Assessing the Degree of Determinant Impact on the Management Outcomes of Drug Sensitive Pulmonary Tuberculosis in Sierra Leone-A Case Study of Rural Bo District.

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Assessing the Degree of Determinant Impact on the Management Outcomes of Drug Sensitive Pulmonary Tuberculosis in Sierra Leone-A Case Study of Rural Bo District.

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Abstract

Purpose: Treatment outcomes of tuberculosis are strongly influenced by the level of socioeconomic status of a population. Predisposing factors of tuberculosis such as undernutrition, diabetes, and AIDS are hinged on the socioeconomic status of a population.

Alcohol, smoking and illicit drug use disorders can predispose to TB especially in hyperendemic setting. Sierra Leone still grapples with socio-economic challenges including all the factors that predispose people to the disease and as well precipitates TB transmission.

Methodology: The study was a retrospective cohort study to assess the degree of impact on the determinants of drug sensitive pulmonary tuberculosis treatment outcomes in patients managed in catchment areas in the rural Bo district of Southern Sierra Leone. Data were collected from 2176 participants with even ID numbers enrolled from January 2018 to January 2022 out of the population of 533,900. Sample was calculated at a 99% confidence level and 3% margin of error.

Findings: A Chi^2 test was performed between age: α= <15 yrs β= $\geq$15yrs and exit which showed a statistically significant relationship between the two, χ^2 (4) = 188.32, p = <0.001, Cramér's V = 0.29 with the calculated p-value of <0.001 that is lower than the defined significance level of 5%. There was also a statistically significant relationship between source of income and exit, χ^2 (12) = 94.57, p = <0.001, There was a statistically significant relationship between food security and exit, χ^2 (4) = 15.32, p = 0.004, Cramér's V = 0.08. The calculated p-value of 0.004 is lower than the defined significance level of 5%.

Unique contribution to theory, practice and policy: Shows that favorable treatment outcomes are a combination of use of chemotherapy, psychosocial care, social, economic and economic moderation strategies especially in the global South where the majority of the patients live in poverty.

Keywords: *Tuberculosis, Cohort study, Determinants, Management Outcomes, Rural*

1. INTRODUCTION

Tuberculosis (TB) remains one of the leading causes of death due to an infectious disease, with more than 10 million people estimated to be falling ill with TB each year and around 1.5 million deaths. A human rights-based and comprehensive response to the global TB epidemic requires that TB is addressed in all vulnerable groups including refugees, migrants, displaced populations and those living in settings of conflict. Even though TB is preventable and treatable, the increase in the number of TB patients in many nations turns out to be a global challenge and thus requires concerted efforts to tailor strategies to control and manage it (WHO operational handbook on tuberculosis. 2023).

After many years of intervention with chemotherapy, improved technology and skilled human resources to significantly control and then end TB on planet Earth yielded little dividend. This may be partly due to the less attention to handling the hindrances caused by culture, socioeconomic and other determinants. This study may throw light on the unseen determinants that heavily influence TB treatment outcomes.

TB infection prevention and control should be part of national TB programs and part of the measures taken at all levels of the country to prevent the transmission of infectious conditions. This does not only include the administration of TB preventive prophylactic treatment but also making better the nutritional, socio-economic and psychological status of the patient that will prevent poor adherence that will eventually lead to the spread of the disease. This underscores the significance of implementing comprehensive, well-coordinated, multi-sectoral initiatives across all levels of healthcare and other settings that are susceptible to TB transmission (WHO operational handbook on tuberculosis. 2023).

Tuberculosis mostly affects adults in their most productive years. However, all age groups are at risk. Over 80% of cases and deaths are in low- and middle-income countries. TB occurs in every part of the world. In 2021, the largest number of new TB cases occurred in WHO's South-East Asian Region (46%), followed by the African Region (23%) and the Western Pacific (18%). Around 87% of new TB cases occurred in the 30 high TB burden countries, with more than two thirds of the global total in Bangladesh, China, the Democratic Republic of the Congo, India, Indonesia, Nigeria, Pakistan, and the Philippines.

Globally, close to 1 in 2 TB-affected households face costs higher than 20% of their household income, according to latest national TB patient cost survey data.

Those with compromised immune systems, such as people living with HIV, undernutrition or

diabetes, or people who use tobacco, have a higher risk of falling ill. Globally in 2021, there were 2.2 million new TB cases that were attributable to undernutrition, 740 000 new TB cases worldwide were attributable to alcohol use disorder and 690 000 were attributable to smoking (WHO TB Report Factsheets. 2023).

