http://jmscr.igmpublication.org/home/
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v12i05.05

IGM Publication Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

The Burden of Drug-Resistant Tuberculosis among Kenya's Devolved Health Units and Associated Treatment Outcomes

Authors
Mutabari David[1]*, Dr Idah Orowe[2], Dr Anthony Karanja[3], Dr Hillary Kipruto[4]
[1]Department of Public & Global Health, University of Nairobi
[2]Department of Mathematics, University of Nairobi
[3]Department of Mathematics, Maasai Mara University
[4]Department of Public & Global Health, University of Nairobi

Abstract

Background: *A devolution is a form of decentralisation or the transfer of authority and responsibility from central to lower levels of government for a range of public functions. The drafters of the 2010 Kenyan constitution chose to devolve functions to 47 newly created counties. In Kenya, health is a devolved function that county governments run. Tuberculosis is managed at the county level in coordination with the National Leprosy Tuberculosis and Lung Disease Program (NLTP) with a mission of End TB Strategy to achieve a 95% decline in deaths due to tuberculosis compared with the 2015 baseline and reach an equivalent 90% reduction in tuberculosis incidence rate.*

Methods: *This was a retrospective cohort study that collected data from health facilities accredited by the NLTP for drug-resistant tuberculosis treatment. The study population included patients who tested positive for drug-resistant tuberculosis from 2014 to 2019. Data was sourced from NLTP Electronic Medical Records (TIBU-System). After abstraction, the data was entered into Excel and analysed through STATA software version 13.*

Results: *Of the 2674 enrolled patients in total, there were more males affected with DRTB at 64 % compared to the female patients. The public facilities carried the immense burden of diagnosis and treatment of the patient, having a cumulative number of 83 %, while the prison sector had the lowest number. For the resistance pattern, the new, relapse, and failure of first-line drugs accounted for most drug-resistant cases at 80 %, with only 65 % of the total cases having been done a gene-expert test at the point of screening.*

Conclusion: *With a devolved health unit in Kenya, there needs to be a more coordinated support system from the national government to the county health units in terms of surveillance of TB disease. Regional centralised laboratories for diagnosis and monitoring of TB would reduce the time it takes for samples to come to Nairobi for testing, which takes time before patents are initiated on treatment.*

Background

Devolution is a form of decentralisation or the transfer of authority and responsibility from central to lower levels of government for a range of public functions. The drafters of the 2010 Kenyan constitution chose to devolve functions to 47 newly created counties based on Kenya's 1992 district framework (Republic of Kenya, 1992). These new functions would be administered by locally elected politicians and civil servants, with formula-driven funding from the national government and limited locally generated revenue[(1)]. In Kenya, health is a devolved function that county governments run, and tuberculosis is managed at the county level in coordination with the National Leprosy Tuberculosis and Lung Disease Program (NLTP). According to the National TB Prevalence Survey Report 2016, the burden of TB in Kenya was 426 cases per 100,000 population[(2)]. An estimated 147,000 people fell ill with TB in 2019. Only 86,385 were diagnosed, treated, and notified of the national TB program, which undermines the End TB Strategy to achieve a 95% decline in deaths due to tuberculosis compared with the 2015 baseline and reach an equivalent 90% reduction in tuberculosis incidence rate[(3)].

Literature Review

In 2018, WHO estimated that the global burden of TB was 10 million cases and 1.45 million deaths[(4)], with an estimated 500,000 cases being resistant to rifampicin. Second-line treatment for these cases is costly, with an average treatment success of only 56%, compared to 85% for drug-sensitive TB[(5)]. TB continues to be a significant public health problem, with the African region accounting for 23% of new cases and 31% of TB-related deaths[(6)]. It remains undiagnosed due to inadequate access to diagnostic tools that simultaneously detect tuberculosis and screen for resistance[(7)]. In Kenya, W.H.O estimates that 1.3% of new T.B. cases and 4.4% of previously treated T.B. cases have MDR/RR T.B. According to the Kenya drug resistance survey of 2014, the prevalence of isoniazid mono-resistance among new patients was 5.5%[(8)]. In 2021, the estimated TB incidence in Kenya was 133,000, and an estimated 32,000 people died from TB. Kenya notified 76,010 incident TB cases, and 64 % of the total notified bacteriologically confirmed individuals with TB were tested for rifampicin resistance[(9)].

Methodology

Study design: Retrospective cohort study.

Study site: Data were collected retrospectively from all health facilities accredited by the National Tuberculosis and Leprosy Board for drug-resistant tuberculosis treatment.

