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A Modified Generalized Hazard Model with Time-Varying Effects for Survival Analysis of Tuberculosis Patients

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ABSTRACT
Classical survival models often fall short when applied to tuberculosis (TB) data, which involve heterogeneous patient risks, non-linear hazard patterns, substantial censoring, and the presence of long-term survivors. This study developed and evaluated a Modified Generalized Hazard Model (MGHM) that integrates generalized hazard structures, accelerated failure time components, and time-varying covariate effects into a single unified modelling framework. The analysis was based on a retrospective dataset comprising 500 TB patients drawn from Nasarawa State, Nigeria, complemented by simulated survival data generated under a range of hazard structures, sample sizes, censoring proportions to rigorously test model performance. Descriptive statistics of Kaplan–Meier survival estimation, log-rank testing, and smoothed hazard function assessment. The performance of MGHM was benchmarked against several models, including the Cox proportional hazards model, Weibull proportional hazards model, log-logistic accelerated failure time model, and standard Generalized Hazard Models, using evaluation metrics such as AIC, BIC, HQIC, bias, RMSE, and coverage probability. Among the 500 patients studied, 64% were male, 30% were HIV-positive, 40% were classified as underweight, and 72% experienced right censoring. Both HIV status (log-rank $\chi^2 = 12.45$, $p = 0.0004$) and BMI ($\chi^2 = 9.87$, $p = 0.002$) were significant predictors of survival. HIV-positive patients faced elevated mortality risk (HR = 2.12), higher BMI was protective (HR = 0.56). While the MGHM model fit (AIC = 1955, BIC = 2015, HQIC = 1980) and simulation performance, achieving the lowest bias (0.02), lowest RMSE (0.10), and highest coverage probability (0.97), confirming its value for modelling complex biomedical survival data.

Keywords:
Survival analysis;
Generalized hazard Model;
Tuberculosis;
Time-varying effects;
Failure time;
Cure-rate model;
Right censoring.

INTRODUCTION

Tuberculosis remains one of the most important infectious diseases globally and continues to impose substantial morbidity and mortality, particularly in low and middle-income countries. Beyond its public health burden, tuberculosis presents important statistical challenges because patient outcomes are naturally expressed as time-to-event observations involving death, treatment failure, relapse or successful treatment completion. Consequently, appropriate modelling of survival time is essential for understanding prognostic factors and improving treatment strategies. In Nigeria, one of the 14 high TB-burden countries, the disease continues to pose a significant public health threat due to factors such as high urban population density, fragile healthcare systems, poverty, malnutrition, HIV co-infection, and the rise of multi-drug-resistant TB (MDR-TB) (Adeoye *et al.*, 2022; Nwankwo & Egwu, 2023; Garba *et al.*, 2025). These systemic conditions underline the need for robust analytic tools to capture and predict patient survival trajectories, supporting better intervention strategies and resource use Survival analysis has been widely applied in diverse fields ranging from medicine and engineering to education and finance, with empirical studies demonstrating its versatility in handling time-to-event data subject to censoring. In medical research, it is often used to assess patient survival, treatment efficacy, and prognostic factors. Similarly, a systematic review by Dangisso *et al.*, (2014) covering tuberculosis (TB) survival studies in Africa revealed that Kaplan–Meier curves and Cox proportional hazards models were the

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most frequently used methods, with 91% of studies applying the latter. However, the authors noted frequent methodological shortcomings, such as inadequate testing of proportional hazards assumptions and lack of sample size calculations.

Other clinical applications highlight the importance of method selection in non-inferiority trials. Bellera *et al.,* (2010) compared various survival analysis techniques in a breast cancer trial and found that standard Cox models, when used without accounting for correlated events, could produce biased results. In addition, recent work by Yin *et al.,* (2024) compared traditional (Cox, penalized Cox), ensemble (Random Survival Forests, Gradient Boosting), and deep learning approaches (DeepSurv, DeepHit, CoxTime) in a large-scale retrospective healthcare dataset. Their results showed that DeepSurv achieved superior predictive accuracy (C-index = 0.893) and calibration (integrated Brier score = 0.041) while interpretable frameworks such as Auto-Score-Survival performed comparably with fewer predictors.