The wish of everyone is not for wealth but to be able to live an average life having square meals, shelter, clothing, and treatment. It is generally known that in the developing world including Sierra Leone, we live under the towers of poverty, disease and other socio-cultural influences. In a situation where these are unavailable; adherence, antibiotic resistance, failure, late presentation of the patient, loss to follow-up, and eventually death are the usual experiences. There are so many determinants that affect TB treatment outcomes which might be due to causes that are socio-economic, cultural, innate, physical, chemical (subtle drug-drug interaction among others), etc.

This research aims at assessing tuberculosis treatment outcomes in relationship to the determinants that significantly influence treatment outcomes. It will also look at various determinants to find those that have a high degree of impact on patient management outcomes. TB is the quintessential disease of poverty; as such, social determinants such as economic inequalities, lack of universal health coverage, and barriers to care -including out-of-pocket patient costs - play a disproportionate role in the epidemiology of TB. Similarly, because they are highly prevalent on a population level, undernutrition, indoor air pollution, heavy alcohol use, and smoking are associated with the greatest population-attributable fractions of TB worldwide. The strong association between poverty and TB is well known at the ecological level however, the relationship/association at the individual level is still controversial at some level (Cervantes. 2016).

Social protection is very important and the various ways to implement it include social assistance or transfers in which it is assumed that cash transfers can aid in TB prevention, care and support either indirectly by influencing the social determinants (such as household / individual living conditions or food security), or directly if conditioned on health-seeking behaviours relevant for TB (i.e. TB testing and preventive therapy among household TB contact, TB treatment completion, BCG vaccination in children). These distal social determinants can act on a number of proximal mediators (here identified as HIV, smoking, alcohol consumption/drug abuse, malnutrition, etc.) which ultimately will result in the impact on TB prevention, TB treatment or TB cost mitigation depending on which specific stage of the disease or population is targeted by the intervention (Craig, et al. 2017, Fuady, et al. 2019, Klein et al. 2019)

These known risk factors enable targeted delivery of interventions, including structural interventions to address the social determinants of TB and disease-specific interventions such as

case finding and testing/treatment for latent TB infection. Socioeconomic determinants of health include the social, political, and economic conditions in which people are born, develop, live, work, and age (Duarte, et al. 2018).

There is increasing evidence of the role of socioeconomic determinants in TB epidemiology as they can influence all the stages of TB pathogenesis (from exposure to risk behaviours and access to health care). Additionally, TB can affect the socioeconomic status of the individual (Lonnroth, et al. 2009).

Identifying the determinants of treatment outcomes is necessary to improve control strategies and programs for TB (Sartika, 2022). The fact that scientific evidence on determinants of TB management income is limited and varies from one demographic to another, this study aims to describe the potential determinants of TB treatment outcomes regarding the patient's internal and external factors. Patients lost to follow-up and treatment failure are some of the major public health issues because they increase the number of not treated that will become infectious in the population at risk of TB which may lead to approximately 70 % of smear-positive patients dying within 10 years of disease progression. Emphasis is laid on the establishment and strengthening of efficient referral and contact tracing mechanisms in the program in order to improve patient treatment outcomes (Teferi, et al. 2021). Assessment of the level of adherence to anti-TB treatment, treatment outcomes and identifying factors associated with non-adherence and poor treatment outcomes are vital for improving TB treatment adherence and treatment outcomes which in turn saves the population from the danger of a resistant strain (Tesfahuneygn et al. 2015).

Cultural beliefs (myths) and the economic status of a family or individual determine decision-making for health facility visits as well as some reasons for adherence. The decision-making process to start treatment or continue taking medication after the commencement of treatment is important in determining the outcome of treatment.

The assessment of certain factors that contribute to treatment adherence and knowledge of TB transmission among patients on TB treatment established that 29.8% of TB patients failed to comply with the TB drug-taking regimen once they started feeling better (Kaona. 2004).

Ending the TB epidemic by 2030 needs a deeper look into not only the partial aspect of universal coverage, chemotherapy, and capacity building of staff but also a closer look at those determinants that create obstacles to success in TB management (WHO TB Report. 2022). The epidemiology of tuberculosis reflects on how these social determinants are distributed, with a clear influence on the stages of the natural history of the bacilli - risk of exposure, susceptibility to progression of disease, time to diagnosis and treatment, compliance and successful treatment (Hargreaves, et al. 2011).