Study population: It included all patients who had tested positive for drug-resistant tuberculosis from 2014 to 2019. Data abstraction and analysis:

Data was sourced from the Kenya National Tuberculosis and Leprosy Board's Electronic Medical Records (TIBU-System). After abstraction, the data was entered into Excel and analysed through STATA software version 13. Data analysis: Descriptive statistics were used to describe the socio-demographic and disease characteristics of the study participants. The Cox proportional hazards regression model was used to determine factors associated with sputum conversion time from the devolved health units. Adjusted Hazard Ratios (AHR) with 95% confidence intervals were computed, and statistical significance was declared when it was significant at a 5% level (p-value < 0.05).

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

For this study, we included DRTB patients who had been enrolled for treatment in the 47 counties DRTB treatment centres registered under the NLTP, including the sector of care (private, mission, public), type of resistance pattern a patient was enrolled on for treatment, registration group(new, relapse, failure of first-line drugs) country of treatment, age group a patient enrolled on (below 20, 20-30, 31-49, above 50), and the treatment outcome for the enrolled patients.

1. Enrollments

In total, we had 2674 patients. We saw a progressive increase from 2014 to 2018, with a significant drop in 2019 cumulatively and quarterly compared to the previous year. 2018 had a peak of registered patients on treatment immediately after Kenya's first TB survey was released on a national-level platform.

Table 1: Yearly enrollment for the DRTB from 2014 to 2019 per quarter

	Quarter				
Year	1	2	3	4	Total
2014	87	73	52	102	314
2015	93	117	126	119	455
2016	121	113	108	112	454
2017	164	118	130	136	548
2018	155	240	194	118	707
2019	177	19	0	0	196
Total	797	680	610	587	2,674

2. Care and Treatment Centers

As with the national guidelines for leprosy, tuberculosis, and lung disease, all centres that treat drug-resistant tuberculosis had to be registered by the body for ease of drug supply, monitoring, and documentation of treatment outcomes. In general, all 47 counties had treatment centres, including private, mission, and public facilities.

Table 2: Treatment and care centres of DRTB in Kenya

			Freq.	Percentage	Valid	Cum.
Valid	1	Baringo	31	1.16	1.16	1.16
	2	Bomet	35	1.31	1.31	2.47
	3	Bungoma	46	1.72	1.72	4.19
	4	Busia	32	1.20	1.20	5.39
	5	Elgeyo Marakwet	15	0.56	0.56	5.95
	6	Embu	57	2.13	2.13	8.08
	7	Garissa	134	5.01	5.01	13.09
	8	Homa Bay	59	2.21	2.21	15.30
	9	Isiolo	25	0.93	0.93	16.23
	10	Kajiado	42	1.57	1.57	17.80
	11	Kakamega	51	1.91	1.91	19.71
	12	Kericho	28	1.05	1.05	20.76
	13	Kiambu	98	3.66	3.66	24.42
	14	Kilifi	60	2.24	2.24	26.66
	15	Kirinyaga	69	2.58	2.58	29.24
	16	Kisii	48	1.80	1.80	31.04
	17	Kisumu	66	2.47	2.47	33.51
	18	Kitui	72	2.69	2.69	36.20
	19	Kwale	24	0.90	0.90	37.10
	20	Laikipia	33	1.23	1.23	38.33
	:		:	:	:	:
	29	Murang'a	74	2.77	2.77	58.45
	30	Nairobi	428	16.01	16.01	74.46
	31	Nakuru	108	4.04	4.04	78.50

32	Nandi	21	0.79	0.79	79.28
33	Narok	49	1.83	1.83	81.11
34	Nyamira	31	1.16	1.16	82.27
35	Nyandarua	17	0.64	0.64	82.91
36	Nyeri	54	2.02	2.02	84.93
37	Pokot	70	2.62	2.62	87.55
38	Samburu	17	0.64	0.64	88.18
39	Siaya	86	3.22	3.22	91.40
40	Taita Taveta	25	0.93	0.93	92.33
41	Tana River	11	0.41	0.41	92.74
42	Tharaka Nithi	16	0.60	0.60	93.46
43	Trans Nzoia	22	0.82	0.82	94.28
44	Turkana	79	2.95	2.95	97.23
45	Uasin Gishu	45	1.68	1.68	98.92
46	Vihiga	24	0.90	0.90	99.81
47	Wajir	5	0.19	0.19	100.00
Total		2674	100.00	100.00	

The total number of health care facilities 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.