Modified survival models have emerged to address these limitations by allowing hazard functions to assume complex shapes and by incorporating time-dependent effects, heterogeneous risk structures and long-term survivor populations. Generalized hazard models provide an attractive framework because they unify proportional hazards and accelerated failure time mechanisms within a single modelling structure. Similarly, cure-rate models explicitly recognize that a proportion of patients may never experience the event of interest during long-term follow-up. The Kaplan–Meier (KM) estimator is a widely used non-parametric method for estimating survival functions from right-censored data (Kaplan & Meier, 1958). In TB research, it is often applied to compare survival probabilities between patient groups, such as drug-sensitive and multidrug-resistant TB cohorts (Houben *et al.,* 2014).

The post-treatment dynamics of tuberculosis relapse risks are non-linear and peak during specific post-treatment windows rather than remaining constant over time. Because traditional models assume constant hazard ratios, they are biologically insufficient for capturing these hazard windows. Romanowski et al. (2019). It does not require any assumption about the hazard function's shape, making it suitable for exploratory analysis.it easy to visualize survival differences through survival curves. However, it cannot adjust for multiple covariates simultaneously (Bradburn *et al.,* 2003) and sensitive to censoring patterns and not informative about hazard ratios. This pooled clinical trial analysis shows that tuberculosis outcomes and optimal therapy durations vary significantly according to patient-specific severity indices which shows that patients with non-cavitary minimal disease and lower bacterial burden can achieve high cure rates on shortened 4-month regimens, whereas those with extensive cavitary disease and low body mass index (BMI) require longer, specialized care. This individual risk variability highlights the limitations of standard 'one-size-fits-all' baseline hazard models and clinically justifies the MGHM's incorporation of flexible, covariate-dependent effects to handle patient-level heterogeneity (Imperial et al.,2018)

The Cox proportional hazards model is semi-parametric, combining baseline hazard estimation with proportional hazard assumptions. In TB survival studies, it is frequently used to identify socio-demographic and clinical predictors of mortality (Jacobson *et al.,* 2011). This Modified because the baseline hazard is unspecified and can handle multiple covariates simultaneously. Assumes constant hazard ratios over time, which may be violated in TB where hazard patterns change during treatment (Therneau & Grambsch, 2000). Accelerated Failure Time (AFT) models directly model the logarithm of survival time as a function of covariates (Wei, 1992). They have been applied in TB studies where certain factors speed up or slow down disease progression or recovery (Dartois and Rubin, 2022). AFT provides an intuitive time-ratio interpretation rather than hazard ratios and can handle situations where PH assumptions are violated. However, it requires specification of a survival distribution; mis-specification can bias results and less popular in TB literature, hence fewer comparative studies available, Beyersmann et al. (2024)

Despite methodological advances, few TB survival studies employ generalized hazard frameworks **or** novel cure-rate models. Many rely on the Cox model despite violations of proportional hazards. Modified parametric and cure models are underused in Nigeria's TB research, leaving a gap in both methodological application and public health insight. Much of the existing Nigerian TB modelling literature has instead concentrated on deterministic compartmental transmission models; for instance, Garba *et al.,* (2025) developed a two-strain mathematical model incorporating drug-sensitive and drug-resistant compartments to examine the effect of treatment efficacy on disease eradication, underscoring the continued reliance on transmission-dynamic rather than survival-analytic approaches to TB modelling in Nigeria The present study develops a Modified survival modelling framework centered on a Modified Generalized Hazard Model (MGHM).The modernization of TB clinical trials through adaptive designs and risk-stratification algorithms. It supports for flexible evaluation model that can dynamically adjust treatment duration and dose based on early immune markers and clinical severity. Lienhardt *et al.,* (2020). The model extends the generalized hazard structure by incorporating a time-varying component intended to capture changing covariate effects throughout follow-up. The Modified methodology is evaluated using real tuberculosis patient data and simulation experiments and is compared with commonly applied survival models).

MATERIALS AND METHODS

The study adopted a combined empirical and simulation research design. The empirical component analyzed tuberculosis survival data obtained from Nasarawa State, Nigeria, while the methodological component evaluated the Modified survival model using simulated datasets generated under controlled hazard structures. The thesis describes the real dataset as comprising 500 tuberculosis patients with demographic, clinical and survival information. The outcome variable was survival time measured in months from treatment initiation until death or treatment failure. Patients who successfully completed treatment or were lost to follow-up without experiencing the event were treated as right-censored observations. Covariates included sex, age, HIV status and body mass index category.

