International Journal of Research in Medical Sciences
David M et al. Int J Res Med Sci. 2024 Jul;12(7):2286-2293
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20241873

Original Research Article

Factors associated with sputum conversion time among patients with drug-resistant tuberculosis in Kenya

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Received: 29 April 2024
Revised: 30 May 2024
Accepted: 20 June 2024

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ABSTRACT

Background: Drug-resistant tuberculosis (DR-TB) is a form of antimicrobial resistance that is difficult and costly to treat. It is caused by TB bacteria that are resistant to at least one of the first-line existing TB medications, resulting in fewer treatment options and increasing mortality rates. Treatment for this form of TB, known as DR-TB, requires a minimum of 18-24 months of treatment with drugs that are less effective, more toxic, and more expensive than those needed for drug-susceptible TB.
Methods: This was a retrospective review of secondary data for patients diagnosed with DR-TB in Kenya from 2014 to 2019. Each patient had a two-year follow-up period to monitor sputum conversion time and the associated factors. The enrolled patients comprised all patients diagnosed with DR-TB within the 47 counties in Kenya and enrolled at any drug-resistant registered treatment center.
Results: A total of 2674 patients were enrolled for review to establish factors associated with conversion and we only found out that the type of resistance a patient enrolled on gender, intensive phase regiment, modification of intensive phase, and waiting time before treatment initiation were the only significant factors that would influence when a patient would convert from being sputum positive to negative.
Conclusions: Patients with resistant TB require correct diagnosis and timely start of medication with good follow-up to avoid being lost to follow-up or failing on the medication started. Additionally, healthcare workers need continuous training to gain more knowledge in case of detection for patients coming to hospitals.

Keywords: Drug-resistant tuberculosis, Drug susceptibility testing, Multidrug-resistant tuberculosis, National tuberculosis, Leprosy, Lung disease, World Health Organization

INTRODUCTION

In the year 2020, 9.9 million people were estimated to have gotten sick with tuberculosis disease, and out of these 1.5 million people died from it, out of these numbers we also did have nearly 500,00 thousand patients developing DR-TB.[1] DR-TB is a form of antimicrobial resistance majorly due to resistance to at least one of the first-line TB drugs leading to fewer treatment options. This problem is due to these first-line TB drugs; isoniazid (H) and rifampin (R) simultaneously, the backbone medication for TB. DR-TB treatment requires a minimum of 18-24 months of treatment with drugs that are more toxic and more expensive than those needed for normal TB; unfortunately, the rate of success of treatment for this form of TB hardly reaches 70%.

The global epidemiology of drug resistance has worsened over the past 40 years which leads to the use of second-line anti-TB medications, which are less potent, more toxic, more expensive, and require extended periods of treatment. XDR-TB is defined as MDR-TB plus resistance to any fluoroquinolone and any second-line injectable drugs, the two most effective classes of second-line anti-TB drugs.[2] The disease continues to have poor detection and treatment rates globally, and patients with DR-TB is rising. The nations that contributed to almost half of these 558,000 cases: were India (24%), China (13%), and the Russian federation (10%).[3]

Africa has over 1 billion people leading to a disproportionate spread of TB having 2.6 million of the 10.4 million worldwide TB cases making the continent a major geographical area for health interventions. In Sub-Saharan Africa particularly, rates rapidly escalated in the early 1990s due to a late response to the HIV epidemic. Out of this, incidence rates were the highest globally which has resulted in the task of ending the fight against tuberculosis challenging because of the emergence of DR-TB infection.[4] Additionally, poor health infrastructure, low levels of literacy, gender inequity, a high burden of TB in the region, and poverty exacerbate the spread of DR-TB.[5]

The key influence accountable for the vast TB disease burden in Kenya is the coexisting HIV epidemic, topped up with other burdens which include poverty and social deprivation that have led to the mushrooming of peri-urban slums, congestion, and limited access to general health services. Recently, there have been increasing concerns about the emergence of drug-resistant TB. This threat poses a significant challenge in the fight against TB in resource-limited countries like Kenya.[6]

From the reviewed data both globally and within the Sub-Saharan region, this study was developed to evaluate factors associated with sputum conversion time among patients with DR-TB in Kenya.