3. Health sector distribution

The health sector is divided into the following categories: public, private, mission, and prison; hence when it comes to drug-resistant TB management, the NLTP has allowed different players to recruit and treat cases diagnosed with DRTB following its guidelines.

Table 3: Health sector treatment centre distribution in Kenya

Sector	Freq.	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	

Patients were generally enrolled for care among all models for the study period. Still, the numbers presented to show that the public health model had a more significant treatment and care burden, as it enrolled and followed up to 80 % of all patients who had DR-TB from 2014 to 2019.

4. Registration Categories of DRTB on Enrollment in Kenya

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: 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.

Table 4: Registration categories of DRTB patients in Kenya

		Freq.	Percentage	Valid	Cum.
Valid	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	

It was evident that across the country, three categories accounted for close to 78% of the total drug-resistant tuberculosis cases in Kenya, including FFT (26.81%), New (36.80 %), and R (16.79 %).

5. Age Distribution

Patients who were enrolled were done with age categories. Thus, we categorised them into groups to see which ages were more affected by the disease. The types of patients who got registered for the treatment of drug-resistant tuberculosis were;

a) Young people – aged below 20 years
b) Young adults - aged between 20 to 40 years
c) Middle-aged – aged between 40 to 50 years
d) Old aged – aged above 50 years

Table 5: Age category distribution in Kenya for DRTB patients

		Freq.	Percentage	Valid	Cum.
Valid	0 Young_people	638	23.86	23.86	23.86
	One young adult	632	23.64	23.64	47.49
	Two middle-age	845	31.60	31.60	79.09
	Three old	559	20.91	20.91	100.00
	Total	2674	100.00	100.00	

We see more middle-aged patients getting DR-TB infections than the other age groups from the numbers.

Table 6: Age distribution and DRTB resistance pattern in Kenya

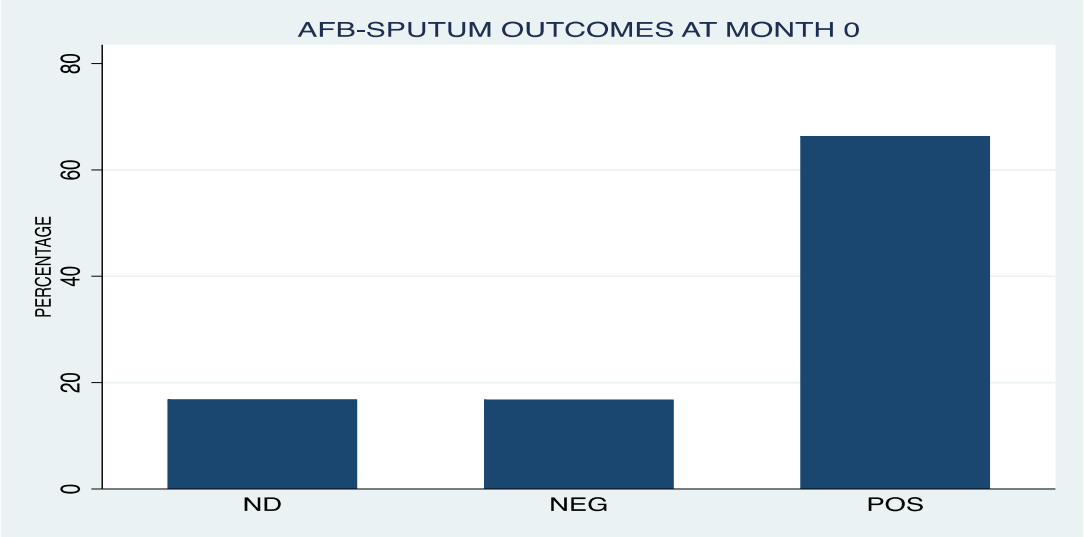
	Resistance Pattern				
Age clases	MDR	Mono TB	PDR	Pre XDR	XDR
Young_people	201	166	13	2	246
young adults	233	136	13	4	231
middle age	280	211	20	6	316
old	145	162	18	4	212

The middle age group had a uniform distribution of different types of DR-TB, with the XDR type being the least reported among all age categories enrolled.

6. Sputum Testing for Presumptive Cases of DRTB in Kenya

As guided by the NLTP, all patients who present with a cough for any duration should undergo sputum testing of either AFB, Gene-Expert, LPA, or culture. This depends on the facility and availability of the required test.

Graph 1: AFB outcome results at month zero for DRTB patients in Kenya



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 the patients had missing records of the AFB report from those enrolled for DR-TB follow-up.