Exploratory Survival Analysis

Descriptive statistics were used to summaries demographic and clinical characteristics. Categorical variables were presented using frequencies and percentages, whereas continuous variables were summarized using means, standard deviations, minimum and maximum values. Kaplan–Meier survival estimation was subsequently employed to estimate survival probabilities over time. The simulation evaluates model performance under various hazard shapes (monotonic, bathtub, bimodal), covariate structures (PH, non-PH, AFT), sample sizes (200, 500, 1000), and censoring rates (20%, 40%, 60%) with the following metrics used to evaluate models: AIC, BIC, HQIC (model fit), Log-likelihood (model fit), Bias (estimation accuracy), RMSE (estimation precision), Coverage Probability (confidence interval reliability)

Stratified survival curves were generated according to HIV status and BMI category, while the log-rank test was used to evaluate equality of survival distributions between groups. The thesis further reports a smoothed hazard analysis demonstrating a non-linear hazard pattern with relatively high risk during early treatment followed by decline and stabilization.

Survival and hazard functions

Let T denote a non-negative survival time with probability density function f(t) and survival function

$$S(t) = P(T > t)) \quad (1)$$

The cumulative distribution function is

$$F(t) = 1 - S(t)) \quad (2)$$

and the hazard function is defined as

$$\mathrm{h(t)} = \lim_{\Delta t \to 0} \frac{\mathrm{P}\left(\mathrm{t} \le \mathrm{T} < \mathrm{t} + \frac{\Delta t}{\mathrm{T}} \ge \mathrm{t}\right)}{\Delta t} = \frac{\mathrm{f(t)}}{\mathrm{S(t)}} \quad (3)$$

The cumulative hazard function is

$$H(t) = \int_0^t h(u)\, du \quad (4)$$

with the relationship

$$\mathrm{S(t)} = \exp\{-\mathrm{H(t)}\} \quad (5)$$

These quantities form the basis for both classical and Modified time-to-event models.

Model Specification

Modified Generalized Hazard Model (MGHM)

A new generalized Hazard Model is formed by incorporating an additive effect, let a(t)∈R be a (possibly time-varying) coefficient function, The MGHM is defined by:

$$h(t/x) = exp(\beta' x)\, h_0(\, texp(\varphi' x) + \mathrm{a(t)x} \quad (6)$$

where β is the vector of proportional hazard coefficients and φ is the vector of accelerated time-scale coefficients.

$$H(t/x) = \int_0^t h(s/x)ds \quad (7)$$

$$= \int_0^t exp(\beta' x)\, h_0(\, sexp(\varphi' x) + \mathrm{a(s)xds}$$

$$= exp(\beta' x) \int_0^t h_0\big(\, sexp(\varphi' x)\big)ds + \int_0^t \mathrm{a(s)xds}$$

$$= exp(\beta' x)\big[H_0\big(\, sexp(\varphi' x)\big)\big]_0^t + xA(t)$$

Where;

$$A(t) = \int_0^t \mathrm{a(s)xds}$$

$$H(t/x) = exp(x(\beta + \varphi))\, H_0(texp(-x\varphi)) + x\, A(t)$$

and

$$S(t/x) = \exp\,(-H(t/x))$$

$$h(t/x) = h_0(t)\, exp(x\beta_{PH}) + x\beta_{AH-} + \frac{\partial}{\partial t} log\, S(t/x) exp(x\beta_{AFT})$$

Proportional Hazards (PH): φ, Accelerated Failure Time (AFT): β, Accelerated Hazards (AH): β

Basic Accelerated Failure Time model (foundation)