METHODS

This study was a retrospective review of secondary data for patients diagnosed with DR-TB in Kenya from 2014 to 2019. The study site included all health facilities registered under the national tuberculosis, leprosy, and lung disease program in Kenya to treat DR-TB. Sample size calculation was through a purposive sampling method for all drug-resistant TB cases enrolled from 2014 to 2019 excluding drug-sensitive cases resulting in a total sample size of 2674 patients. The inclusion criteria were; all patients diagnosed with DR-TB between 2014 to 2019 and put on treatment and the exclusion criteria were patients diagnosed with DR-TB before 2014, Patients diagnosed with DR-TB after 2019, and Patients with drug-sensitive tuberculosis. Each patient had a two-year follow-up period to monitor sputum conversion time and the associated factors with the definitive treatment outcome. Study variables included social demographics variables, year of enrollment, a quarter of enrollment, type of resistance patterns, and county of enrollment, data was extracted from the NLTP electromedical system-(TIBU), which was downloaded to excel, and then the data was exported to STATA version 13 for further analysis. Before analysis, data was cleaned and edited using simple frequencies and cross tabulation; re-categorization of categorical variables and categorization of continuous variables was done to be suitable for analysis. Descriptive non-parametric survival analysis, such as the Kaplan-Meier survival curve, was used to estimate sputum conversion patterns. Months were used as a time scale to calculate the median time to sputum conversion. A log-rank test was used to test for any difference in sputum conversion time. A Cox proportional hazards regression model was used to determine factors associated with sputum conversion time. Adjusted hazard ratios (AHR) with 95% confidence intervals were computed, and statistical significance was declared when it was significant at a 5% level ($p<0.05$). To assess model adequacy for the proportional hazard model, the proportional hazard assumption was checked by log-log plot and global test, and the overall adequacy of the proportional hazard model was assessed using the Cox-Snell residual graph.

Ethical consideration

Ethical clearance was obtained from the Kenyatta national hospital/university of Nairobi ethics board under ethical review number P378|05|2019. A formal letter was also written to the national leprosy, tuberculosis, and lung disease program to abstract data from their system.

RESULTS

Enrollment

From 2014 to 2019, 2674 patients were enrolled with DR-TB treatments across the 47 counties in Kenya. According to the program policies, client registration was done and reported quarterly per the national tuberculosis and leprosy board. The enrollment recorded a sequential increase of patients registered for DR-TB treatment, but in 2019, it was recorded as the least enrolled patient for DRTB treatment (Table 1).

Care and treatment centers

From this (Table 2), we can point out that the burden of DR-TB was higher in the towns, with Nairobi leading with the number of patients enrolled for treatment, with 14% of the total enrolled patients.

Health facilities

The total number of health care facilities following the patients was 1095, distributed among the 47 counties in Kenya, with Nairobi County having the most significant

number of 428 (16%). However, in general, every county of the republic had a facility to follow up with clients who were diagnosed with DR-TB and have their results tallied to the NTLP (Table 3).

All models generally enrolled patients for care during the study period. Still, the numbers presented show that the public health model had a more significant treatment and care burden, enrolling and following up to 80 % of all patients who had DR-TB from 2014 to 2019.

Treatment models for DR-TB patients

In the Kenya system, the treatment strategies have been classified as follows (Figure 1); community-based model, Facility-based model and isolation model.