The World Health Organization identified the need for a holistic approach to TB, including the underlying socioeconomic determinants of TB in order to achieve its elimination (Uplekar, et al. 2015).

TB stigma, recognized as a social determinant of health and health inequalities, associated with a lack of social support can potentially lead to non-compliance and poor treatment outcomes (Creswell, et al. 2011).

1.1 Trigger and Rationale

It is a generally accepted idea that the tuberculosis epidemic is strongly influenced by the level of the population's socio-economic development. In most cases, health-related risk factors such as undernutrition, diabetes, and HIV infection are hinged on the socio-economic status of the nation. Alcohol, smoking and illicit drug use disorders can predispose people to the disease in sub-Saharan Africa where the disease is holoendemic. All the mentioned factors that predispose people to the disease are on the rise in Sierra Leone and by extension the world. Several years after the 11-year brutal war, Sierra Leone still grapples with economic and social challenges which in turn has increased drug abuse and malnutrition. The poor economic status of the people makes them eat whatever they can get irrespective of the food's non-healthiness (unbalanced diet) and hence increase in NCDs and malnutrition which in turn affects the patient's treatment outcome. Therefore, strengthening clinical and programmatic interventions for patients at high risk of treatment lost-to-follow-up is mostly recommended if the factors surrounding the cause are known.

1.2 Methodological tool adopted

This study is a retrospective cohort study using multi-centre secondary data collected by the respective facilities from 1st January 2018 to 1st January 2022 confirmed TB patients. The data was collected from records, reports and registers of patients in the facility and if more information is needed the staff at the respective treatment centre helped in its collection.

2. LITERATURE REVIEW

As social determinants may play an important role in tuberculosis control and the improvement of patient treatment outcomes, Zille et al. (2015) concluded that social inequalities should be addressed as part of the TB control strategy. The study covered the social indexes used such as the Human Development Index (HDI) and the Gini index in Brazil and concluded that dimensions of longevity, education and income of each municipality or rural, range from 0 to 1, the closer to 1 the more developed with the degree of income concentration in urban: rural group almost 0: 1 which is next to zero equality situation.

In Sierra Leone today, spiritual and religious beliefs and practices are commonplace in the general population and psychological variables might have increased substantially in the last 2 decades which is in line with the study done by Harrington, et al. (2015) on North America. Even though religion and spirituality are poorly understood because of the limited study done in that discipline, people in most cases first seek help when they are told (not all the times) that the cause of their illness is spiritual such as saying that the cause of the disease is an enemy and sometimes even accusing a first-degree family member to be responsible for it. The reason for the mention of spirituality and religious beliefs is not in any way to downplay the good impact that religion has on the health of individuals but to demystify this topic with the hope of increasing good health-seeking behaviour when one is sick.

A multi-site retrospective cohort study of determinants of early diagnosis, treatment, and prevention of TB in African Americans by Pagaoa, et al. (2013), discovered that sputum smear positivity, cavitary disease, and drug use in TB cases were associated with increased risk of TB infection in their contacts. The study concluded that TB control programs should ensure that all such high-priority contacts are identified and evaluated in a timely fashion.

Migrants being a heterogeneous group with unhealthy conditions faced before, during and after migration often pose physical, mental and social well-being risks to most migrants even though there are certain subgroups more vulnerable than others. Several health determinants and TB interplay to increase the vulnerability of migrants to tuberculous infection, TB disease and poor treatment outcomes, making them a key population for TB (Dhavan, et al. 2017).

 Evidence exists pointing out how non-adherence to treatment remains a major hurdle to efficient tuberculosis control in developing countries, it is reflected in the fact that many tuberculosis (Tb) patients do not complete their six-month course of anti-tuberculosis medications, not aware of the importance of sputum re-examinations, thereby putting themselves and others at risk of developing multidrug-resistant forms of tuberculosis and relapse (Woimo, et al. 2027). Distance between home and treatment facility, lack of awareness about the importance of treatment completion and cost of transportation were the major barriers to adherence which affects the outcome of treatment, recommendations shall be around creating awareness about anti-TB treatment, and decentralization of drug pick-ups to the lowest level of health institutions (Woimo, et al. 2027).