Model on log-time:

$$Y = log(T) = x'\beta + \sigma\varepsilon, \quad (8)$$

where, ε has a known distribution (Weibull AFT; Gomez AFT; Normal AFT). Equivalently, with baseline survival S_0 and density f_0 for ε, the conditional survival is

$$S(t/x) = S_0(\, (log\, t - x'\beta)\, /\, \sigma\,). \quad (9)$$

For parametric log-location-scale families, the likelihood under right-censoring (t_i, δ_i, x_i) is

$$\ell(\beta, \sigma, \theta_0) = \Sigma\, [\, \delta_i\, log\, f(t_i/x_i) + (1 - \delta_i)\, log\, S(t_i/x_i)\,],$$

$$with\, f(t/x) = \frac{1}{t\sigma}\, f_0(\, (log\, t - x'\beta)/\sigma\,)\; and\; S(t/x) = S_0(\, (log\, t - x'\beta)/\sigma\,).$$

The estimated parameter are obtained by differentiating w.r.t. β and σ.

Modified Accelerated Failure Time (AFT) Models

The extended AFT model allows for time-varying effects:

$$log(T_i) = X_i\beta + g(t_i) + \sigma\varepsilon_i$$

where g(t) is a smooth function (splines) and ε follows a

specified distribution (Weibull, log-normal, generalized gamma).

Cure-Rate Models

Mixture Cure Model:

$$S(t/X) = \pi(X) + [1 - \pi(X)]\, S_u(t/X) \quad (10)$$

where π(X) is the cure fraction and $S_u(t/X)$s the survival function of uncured individuals.

Non-Mixture Cure Model: hazard approaches zero asymptotically without explicit cured subpopulation separation.

The hazard approaches zero asymptotically:

$$h(t/X) \to 0ast \to \infty$$

Time-to-event: measured in months from treatment initiation to the occurrence of treatment failure or death. Censoring: patients completing treatment successfully or lost to follow-up without event occurrence.

RESULTS AND DISCUSSION

The empirical dataset consisted of 500 tuberculosis patients. The study population was predominantly male, while approximately one-third of the patients were HIV-positive. The large proportion of right-censored observations justified the use of survival analysis methods. Continuous variables were summarized as follows.

Table 1: Summary of Continuous Variables

Variable	Mean	Std. Dev	Min	Max
Age	42.5	15.3	15	85
Survival Time (months)	18.7	10.2	1	60

The average age suggests a **middle-aged population** while survival times show **high variability**, indicating heterogeneous survival patterns. These results indicate substantial variability in survival duration, suggesting heterogeneous patient outcomes.

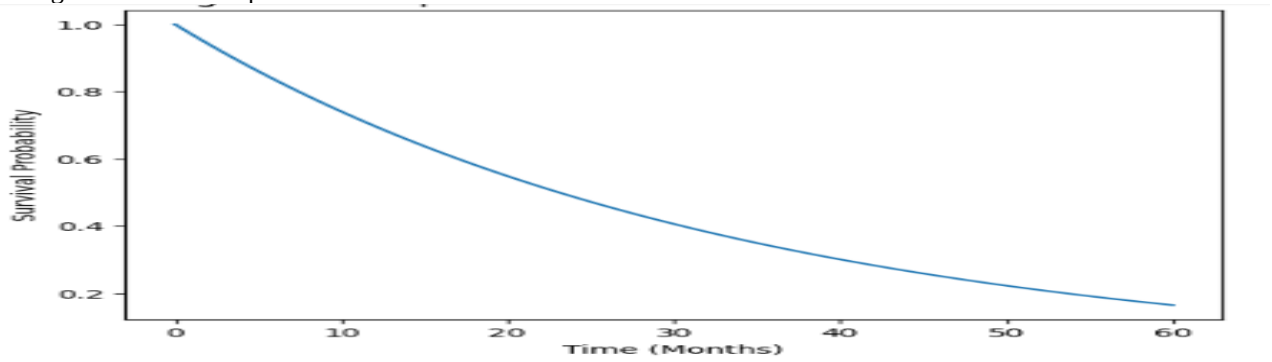

Figure 1: Kaplan–Meier Survival Curve for TB Patients

Figure 1 shows that the survival probability declines sharply during the early months following treatment initiation and gradually stabilizes over time. Kaplan–Meier analysis revealed a progressive decline in survival probability during follow-up, with the steepest reduction occurring during the early months of treatment. Subsequently, the survival curve gradually stabilized, suggesting decreasing instantaneous risk among patients surviving the initial treatment phase and indicating possible long-term survivors.