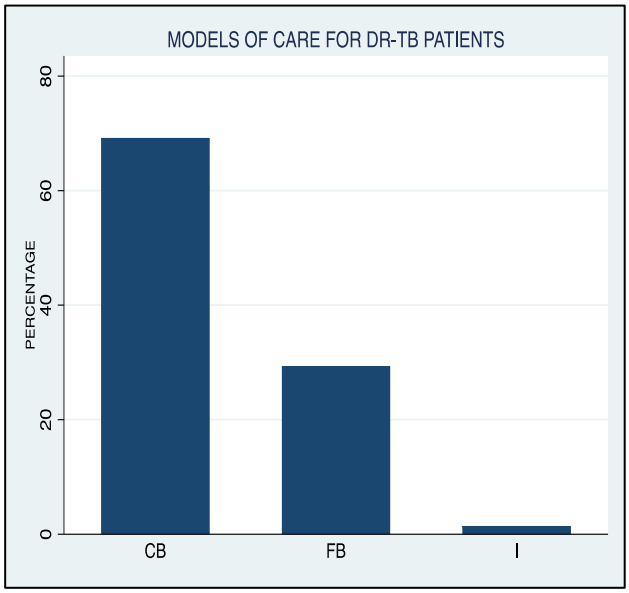

Figure 1: Representing models of care for DR-TB.

Registration categories

For patients enrolled for drug resistance tuberculosis, a review of patterns of resistance was done to establish types and the specifics of the resistance each patient had registered with where the following was recorded (Table 4) New-N, relapse-R, after the failure of category 1 treatment-FFT, after failure of category 11 treatment-FRT, transfer in-TI, return after loss to follow up-LTFU and others-O.

Sputum testing

A total of 2674 patients were screened for an AFB, of which 62% had a positive AFB and 15% were negative. Up to 5% of patients had missing records of AFB report from those enrolled for DR-TB follow-up (Table 5).

Patients who had tested sputum positive during the screening point were subjected to the GeneXpert test, and more than 50 % of them showed to have an RR type of DR-TB. GeneXpert reported some clients with MTB where AAF was unfavorable and vice versa. However, overall, GeneXpert was able to pick up and tell us more than what a sputum-AFB could at beginning (Table 6).

Resistance patterns of patients enrolled for DR-TB treatment in Kenya indicated that MDR, RR, and mono-resistance comprised up to 95% of all the reported cases related to tuberculosis resistance. At same time, burden of pre-XDR, XDR, and PDR was less than 3% (Table 7).

Cox proportional hazard model on sputum conversions

We simulated a Cox proportional model on conversion patterns for patients enrolled for DR-TB. The model described the potential relationship between covariates and sputum conversion. This enabled us to determine the different influencers by independent variables with the conversion time of patients enrolled for DR-TB. In this model, the dependent variable was the 'hazard.' The hazard is the probability of experiencing an event, which in this case was 'sputum conversion' given that the patient had survived up to the allowable period considered as the 'right' moment of conversion by the national tuberculosis board, which, in our case was between 4 months and eight months.

In principle, we tested for the proportionality assumption for the PH assumption using graphical diagnostics. We found the following covariates satisfying the assumption: sector, gender, waiting for treatment, type of TB resistance, LPAR if, and LPAH (Table 8).

The model was presented as follows;

$$h(t) = h_0(t)\exp\left(b_1x_1 + b_2x_0 + \cdots + b_px_p\right)$$

Where; $h(t) =$ expected hazard a time t, $h_0(t) =$ baseline hazard, $\mathrm{X1}, \mathrm{X2}, \ldots, \mathrm{Xp} =$ Predictors and $\mathrm{b1}, \mathrm{b2}, \ldots, \mathrm{bp} =$ coefficients

The findings were after accounting for year, quarter, sector_1, modelofcare_1, intens_phse_regimen_1, mod_intens_phse_regmn_1, and county_1. we found that sector_1 was receiving treatment, the year of enrollment, the quarter of enrollment, the model of care the client was on, and the county of origin had no statistically significant associations between when a person converted their sputum. We had only two statistically significant risk factors positively affecting the conversion times of the DR-TB patients, i.e., "the intensive phase regimen given and the modification of the intensive phase regimen" (Table 9).

Table 1: Summary of demographic distribution.