Table 7: Gene-Expert results tabulation for DRTB patients in Kenya

		Freq.	Percentage	Valid	Cum.
Valid	1 Invalid/no result/error	1	0.04	0.04	0.04
	2 MTB detected Rifampicin resistance detected	1672	62.53	65.59	65.63
	3 MTB detected Rifampicin resistance	7	0.26	0.27	65.91
	Indeterminate				
	4 MTB detected Rifampicin resistance not detected	464	17.35	18.20	84.11
	5 MTB not detected	48	1.80	1.88	85.99
	6 Not Done	357	13.35	14.01	100.00
	Total	2549	95.33	100.00	
Missing.		125	4.67		
Total		2674	100.00		

62 % had MTB-RR type, of which 17% had not recorded any RR in their results but had been classified as DR-TB patients.

Table 8: Sputum Culture Outcome for DRTB patients in Kenya

		Freq.	Percentage	Valid	Cum.
Valid	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		

For culture outcome, we could only account for 65% of the total enrolled patients who had taken a test. In contrast, cumulatively, we had the missing results and the ones who were not done the culture totalling 34 %, which is a very significant number to influence the pattern of spread to the community or affect treatment outcomes for the patients enrolled for care and treatment.

Graph 2: Graph of Gene-Expert and Sputum Culture Outcomes

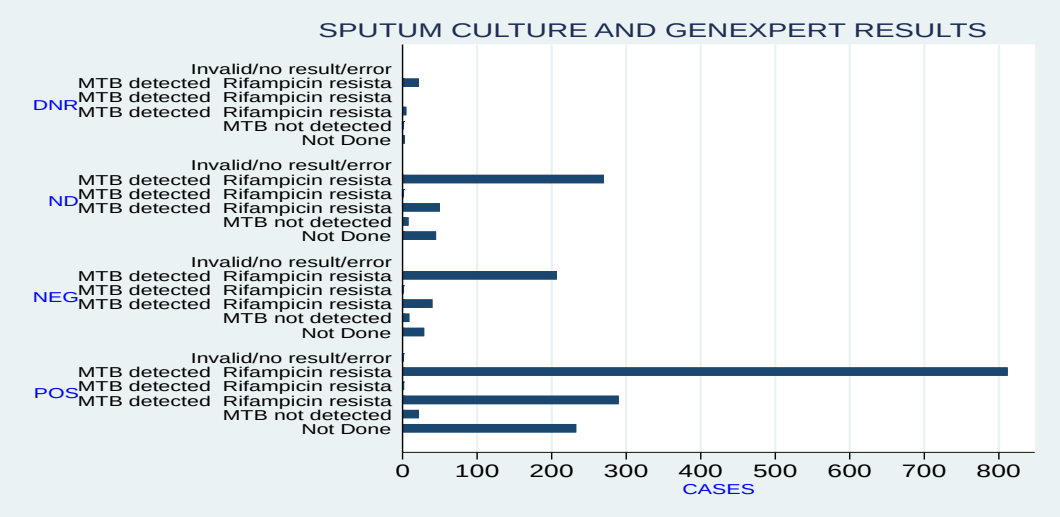


Table 9: Resistance Pattern categories for sputum culture results

		Freq.	Percentage	Valid	Cum.
Valid	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
	6 XDR	8	0.30	0.30	100.00
	Total	2627	98.24	100.00	
Missing.		47	1.76		
Total		2674	100.00		

From the data reviewed, it was evident that the resistance patterns indicated that MDR, RR, and Mono-resistance comprised up to 95 % of all the reported cases related to tuberculosis resistance. At the same time, the burden of Pre-XDR, XDR, and PDR was less than 3 %.