In this cross-sectional study of 452 new TB cases extracted from the Urmia TB management centre during a 5-year period, Kolifarhood, et al. (2015) used the geographical information system (GIS), health centres and study subjects' locations were geocoded on digital maps in a bid to identify the statistically significant geographical clusters using the average nearest neighbour index. Logistic

regression analysis showed that there was an association between spatial and non-spatial variables in the occurrence of adverse treatment outcomes. The spatial clusters of TB cases were concentrated in older, impoverished and outskirts areas. Although there was a tendency toward higher odds of adverse treatment outcomes among urban TB cases, this finding after adjusting for distance from a given TB healthcare centre did not reach statistically significant which highlights the effects of spatial and non-spatial determinants on the TB adverse treatment outcomes, particularly in what way the policies of healthcare services are made.

In some settings, old age, HIV co-infection and health facilities were the independent predictors of unsuccessful TB treatment outcomes as expressed by Araia, et al. (2022).

To identify the characteristics, unsuccessful TB treatment rate, and determinants of unsuccessful TB treatment outcome among patients with TB-HIV coinfection in Kuala Lumpur, analysis of the results of 235 randomly selected patients with TB-HIV as done, TB treatment outcome was successful in 57.9% (cured and completed treatment) and unsuccessful in 42.1% (died, failed, or lost to follow-up). Nearly half of the patients with TB-HIV had unsuccessful TB treatment outcomes. Therefore, it is important to ensure that such patients receive DOTS and continuous TB treatment of >6 months. It is crucial to strengthen and widen the coverage of DOTS, especially among high-risk groups, in healthcare settings. Strict follow-up by healthcare providers is needed for patients with TB-HIV to gain treatment adherence and for better rates of successful TB treatment (Selimin, 2021).

The study by Cury, et al. (2019) aimed to determine whether the rates of poor TB treatment outcomes varied geographically across Ethiopia at district and zone levels and whether such variability was associated with socioeconomic, behavioural, healthcare access, or climatic conditions, revealed significant spatial variation in poor TB treatment outcomes in Ethiopia that was related to underlying socioeconomic status, knowledge about TB, and climatic conditions.

Sierra Leone started the Direct Observation Treatment Strategy (DOTS) for the treatment of pulmonary tuberculosis in 1992. The country's pulmonary tuberculosis (PTB) treatment program is now standardized according to the international scale. Under the national standardized PTB treatment system, the regimen for new PTB patients consists of a 2-month intensive treatment phase with isoniazid, rifampicin, pyrazinamide and ethambutol, followed by a 4-month continuation phase with rifampicin and isoniazid. The significantly high and growing number of annual PTB and DRTB incidence rates during this HIV/AIDS epidemic reinforces the need for routine PTB treatment monitoring and supervision as well as compulsory HIV testing for tuberculosis patients seeking treatment (Kangbai. 2013). This journal is great but trying to find out

the causes of the increase in incidence may help more.

DR-TB treatment success rates in Sierra Leone were like global rates. People receiving short DR-TB regimens had the highest treatment success rates. Underweight, older age, advanced disease, and non-communicable comorbidities (NCDs) were associated with adverse DR-TB treatment outcomes. These findings suggest nutritional support, active case-finding, and linkage with NCD management should be evaluated as potential strategies to mitigate adverse DR-TB outcomes in Sierra Leone (Carlos, et al. 2021).

Successful treatment outcome was high among HIV/TB co-infected as well as TB mono-infected should both be treated with standard treatments. Strengthening patient management in a collaborative approach and use of novel drugs as well as research will increase the survival rate of patients treated. With standard treatment and patient-centred care, the outcome of TB patient management will not be hinged on their HIV status. The adoption of this theory into policy in TB programmes will improve the success rate of TB management (Tommy. 2023).

The educational level, geographic location, and year of treatment were significantly associated with treatment completion. Overall, program performance improved as the number of dropouts decreased significantly between 2013 and 2015. The social change implication of this study was that it identified HIV-positive patients and rural communities as areas needing specific attention such as the assignment of case managers to ensure compliance thereby improving DOTS program performance, thereby reducing the incidence and transmission of TB (Sesay, 2018).