Demographic variable	High score variable	Value	Low score variable	Value
Gender	Male	66.5%	Female	33.5%
Year of enrollment	2018	25.6%	2019	7.4%
Type of TB	Pulmonary	98%	Extra pulmonary	2%
Model of care	Community	69.2%	Isolation	1.4%
BMI (kg/m^2)	Underweight	58%	Overweight	3.96%
Resistant pattern	RR	38.2%	XDR	0.31%
Sector of enrollment	Public	83.2%	Prisons	1.27%
County of enrollment	Nairobi	16.1%	Wajir	0.19%
Age of enrollment	Oldest	99 years	Youngest	10 years

Table 2: Care and treatment centers.

County	N	Percentage (%)	Cum.
Baringo	33.6632396	1.26	1.26
Bomet	38.3045515	1.43	2.69
Bungoma	40.6185796	1.52	4.21
Busia	17.0257179	0.64	4.85
Elgeyo Marakwet	10.2900402	0.39	5.24
Embu	42.3455794	1.58	6.82
Garissa	59.5284694	2.23	9.05
Homa Bay	72.399541	2.71	11.76
Isiolo	17.641151	0.66	12.42
Kajiado	41.3552056	1.55	13.97
Kakamega	48.2916092	1.81	15.77
Kericho	29.0503324	1.09	16.86
Kiambu	113.915706	4.26	21.12
Kilifi	61.6872191	2.31	23.43
Kirinyaga	70.9584809	2.66	26.09
Kisii	50.1890366	1.88	27.97
Kisumu	75.1263828	2.81	30.78
Kitui	86.2988592	3.23	34.01
Kwale	29.4176986	1.10	35.11
Laikipia	47.193298	1.77	36.88
Lamu	9.13302609	0.34	37.22
Machakos	92.0233332	3.44	40.66
Makueni	59.34857364	2.22	42.88
Mandera	10.3468494	0.39	43.27
Marsabit	16.08268517	0.60	43.87
Meru	106.503999	3.99	47.86
Migori	52.1981887	1.95	49.81
Mombasa	138.267917	5.17	54.99
Murang'a	69.5098463	2.60	57.59
Nairobi	398.344233	14.91	72.49
Nakuru	108.927858	4.08	76.57
Nandi	20.4494192	0.77	77.34
Narok	70.8562244	2.65	79.99
Nyamira	32.0100919	1.20	81.19
Nyandarua	13.937191	0.52	81.71
Nyeri	56.9303953	2.13	83.84
Pokot	87.3555104	3.27	87.11
Samburu	17.5824481	0.66	87.77
Siaya	102.4061617	3.83	91.60
Taita Taveta	33.5155357	1.25	92.85
Tana River	5.069274485	0.19	93.04
Test County	5.83430508	0.22	93.26

Continued.

County	N	Percentage (%)	Cum.
Tharaka Nithi	15.2286535	0.57	93.83
Trans Nzoia	15.5335295	0.58	94.41
Turkana	74.3234794	2.78	97.19
Uasin Gishu	40.3345336	1.51	98.70
Vihiga	24.4582552	0.92	99.62
Wajir	10.1877836	0.38	100.00
Total	2,672	100.00	

Table 3: Healthcare sector models and the burden of DR-TB.

Sectors	N	Percentage (%)	Cum.
Public	2,225	83.21	83.21
Private	358	13.39	96.60
Other faith based	57	2.13	98.73
Prisons	34	1.27	100.00
Total	2,674	100.00	

Table 4: Registration categories for enrolled patients.

Valid	N	Percentage (%)	Valid	Cum.
1 FFT	717	26.81	26.81	26.81
2 FRT	203	7.59	7.59	34.41
3 LTFU	224	8.38	8.38	42.78
4 New	984	36.80	36.80	79.58
5 O	19	0.71	0.71	80.29
6 R	449	16.79	16.79	97.08
7 TI	78	2.92	2.92	100.00
Total	2674	100.00	100.00	Total

Table 5: AFB sputum results in distribution.