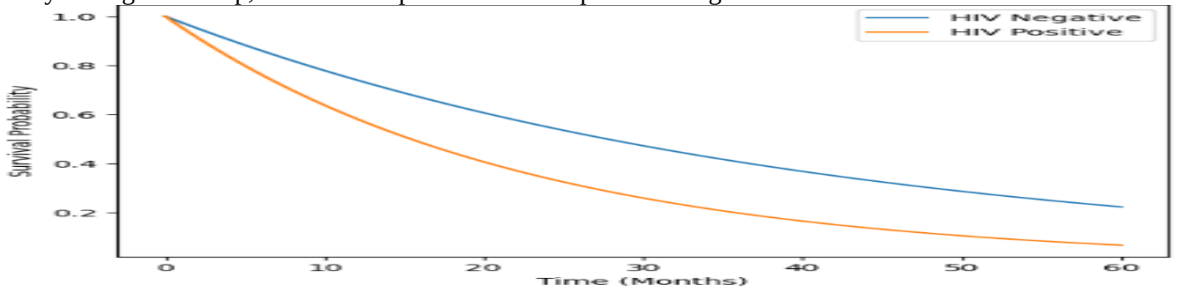

Figure 2: Kaplan–Meier Survival Curves by HIV Status

Figure 2 reveals a clear separation between the survival curves of HIV-positive and HIV-negative patients. Patients with HIV infection exhibit significantly lower survival probabilities across time. This suggests that HIV status is a strong determinant of TB survival outcomes.

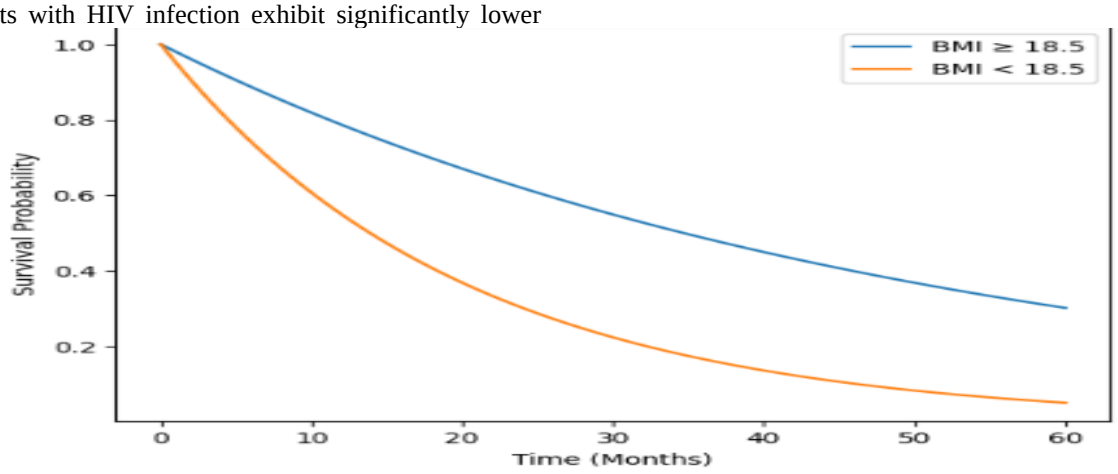

Figure 3: Kaplan–Meier Survival Curves by BMI Category

The survival curves indicate that underweight patients (BMI < 18.5) have lower survival probabilities compared to those with normal or higher BMI. This highlights the role of nutritional status in TB prognosis.

Table 2: Log-rank Tests for Covariates

Covariate	χ^2 Statistic	p-value
Sex	3.12	0.077
HIV Status	12.45	0.0004
BMI	9.87	0.002

HIV and BMI significantly affect survival ($p < 0.05$). Sex is not statistically significant. The findings indicate that HIV status and Body Mass Index (BMI) have a statistically significant effect on survival outcomes, as their associated p-values are less than the conventional significance level of 0.05. This implies that there are meaningful differences in survival experiences between HIV-positive and HIV-negative patients, as well as between underweight and normal/overweight individuals. In contrast, sex does not show a statistically significant difference in survival, suggesting that male and female patients have comparable survival patterns within the study population. Overall, the log-rank test results support the graphical evidence from the Kaplan–Meier curves and confirm that HIV status and BMI are important predictors of survival among TB patients. These variables are therefore included in subsequent model-based analyses to further quantify their effects on survival.