Table 10: Kenya's distribution of DRTB resistance pattern per county

	Resistance Pattern					
County	MDR	Monoresistant TB	PDR	Pre XDR	RR	XDR
Baringo	6	4			21	
Bomet	10	12	2		11	
Bungoma	9	12		2	21	
Busia	6	9	3	1	13	
Elgeyo Marakwet	7	5			3	
Embu	14	25	1		16	
Garissa	94	33			7	
Homa Bay	29	10	1		18	
Isiolo	6	18			1	
Kajiado	14	8		1	14	
Kakamega	18	6	1		26	
Kericho	9	8	1		10	
Kiambu	14	32	2		47	
Kilifi	10	16	1		33	
Kirinyaga	18	26	4		21	
Kisii	17	13			18	
Kisumu	25	25	2		13	
Kitui	26	21	2		19	2
Kwale	15	3			5	
Laikipia	8	8	1		16	
Lamu	2	2			2	
Machakos	29	35	2		25	1
Makueni	12	14			23	
Mandera	2	2			5	
Marsabit	7	2		1	3	
Meru	29	37	2	4	46	
Migori	15	4			25	
Mombasa	34	28	2	1	62	
Murang'a	11	20	3		37	
Nairobi	192	79	15	2	131	4
Nakuru	31	30	2		39	1
Nandi	2	8		1	10	
Narok	5	19	4		21	
Nyamira	16	3			10	
Nyandarua	3	3			11	
Nyeri	5	17	3		29	
Pokot	25	12	4	2	27	
Samburu	7	1			9	
Siaya	17	27	1		40	
Taita Taveta	6	5	1		11	
Tana River		2		1	8	
Test County	3					
Tharaka Nithi	1	3	1		8	
Trans Nzoia	7	3			10	
Turkana	15	16			48	
Uasin Gishu	20	3	2		18	
Vihiga	7	6	1		10	
Wajir	1				4	

The distribution of tuberculosis resistance was similar to most counties with the same geographical and infrastructural developments, apart from Nairobi County, which had the most considerable number of cases of tuberculosis resistance in Kenya.

1. **Cox PH Model of County conversion patterns for patients with DRTB in Kenya**

They were stratified using County to detect which factors influenced differences in their conversion time. We used factors that uniformly affected all the countries bearing in the devolved health system in Kenya. The factors considered were Sector, Model Of Care Registration group, Resistance Pattern, Sex MF, and Health Facility).

Table 11: Cox PH model for Sputum conversion among DRTB in Kenya

```
stcox  Sector_1     Sector_1    ModelOfCare_1 Registrationgroup_1 ResistancePattern_1 SexMF_1 HealthFacility_1
HI
> VStatus_1 BMI_Cat3 Age_reg_Cat2, strata(County)
         Failure _d:  Event_intsv_1 == 1
   Analysis time _t:  Int_prd_M1
                 id:  Serial Number
note: Sector_1 omitted because of collinearity
Refining estimates:
Iteration 0:   log-likelihood = -3461.7378
Stratified Cox regr. -- Breslow method for ties
No. of subjects =         1378                     Number of obs    =      1378
No. of failures =         1041
Time at risk    =         9237
                                                   LR chi2(9)       =     82.43
Log likelihood =   -3461.7378                      Prob > chi2      =    0.0000

                  _t | Haz. Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]

          Sector_1 |    .891345   .0513249    -2.00   0.046     .7962187    .9978361
     ModelOfCare_1 |   .8310321   .0676507    -2.27   0.023     .7084762    .9747885
Registrationgroup_1 |   1.018314   .0186985     0.99   0.323     .9823178     1.05563
ResistancePattern_1 |   1.161405   .0223266     7.78   0.000     1.118459    1.205999
          SexMF_1 |   .8935478   .0620721    -1.62   0.105     .7798073    1.023878
   HealthFacility_1 |   1.000027   .0001058     0.26   0.797     .9998199    1.000235
       HIVStatus_1 |   1.003756   .0683429     0.06   0.956     .8783589    1.147054
         BMI_Cat3 |   1.050001   .0592816     0.86   0.387     .9400087    1.172863
      Age_reg_Cat2 |   .9791583   .0402418    -0.51   0.608     .9033789    1.061295
                                                        Stratified by County
```

Test of proportional-hazards assumption

Time: Time

	chi2	df	Prob>chi2
global test	21.99	9	0.0089

stphtest, rank detail

Test of proportional-hazards assumption

Time: Rank(t)