Valid	N	Percentage (%)	Valid	Cum.
ND 1	426	15.93	16.83	16.83
NEG 2	425	15.89	16.79	33.62
POS 3	1680	62.83	66.38	100.00
Total	2531	94.65	100.00	
Missing	143	5.35		
Total	2674	100		

Table 6: Culture results tabulation.

Valid	N	Percentage (%)	Valid	Cum.
1 DNR	31	1.16	1.44	1.44
2 ND	386	14.44	17.95	19.39
3 NEG	312	11.67	14.50	33.89
4 POS	1422	53.18	66.11	100.00
Total	2151	80.44	100.00	
Missing	523	19.56		
Total	2674	100.00		

Table 7: Table of resistance pattern categories.

Valid	N	Percentage (%)	Valid	Cum.
1 MDR	859	32.12	32.70	32.70
2 Monoresistant TB	675	25.24	25.69	58.39
3 PDR	64	2.39	2.44	60.83
4 Pre XDR	16	0.60	0.61	61.44
5 RR	1005	37.58	38.26	99.70

Continued.

Valid	N	Percentage (%)	Valid	Cum.
6 XDR	8	0.30	0.30	100.00
Total	2627	98.24	100.00	
Missing	47	1.76		
Total	2674	100.00		

Table 8: Cox proportional hazard model 1.

cox year quarter sector_1 modelofcare_1 intens_phse_regimen_1 mod_intens_phse_regmn_1 County_1					
Failure _d: Event_intsv_1=1 Analysis time _t: Int_prd_M1 Id: Serial number Cox regression--Breslow method for ties No. of subjects=137, number of obs=137 No. of failures=113 Time at risk=940 LR chi^2 (7)=122.82 Log likelihood=-463.36472, Prob >chi^2=0.0000					
_t	**Haz. ratio**	**Std. err.**	**Z**	**P>|z|**	**[95% CI]**
Year	1.152979	0.1294298	1.27	0.205	0.9252693 (1.436728)
Quarter	1.006025	0.0975102	0.06	0.951	0.8319654 (1.216501)
Sector_1	0.7980364	0.1441018	-1.25	0.212	0.5601713 (1.136906)
ModelOfCare_1	0.973068	0.227015	-0.12	0.907	0.6159698 (1.537188)
Intens_phse_regimen_1	0.9742304	0.0087677	-2.90	0.004	0.9571967 (0.9915672)
Mod_Intens_phse_regmn_1	0.9363281	0.0215918	-2.85	0.004	0.8949511 (0.9796182)
County_1	1.00269	0.0087219	0.31	0.757	0.9857403 (1.019931)
Estat test, detail, test of proportional-hazards assumption, time: time					
	Rho	**Chi^2**	**Df**	**Prob>chi^2**	
Year	-0.08891	0.99	1	0.3201	
Quarter	-0.08657	0.86	1	0.3535	
Sector_1	0.00754	0.01	1	0.9358	
ModelOfCar~1	0.06324	0.43	1	0.5097	
Intens_p~n_1	0.03161	0.14	1	0.7079	
Mod_Intens~1	-0.05743	0.42	1	0.5185	
County_1	0.00344	0.00	1	0.9701	
Global test		2.51	7	0.9260	

Table 9: Cox proportional hazard model 2.

Stcox. County_1 TypeofTB_1 Registrationgroup_1 ResistancePattern_1					
Failure _d: Event_intsv_1 == 1 Analysis time _t: Int_prd_M1 Id: Serial number Cox regression -- Breslow method for ties No. of subjects=1498, number of obs=1498 No. of failures=1137 Time at risk=10074 LR chi^2(4)=90.76 Log likelihood=-7933.8059, Prob> Chi^2=0.0000					
_t	**Haz. ratio**	**Std. err.**	**Z**	**P>|z|**	**[95% CI]**
County_1	1.003551	0.0025682	1.39	0.166	0.9985303 (1.008597)
TypeofTB_1	1.350987	0.3308787	1.23	0.219	0.835946 (2.183355)
Registrationgroup_1	1.023877	0.0170176	1.42	0.156	0.9910606 (1.05778)
ResistancePattern_1	1.167157	0.0205905	8.76	0.000	1.12749 (1.208219)

After accounting County_1, TypeofTB_1, Registrationgroup_1, and ResistancePattern_1, we found that County, the type of TB, and registration group did not have any significance on time of conversion after a patient has been started on treatment could convert from being sputum positive to sputum negative, but type of resistance pattern a patient was enrolled on influence month of sputum conversion holding all other factors constant.