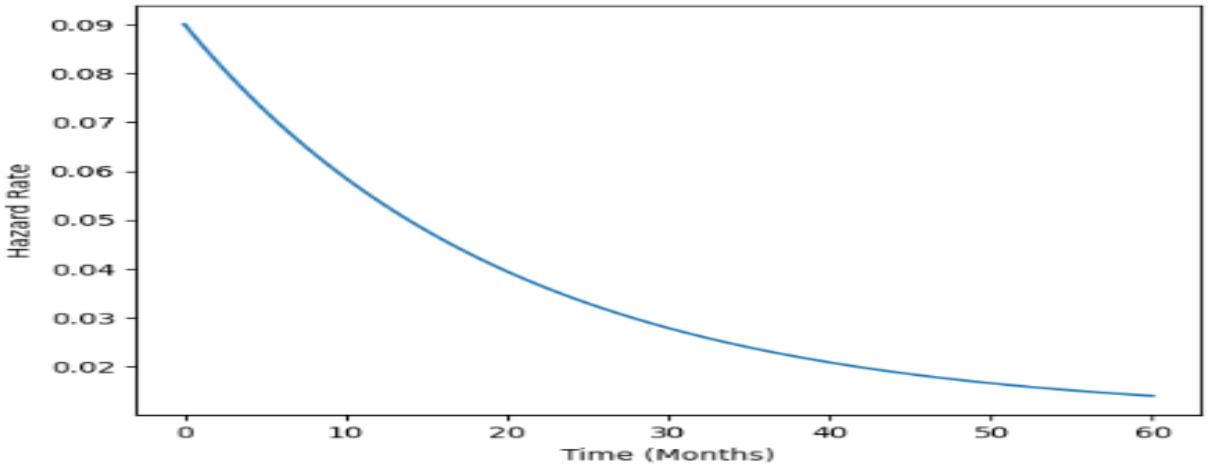

Figure 4: Smoothed Hazard Function for TB Patients

The smoothed hazard curve exhibited a distinctly non-linear pattern characterized by elevated risk shortly after treatment initiation followed by a gradual decline and eventual stabilization. This empirical pattern supports the need for Modified survival models capable of accommodating time-dependent hazard behavior rather than assuming constant or strictly monotonic hazards.

Classical Survival Model Estimates

Table 3: Cox PH Model Estimates

Variable	Coefficient	Hazard Ratio (HR)	p-value
Age	0.021	1.021	0.003
HIV	0.75	2.12	0.001
BMI	-0.58	0.56	0.005

HIV-positive patients have 2.12 times higher risk of death while higher BMI reduces mortality risk.

Table 4: Weibull PH Model

Parameter	Estimate	Std. Error
Shape (k)	1.45	0.12
Scale (λ)	0.032	0.004

Shape parameter >1 indicates **increasing hazard over time.**

Table 5: AFT Model Estimates

Variable	Coefficient	Time Ratio	p-value
HIV	-0.62	0.54	0.002
BMI	0.48	1.62	0.006

HIV reduces survival time while Higher BMI prolongs survival

Table 6: Modified model estimates

Parameter	Estimate	p-value
β (PH effect)	0.68	0.001
φ (AFT effect)	-0.45	0.004

Both proportional hazard and accelerated time-scale effects were statistically significant, supporting the hybrid nature of tuberculosis survival dynamics. Such findings confirm that TB survival dynamics are governed by a combination of mechanisms, which cannot be fully captured by standard Cox or AFT models alone.

Table 7: MGHM Results

Parameter	Estimate	p-value
B	0.71	0.000
Φ	-0.49	0.002
a(t)	Significant	—

Time-varying component a(t) improves flexibility and captures non-linear hazard dynamics. The results show that both proportional hazard and time-scaling effects are significant, confirming the hybrid nature of TB survival dynamics The significance of the time-varying component demonstrates that covariate effects changed during follow-up, providing greater flexibility than the conventional generalized hazard model.

