coronavirus disease 2019

DNTLD-P Division of National Tuberculosis Leprosy and Lung Disease-Program

DOT Directly observed therapy

HIV Human immunodeficiency virus

HIV/AIDS	Human immunodeficiency virus / Acquired immunodeficiency syndrome
LTFU	Loss to follow-up
OR	Odds ratio
SPSS	Statistical Package for the Social Sciences
TB	Tuberculosis
TB/HIV	Tuberculosis / Human immunodeficiency virus
TIBU	Kenya National Tuberculosis Program electronic surveillance system
USAID	United States Agency for International Development
VIF	Variance inflation factor
WHO	World Health Organization

Declarations

Ethics approval and consent to participate

This study used anonymized, secondary programmatic data from the Kenya National Tuberculosis Program. Ethical approval was obtained from the Walden University Institutional Review Board (Approval Number: 10-02-24-0990091). Permission to access the de-identified TIBU dataset was granted by the Division of National Tuberculosis, Leprosy and Lung Disease Program (DNTLD-P). All data handling procedures complied with the Kenya Data Protection Act (2021). Because the study used de-identified retrospective data, the requirement for informed consent was waived.

Consent for publication

Not applicable. The study uses anonymized secondary data with no individual-identifiable information.

Availability of data and materials

The dataset used in this study is owned by the Kenya National Tuberculosis Program and contains confidential health information. De-identified extracts were obtained under a data-sharing agreement and cannot be publicly shared. Researchers may request access to the data directly from the Kenya DNTLD-P subject to institutional approval and data protection regulations.

Competing interests

The **authors declare** no competing interests.

Funding

This research received no grant from any funding agency.

Authors' contributions

LNMN led the design, data abstraction, and interpretation, and wrote substantial portions, including paper reviews. KO contributed to the methodology, data abstraction, analysis and wrote the results portion of the paper. ML contributed to data analysis, and interpretation. EM, MG and AR contributed to data collection and collation. EM, IK and PW reviewed the paper. All authors read, reviewed and approved the final manuscript.

Acknowledgements

The **authors acknowledge** the Kenya National TB, Leprosy and Lung Disease Program for providing access to the TIBU dataset, and the healthcare workers who contributed to routine TB surveillance data. Appreciation is extended to Walden University for ethical oversight and academic support during the study's development with particular gratitude to Drs. Peter Anderson and Marshae McNeal.

Authors' information

LNMN is a medical doctor and public health researcher with expertise in TB, HIV and global health epidemiology and programming. She is affiliated with Centre for Health Solutions- Kenya, and this article is based off her Doctorate thesis from Walden University.

References

1. World Health Organization. 2024 Global tuberculosis report. Geneva; 2024 Oct. Report.
2. Mello FC, de Silva Q, Dalcolmo DR. MP. Tuberculosis: where are we? J Bras Pneumol [Internet]. 2018;44(2):82–82. Available from: https://www.scielo.br/j/jbpneu/a/fktcDt4PrH4BwB3v6q7h8cL/?lang=en&format=pdf
3. World Health Organization (WHO). Global Tuberculosis Report 2023. Global Tuberculosis Report 2023 [Internet]. Geneva. 2023. Report. Available from: https://iris.who.int/bitstream/handle/10665/373828/9789240083851-eng.pdf?sequence=1
4. Cole B, Nilsen D, Will L, Etkind S, Burgos M, Chorba T. Essential Components of a Public Health Tuberculosis Prevention, Control, and Elimination Program: Recommendations of the Advisory Council for the elimination of Tuberculosis and the National Tuberculosis Controllers Association [Internet]. Vol. 69. 2020. Report. Available from: https://www.cdc.gov/mmwr/volumes/69/rr/rr6907a1.htm#:~:text=Ensuring access to laboratory and,disease and move toward elimination.
5. John CA. Realizing the World Health Organization's end TB strategy (2016–2035): How can social approaches to tuberculosis elimination contribute to progress in Asia and the Pacific? Trop Med

Infect Dis. 2019;4(1):1–7. 10.3390/tropicalmed4010028.