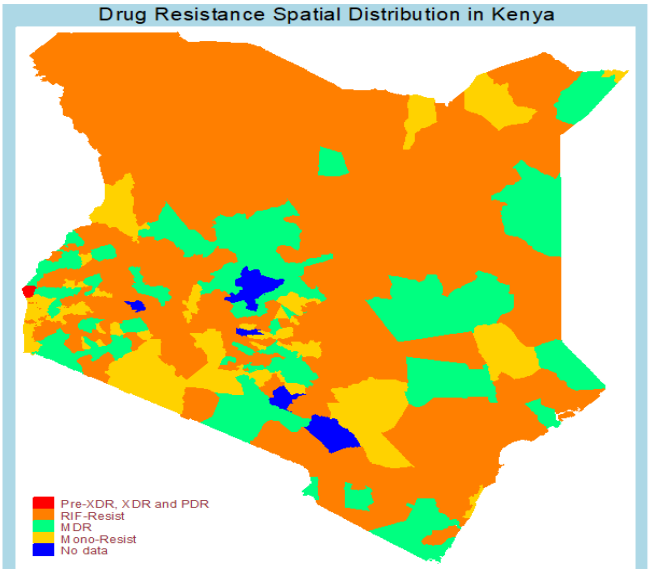
	rho	chi2	df	Prob>chi2
Sector_1	0.02258	0.59	1	0.4441
o.Sector_1	.	.	1	.
ModelOfCar~1	-0.10428	10.96	1	0.0009
Registrati~1	0.00131	0.00	1	0.9665
Resistance~1	-0.06576	5.12	1	0.0237
SexMF_1	-0.02500	0.66	1	0.4158
HealthFaci~1	0.03012	0.94	1	0.3329
HIVStatus_1	0.04631	2.25	1	0.1335
BMI_Cat3	-0.02661	0.76	1	0.3828
Age_reg_Cat2	-0.01877	0.36	1	0.5496
global test		21.63	9	0.0101

Only the Sector where patients got medication, the model of care, and resistance patterns significantly affected how counties could obtain different conversion times for the patients enrolled within their facilities for DR-TB treatment. The rest were not significant enough to influence how counties would result in differences in conversion time.

2. Spatial Distribution of DR-TB in Kenya and the Associated Factors

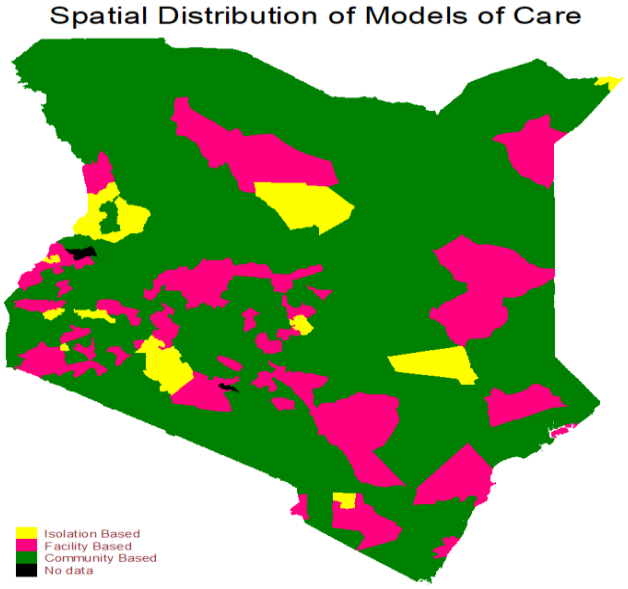
We reviewed the country into regions because of the county effect across borders and then found how different factors were spatially distributed within the country. We had the Central region, the Northern region, the Coastal region, the Western region, and the Lakeside region.

Graph 3: Spatial Distribution of Resistance Patterns in DRTB in Kenya



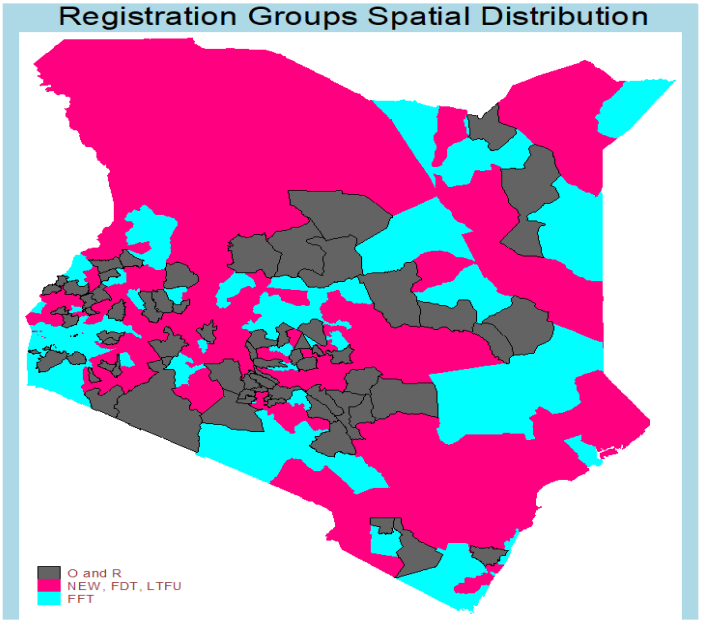
Mono-resistance was uniformly distributed among the 47 counties of the Kenyan Republic. MDR mainly affected the Nyanza region, Nairobi, and Central areas of Kenya, and many Pre-XDR were majorly in the West.