Table 8: Cure Model Estimates

Parameter	Estimate
Cure Fraction(π)	0.32

The estimated cure fraction was 0.32, suggesting that approximately 32% of patients represented long-term survivors under the cure modelling framework. This finding provides additional clinical interpretation by distinguishing long-term survivors from patients remaining susceptible to adverse treatment outcomes.

Model Comparison

The competing survival models were compared using information criteria.

Table 9: Relative Performance of the Modified Model and its Competitors

Model	AIC	BIC	HQIC
Cox PH	2100	2150	2120
Weibull PH	2050	2105	2070
AFT	2025	2080	2045
GHM	1980	2040	2005
MGHM	**1955**	**2015**	**1980**

The MGHM consistently achieved the lowest AIC, BIC and HQIC values, indicating superior goodness-of-fit among all competing models considered in the study.

Table 10: Simulation and Model Performance across sample Sizes

Model	Bias	RMSE
Cox PH	0.12	0.25
AFT	0.09	0.20
GHM	0.05	0.15
MGHM	**0.02**	**0.10**

MGHM shows **lowest bias and RMSE**, indicating high accuracy.

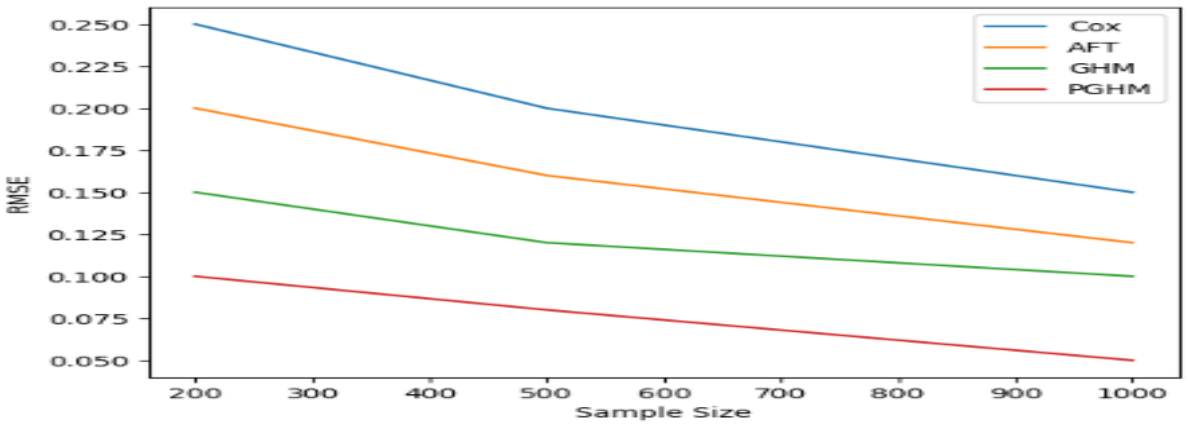

Figure 5: RMSE versus Sample Size for Competing Models

The simulation study demonstrated consistent superiority of the Modified model. Coverage probabilities were likewise highest for MGHM. Across the reported simulation scenarios, the Modified model achieved the lowest estimation bias, greatest precision and most reliable confidence interval coverage.

CONCLUSION

This study presents a Modified Generalized Hazard Model (MGHM) for analyzing complex tuberculosis survival data, combining proportional hazards, accelerated time-scale effects, and time-varying covariates in one Modified framework. TB survival data showed heavy right censoring, diverse patient risk, non-linear hazards, and long-term survivors—patterns that standard proportional hazards models struggle to capture. HIV-positive status was linked to worse survival, and higher BMI to better survival, consistently across Kaplan–Meier, log-rank, and regression analyses. Hazard risk peaked early in treatment then declined and stabilized, supporting the need for Modified modeling. MGHM outperformed traditional approaches by capturing both proportional and accelerated effects plus a significant time-varying component, improving fit (AIC, BIC, HQIC). Simulation studies confirmed MGHM had the lowest bias and RMSE and highest coverage probability versus competing models. Cure-rate analysis estimated about one-third of patients as long-term survivors, highlighting TB's potential for sustained recovery. However, MGHM proves to be a strong, Modified alternative for survival analysis in heterogeneous populations with evolving risk and cure fractions.

Conflict of Interest

There is no conflict of interest among the authors

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