6. World Health Organisation. End TB Strategy [Internet]. Vol. 53. Geneva. 2014. Report. Available from: https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy#:~:text=Strategy principles,Strategy at the country level. PubMed PMID: 25246403.
7. World Health Organization (WHO). Definitions and reporting framework for tuberculosis_2013 Revision. Eurosurveillance [Internet], Geneva. WHO; 2013. Available from: file:///C:/Users/lorraine.mugambi/Desktop/Desktop/LORRAINE/Private/PHD/Tuberculosis in Men/Literature Review/Definitionas and reporting framework for tuberculosis_2013 revision updated Dec 2014 and Jan 2020.pdf PubMed PMID: 23611033.
8. Tibble H, Flook M, Sheikh A, Tsanas A, Horne R, Vrijens B, et al. Measuring and reporting treatment adherence: What can we learn by comparing two respiratory conditions? Br J Clin Pharmacol. 2021;87(3):825–36. 10.1111/bcp.14458 . PubMed PMID: 32639589.
9. Wurie FB, Cooper V, Horne R, Hayward AC. Determinants of non-adherence to treatment for tuberculosis in high-income and middle-income settings: A systematic review protocol. BMJ Open. 2018;8(1):1–4. 10.1136/bmjopen-2017-019287 . PubMed PMID: 29358443.
10. Arinaminpathy N, Chin DP, Sachdeva KS, Rao R, Rade K, Nair SA, et al. Modelling the potential impact of adherence technologies on tuberculosis in India. INT J TUBERC LUNG DIS; 2020.
11. Kastien-Hilka T, Abulfathi A, Rosenkranz B, Bennett B, Schwenkglenks M, Sinanovic E. Health-related quality of life and its association with medication adherence in active pulmonary tuberculosis- a systematic review of global literature with focus on South Africa. Health Qual Life Outcomes. 2016;14(1). 10.1186/s12955-016-0442-6 . PubMed PMID: 26969306.
12. Alipanah N, Jarlsberg L, Miller C, Linh NN, Falzon D, Jaramillo E et al. Adherence interventions and outcomes of tuberculosis treatment: A systematic review and meta-analysis of trials and observational studies. PLoS Medicine [Internet]. 2018. 1–44 p. Available from: https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1002595&type=printable 10.1371/journal.pmed.1002595 PubMed PMID: 29969463.
13. Nezenega ZS, Perimal-lewis L, Maeder AJ. Factors influencing patient adherence to tuberculosis treatment in ethiopia: A literature review. Int J Environ Res Public Health. 2020;17(15):1–12. 10.3390/ijerph17155626 . PubMed PMID: 32759876.
14. Mekonnen HS, Azagew AW. Non-adherence to anti-tuberculosis treatment, reasons and associated factors among TB patients attending at Gondar town health centers, Northwest Ethiopia. BMC Res Notes. 2018;11(1). 10.1186/s13104-018-3789-4 . PubMed PMID: 30285907.
15. Oh AL, Makmor-Bakry M, Islahudin F, Wong ICK. Prevalence and predictive factors of tuberculosis treatment interruption in the Asia region: A systematic review and meta-analysis. BMJ Glob Health. 2023;8(1). 10.1136/bmjgh-2022-010592.
16. Zegeye A, Dessie G, Wagnew F, Gebrie A, Islam SMS, Tesfaye B, et al. Prevalence and determinants of anti-tuberculosis treatment non-adherence in Ethiopia: A systematic review and meta-analysis.

PLoS ONE. 2019;14(1):1–15. 10.1371/journal.pone.0210422 . PubMed PMID: 30629684.