Graph 4: Spatial Distribution Models of Care



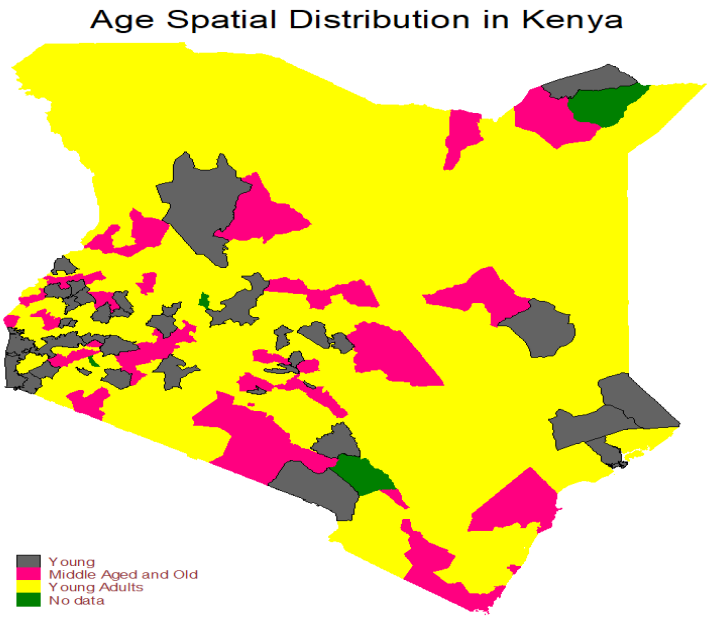
Most patients in the country received care under the community-based method, evenly distributed within the 47 counties of the Kenyan Republic. In contrast, the facility-based care model was distributed within the town areas of the republic, indicating that town areas have more health facilities and more disease severity than rural areas. The isolation-based model was still significant but remotely distributed within the counties.

Graph 5: Registration Group Spatial Distribution



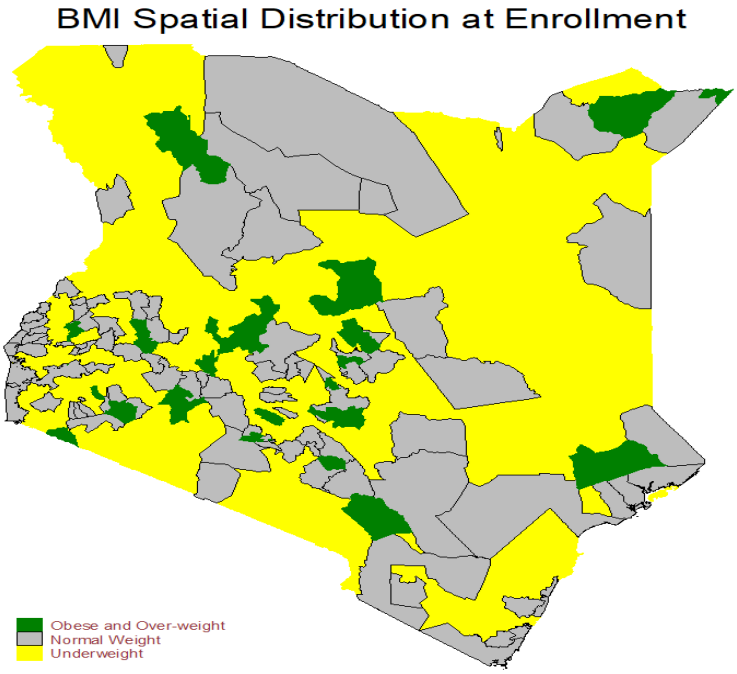
The most significant burden of disease was from the 'New cases, Loss to follow-up patients, and Failure of first-line Medication' cases, which contributed the most considerable percentage of the total DR-TB cases in the Kenyan population and were evenly distributed within the 47 counties. Failure of second-line ant TB showed a major challenge, mostly happening within the significant towns of the Kenyan Republic.