DISCUSSION

The study's total enrolled patients, 2674 cumulatively sampled from 2014 to 2019, have an increasing sequential pattern, which concurs with the national rate of increasing case notification rate in the country as reported by the department of NLTP.[6] It shows a unified effort by various players within the health sector to tackle the increasing burden of DR-TB and TB at large this tallies with the study done in Uganda which points to increased testing among patients with gene-expert.[7]

From the study, there were high cases of DRTB within significant towns in Kenya, which rhymes with tuberculosis nature of spread with congestion and poor sanitation as described by CDC where they articulate that Persons who spend much time in enclosed spaces with people who have infectious TB disease are the most likely to be infected with *M. tuberculosis* having the Nairobi county accounting up to 16% of all the DRTB patient enrolled for treatment during the study period.[8]

The data showed the burden of DR-TB coming from three primary groups: new cases, relapse cases, and patients failing treatment while on first-line TB medication, which accounted for 78% of the total TB cases enrolled for DRTB treatment which matches a study in China, meaning that we have poor management of TB in Kenya leading to poor follow-up for a patient already on care leading them to fail mediation and case detection for patient vising our hospital is low leading missing cases which is synonymous with the surveillance report of 2016 which indicated that screening for TB using cough of more than two weeks would have missed 52% of the cases.[9] Testing all people with any symptom consistent with TB-cough of any duration, hemoptysis, night sweats, weight loss, fatigue, fever, and shortness of breath-would have substantially increased the case yield to 74%.[10]

In relationship to factors influencing sputum conversion, there was a categorization of variables that built models using Cox proportional hazard models to help determine which factors contributed to a patient diagnosed with DR-TB conversion from sputum positive to sputum negative. We found that gender, type of resistance pattern, line probe assay of rifampicin and isoniazid, intensive phase regimen, modification of intensive phase, and waiting time before initiating treatment were factors that influenced when a person would convert from sputum positive to sputum negative where a study in Nigeria found gender as important factor influencing the conversion.[11] Hence, all other factors were not significant enough to determine if one converted from positive to negative. This outcome goes with WHO's advocacy of a joint effort in fighting TB using synchronized approaches to continue supporting member states in building a resilient response to tuberculosis through normative guidance, technical and strategic support, and global monitoring, reporting, and review.[12]

Limitations

Some limitations of this study should be noted. We used retrospective data throughout the country from a system that had been newly started hence real-time data capturing and recording could not be 100% ascertained. Secondly, some patients had missing information on their monitoring expected time and this affected the final number compared to the one we got on enrollment.

CONCLUSION

Kenya as a country faces a challenge in fighting the drug resistance TB due to the devolution of the health docket to the counties and lack of cooperation between the parent ministry and the county department of health in real-time towards addressing various challenges affecting the sector where TB falls into. With that said, we have seen that patients diagnosed with DR-TB require correct diagnosis and timely start of medication with good follow-up to avoid patients being lost to follow-up or failing on the medication started, necessitating them being given other optimum regimens, which might have more severe side effects. The health care workers need continuous training to gain more knowledge in case detection for patients coming to hospitals. They also need to empower community health workers to sensitize the community to health-seeking behaviors when symptoms are synonymous with TB.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: David M, Orowe I, Karanja A, Kipruto H. Factors associated with sputum conversion time among patients with drug-resistant tuberculosis in Kenya. Int J Res Med Sci 2024;12:2286-93.