17. National Tuberculosis Leprosy and Lung Disease Program. Factors Associated With Non-Adherence to Tuberculosis Treatment in Kenya. Nairobi: Report; 2018.
18. World Health Organization. WHO global lists of high burden countries for tuberculosis (TB), TB / HIV and TB, MDR / RR-TB) [Internet]. (2021. Report. Available from: http://apps.who.int/bookorders.%0Ahttps://cdn.who.int/media/docs/default-source/hq-tuberculosis/who_globalhbcliststb_2021-2025_backgrounddocument.pdf
19. World Health Organization (WHO). Global TB Report 2022 Factsheet [Internet]. Geneva. 2022. Report. Available from: https://cdn.who.int/media/docs/default-source/hq-tuberculosis/global-tuberculosis-report-2022/global-tb-report-2022-factsheet.pdf?sfvrsn=88f8d76_8&download=true
20. NTLD-P Ministry of Health Kenya. Kenya Tuberculosis Prevalence Survey 2016. 2016. Report.
21. Enos M, Sitienei J, Ong'ang'o J, Mungai B, Kamene M, Wambugu J, et al. Kenya tuberculosis prevalence survey 2016: Challenges and opportunities of ending TB in Kenya. PLoS ONE. 2018;13(12):1–19. 10.1371/journal.pone.0209098 . PubMed PMID: 30586448.
22. Hanson C, Osberg M, Brown J, Durham G, Chin DP. Finding the Missing Patients with Tuberculosis: Lessons Learned from Patient-Pathway Analyses in 5 Countries. J Infect Dis. 2017;216(Suppl 7):S686–95. 10.1093/infdis/jix388 . PubMed PMID: 29117351.
23. World Health Organization. Compendium of WHO guidelines and associated standards: ensuring optimum delivery of the cascade of care for patients with tuberculosis [Internet]. Geneva. 2018. Report. Available from: https://apps.who.int/iris/bitstream/handle/10665/272644/9789241514101-eng.pdf?sequence=1&isAllowed=y
24. National Tuberculosis Leprosy and Lung Disease Program. Annual Tuberculosis Report 2022 [Internet]. 2023. Report. Available from: https://nltp.co.ke/wp-content/uploads/2024/01/Annual-Report_2022_22_12_2023.pdf
25. Tola HH, Tol A, Shojaeizadeh D, Garmaroudi G. Tuberculosis treatment non-adherence and lost to follow up among TB patients with or without HIV in developing countries: A systematic review. Iran J Public Health. 2015;44(1):1–11. PubMed PMID: 26060770.
26. Balinda IG, Sugrue DD, Ivers LC. More Than Malnutrition: A Review of the Relationship between Food Insecurity and Tuberculosis. Open Forum Infect Dis. 2019;6(4):1–10. 10.1093/ofid/ofz102.
27. Tola HH, Holakouie-Naieni K, Mansournia MA, Yaseri M, Tesfaye E, Mahamed Z, et al. Intermittent treatment interruption and its effect on multidrug resistant tuberculosis treatment outcome in Ethiopia. Sci Rep. 2019;9(1):1–10. 10.1038/s41598-019-56553-1 . PubMed PMID: 31882784.
28. Workie MG, Aycheh MW, Birhanu MY, Tsegaye TB. Treatment interruption among drug-susceptible pulmonary tuberculosis patients in southern ethiopia. Patient Prefer Adherence. 2021;15:1143–51. 10.2147/PPA.S307091.
29. Merid MW, Muluneh AG, Yenit MK, Kassa GM. Treatment interruption and associated factors among patients registered on drug-resistant tuberculosis treatment in Amhara regional state, Ethiopia:

2010–2017. PLoS ONE. 2020;15(10 October):1–10. 10.1371/journal.pone.0240564 . PubMed PMID: 33052983.