Graph 6: Age Groups Spatial Distribution



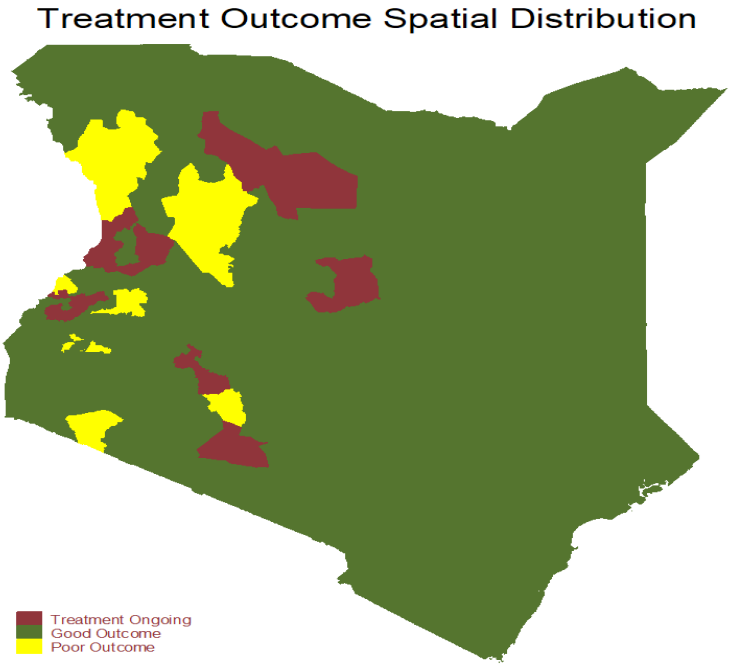
Patients who were enrolled in DR-TB treatment comprised young adults, which we had grouped as being between 20 and 40 years old, and all counties uniformly represented this age bracket. The Middle-aged and older were sparsely distributed but majorly concentrated within Major towns. The keynote is the distribution of the old and middle-aged population, which may indicate the care they require from these young adults who transmit the disease due to compromised immunity.

Graph 7: BMI Spatial Distribution at Enrollment



From the patients enrolled and the nature of the TB disease, most patients were underweight to malnutrition and were within the 47 counties of the Kenyan Republic. Still, the keynote is that some counties recorded patients as obese and overweight irrespective of the tuberculosis nature, making patients emaciated.

Graph 8: Treatment Outcome Spatial Distribution



The Kenyan population of patients who had DR-TB showed good treatment outcomes by either converting their sputum at the end of the follow-up period or completing their DR-TB mediation, and clinically, they were stable with no symptoms. Of note is that some counties in the western region and Rift Valley had consistently poor Outcomes.

Discussion

From this study, it was evident that drug-resistant tuberculosis was prevalent more within the urban areas compared to the rural setting, which was going with the natural transmission of the disease, which has been described by "long" stating that proximity to the source patient is also a determinant of transmission with overcrowding increasing the risk of disease spread[10]. From this, we saw more enrollments from the urban regions, which could have been due to the concentration of health facilities within the town areas compared to the rural areas, which had to have a centralised centre for sending suspected cases for gene expert testing. With this, it was evident that they took more time before initiating patients on treatment than facilities with machines for doing the Gene-Expert within their premises. Additionally, we found that the common resistance type from the 47 counties was rifampicin resistance. This could have been attributed to the wide use of ant-TB with possible poor monitoring and follow-up, resulting in the high numbers of patients presenting with rifampicin resistance. The most affected group with tuberculosis was 40 to 50 years old, with men carrying a high burden of the disease compared to the female patients, which rhymed with WHO reporting; globally, men account for a higher proportion of notified TB cases of around 60-65% [11]. For the nutritional status, generally, the majority of the enrolled patients in all 47 counties had low BMI, indicating the need for nutritional supplementation within the treatment facilities handling DRTB patients. Supplementation then, we have a higher probability of having favourable treatment, which W.H.O. has asserted with the evident link between under-nutrition and active TB; nutrition screening, assessment, and management are integral components of TB treatment and care[12]. The treatment outcome was a success across the 47 counties. However, looking at the western and Nyanza regions, they had a significant number of poor outcomes, signifying death or loss to follow-up within the counties in those regions.

Conclusion

Given that health is a devolved function, there needs to be a more concerted effort to ensure there are laid down structures for coordinating the management of tuberculosis in general from the NLTP, which is under the national government and respective county health boards in practical and not in paper from which we can increase case detection rate with better treatment outcomes. Additionally, from the study, we have established a gap between diagnosis and the start of treatment where some countries take a longer time from sputum collection for gene-expert to culture reports; hence, if we had a regional reference lab with proper sample logistic system, it cut time taken to deliver samples to Nairobi for the marginalised counties leading to early treatment and less spread of the disease in the community.

Acknowledgement

We want to acknowledge the National Leprosy, Tuberculosis, and Lung Disease for allowing us to use the data.

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