30. Tran CH, Moore BK, Pathmanathan I, Lungu P, Shah NS, Oboho I, et al. Tuberculosis treatment within differentiated service delivery models in global HIV/TB programming. J Int AIDS Soc. 2021;2021(S6):25809. 10.1002/jia2.25809/full.
31. Masini Eo, Mansour O, Speer C, Addona V, Hanson CL, Sitienei JK, et al. Using survival analysis to identify risk factors for treatment interruption among new and retreatment tuberculosis patients in Kenya. PLoS ONE. 2016;11(10):1–19. 10.1371/journal.pone.0164172 . PubMed PMID: 27706230.
32. Kimani E, Muhula S, Kiptai T, Orwa J, Odero T, Gachuno O. Factors influencing TB treatment interruption and treatment outcomes among patients in Kiambu County, 2016–2019. PLoS ONE. 2021;16(4 April):2016–9. 10.1371/journal.pone.0248820 . PubMed PMID: 33822794.
33. Wekunda PW, Omondi Aduda DS, Guyah B. Determinants of tuberculosis treatment interruption among patients in Vihiga County, Kenya. PLoS ONE. 2021;16(12 December):1–15. 10.1371/journal.pone.0260669 . PubMed PMID: 34855844.
34. Mbuthia GW, Nyamogoba HDN, Chiang SS, McGarvey ST. Burden of stigma among tuberculosis patients in a pastoralist community in Kenya: A mixed methods study. PLoS ONE. 2020;15(10 October). 10.1371/journal.pone.0240457 . PubMed PMID: 33057420.
35. Bakri TK, Akmal R, Vonna A, Sari F. The Impact Of Adverse Drug Reaction Occurrence To Drug Adherence Level: A Cross- Sectional Study In Patients With Tuberculosis. JfgStfbAcId [Internet]. 2021;8(2). Available from: https://www.jfg.stfb.ac.id/index.php/jfg/article/view/194
36. Gashu KD, Gelaye KA, Lester R, Tilahun B. Effect of a phone reminder system on patient-centered tuberculosis treatment adherence among adults in northwest ethiopia: A randomised controlled trial. BMJ Health Care Inf. 2021;28(1):1–10. 10.1136/bmjhci-2020-100268 . PubMed PMID: 34172505.
37. Kenya National Bureau of Statistics. 2019 Kenya Population and Housing Census Volume 1: Population by County and Sub-County. 2019 Kenya Population and Housing Census [Internet]. 2019. 49 p. Available from: https://www.knbs.or.ke/?wpdmpro=2019-kenya-population-and-housing-census-volume-i-population-by-county-and-sub-county
38. Moturi AK, Suiyanka L, Mumo E, Snow RW, Okiro EA, Macharia PM. Geographic accessibility to public and private health facilities in Kenya in 2021: An updated geocoded inventory and spatial analysis. Front Public Health. 2022;10. 10.3389/fpubh.2022.1002975 . PubMed PMID: 36407994.
39. NTLDP D of NTL and LDP. Tuberculosis Annual Report:2021 [Internet]. 2021;(December). Available from: https://www.nltp.co.ke/wp-content/uploads/2022/07/DNTLDP_AnnualReport_2021_compressed.pdf
40. NTLD-P Ministry of Health Kenya. Tuberculosis Annual Report 2019 [Internet]. Nairobi. 2019. Report. Available from: https://www.nltp.co.ke/download/annual-report-2019-2/#
41. Cáceres G, Calderon R, Ugarte-Gil C. Tuberculosis and comorbidities: treatment challenges in patients with comorbid diabetes mellitus and depression. Therapeutic Advances in Infectious

Disease. SAGE Publications Ltd; 2022. 10.1177/20499361221095831.

42. Huangfu P, Ugarte-Gil C, Golub J, Pearson F, Critchley J. The effects of diabetes on tuberculosis treatment outcomes: an updated systematic review and meta-analysis. Int J Tuberc Lung Dis. 2019;23(7):783–96. 10.5588/ijtld.18.0433 . PubMed PMID: 31439109.
43. Sharma D, Gupta A, Mms R, Atl Q. Tuberculosis treatment outcomes of diabetic and non-diabetic TB/HIV co-infected patients: A nationwide observational study in Brazil. Report; 2022 Sep.
44. Araujo-Pereira M, Vinhaes CL, Barreto-Duarte B, Villalva-Serra K, Queiroz ATL, Andrade BB. Intersecting epidemics: deciphering the complexities of tuberculosis-diabetes comorbidity. Front Tuberculosis. 2024;2. 10.3389/ftubr.2024.1487793.
45. Ausi Y, Santoso P, Sunjaya DK, Barliana MI. Between Curing and Torturing: Burden of Adverse Reaction in Drug-Resistant Tuberculosis Therapy. Patient Preference and Adherence. Dove Medical Press Ltd; 2021. pp. 2597–607. 10.2147/PPA.S333111.

Tables

Tables 1 to 5 are available in the supplementary files section.

Figures

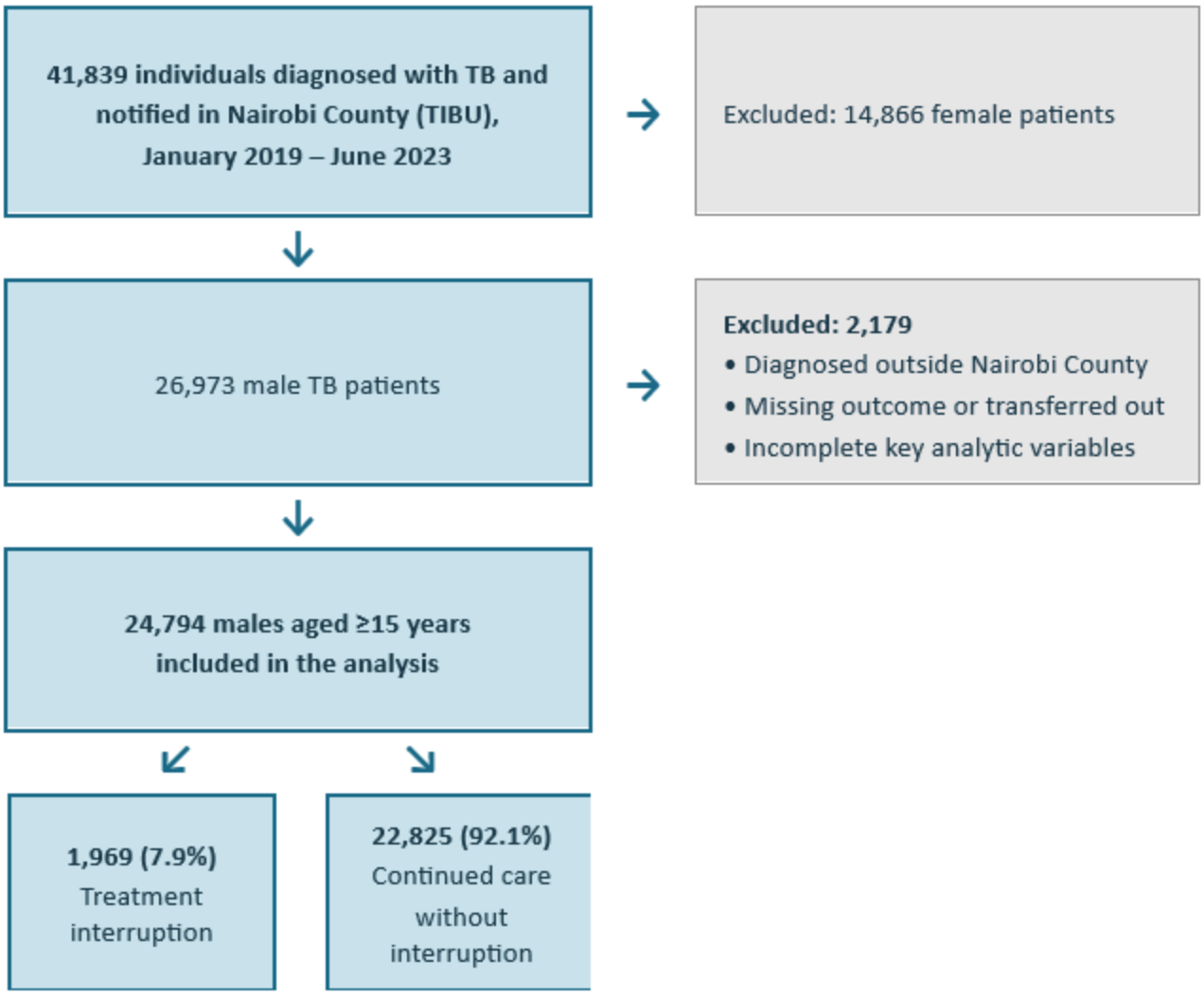


Figure 1

Participant flow through the study: male tuberculosis patients aged ≥15 years, Nairobi County, January 2019–June 2023.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables.docx