The impact and disruption of infectious disease outbreaks stretch far beyond their direct death toll, as they often overburden health systems, reduce treatment-seeking behaviours, and interrupt treatment regimens. This study examines the impact of the 2014-2016 Ebola virus outbreak on tuberculosis (TB) treatment outcomes at the 34 Military Hospital in Freetown, Sierra Leone. We used retrospective data from 1, 085 TB patient outcome data registers to build a multinomial logistic regression model to evaluate the change in TB treatment outcomes before and after the Public Health Emergency of International Concern (PHEIC) declaration in August 2014. These results showed that HIV status, patient age, whether patients had active versus latent TB, and the time since the start of the outbreak were significantly associated with TB treatment outcomes. The model showed an increase in the probability of unknown and unsuccessful (died or treatment failed) treatment outcomes each month after the PHEIC declaration, across age groups, TB status, and HIV status (Hogan, et al. 2022).

In a retrospective study conducted of adult TB patients aged ≥15 years who were treated at Connaught Hospital in Freetown, Sierra Leone from January through December 2017, a

multivariate logistic regression was used to identify predictors of mortality. It was concluded that suboptimal TB treatment outcomes were observed in Sierra Leone in 2017. More local and international action is warranted to help achieve the 2035 global TB elimination targets (Lakoh, et al. 2020).

3. RESEARCH QUESTION, AIMS, OBJECTIVES AND HYPOTHESIS

3.1 Aims

To know the determinants that have a high degree of impact on TB treatment outcomes. When concluded this study shall fill the gap in evidence by identifying the determinants of unsuccessful TB treatment outcomes in Bo district and by extension Sierra Leone.

3.2 Objective

This study aimed to identify the characteristics, unsuccessful TB treatment rate, and determinants of unsuccessful TB treatment outcomes among patients with TB using data from January 2018 to January 2022 from TB treatment centres in the Bo district of Sierra Leone.

3.3 Research Questions

a) What are the determinants of maximum impact on drug-sensitive pulmonary TB treatment outcomes in rural communities?

b) What are the ways to increase favourable drug-resistant pulmonary TB outcomes in rural areas?

3.4 Hypothesis testing

  Tackling the major determinants that impact drug-sensitive pulmonary TB treatments will yield a high, success rate of$\geq$ 90% irrespective of when the patient is found in society.

4. METHODOLOGY

4.1 Study Design

The study was a retrospective cohort study that assessed the degree of impact on the determinants of DS-PTB treatment outcomes in patients.

4.2 Study Population and Area

The study area was the catchment area of all TB treatment centres run by the Ministry of Health in the rural part of the Bo district of Southern Sierra Leone.

4.3 Sample Number and Subject Selection Methods

According to Statistics Sierra Leone (https://www.statistics.sl), the 2021 mid-term census states

that Bo district has a total population of 756,975 (males - 366,346 and Females - 390,629) which is about 10% of the national population. Of the total population of the district, the urban populations are 223,075 and the rural 533,900. The district has an estimated 2.36% annual population change between 2004 to 2021(https://www.statistics.sl).

 With the population at risk of 533,900 (rural population), the sample size collected on even numbers was 2,176 compiled at 8 rural TB treatment centres in the Bo district of Sierra Leone with at least 250 per centre. The actual sample size at a 99% confidence level and 3% margin of error would have been 1,836 instead of 2,176 (https://www.qualtrics.com/blog/calculating-sample-size/). Medical records from TB registers and patient files were evaluated for completeness and then entered the database.

4.4 Inclusion Criteria

Patients with even ID numbers commenced on treatment between 1st January 2018 and 1st January 2022 with clear outcomes (death, cured, completed treatment, lost to follow-up, treatment failure and transferred out).

4.5 Data Collection and Management

Data on demographics, socio-cultural, economic, clinical status, management, distance from facility, and outcome were collected and analyzed. In addition, patient files were reviewed to enable analysis of desired variables. Client/patient's available consultation cards/files at the designated treatment Centres were a good source of information. On completion, the data was entered into the computer database, cleaned and processed with the assistance of software was accomplished. Analyses of the data commenced immediately after generating the desired information needed to identify the principal determinants that impact DS-PTB treatment outcomes.

5. DATA, MANAGEMENT AND REPORTING

Cleaned-up aggregate data was collated and analyzed using software capable of doing so such as datatab.

5.1 Variable Abstraction

1. *Cured:* A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear or culture-negative in the last month of treatment and on at least one previous occasion.

2. *Treatment completed:* TB patient who completed treatment without evidence of failure, but

there was no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because they were not done or because results were not available.

3. *Treatment success:* The sum of cured and treatment completed.Died: A TB patient who dies for any reason before starting or during treatment.

4. *Treatment failed:* A TB patient whose sputum smear or culture is positive in the 5th month or later during treatment.

5. *Lost to follow-up:* A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.

6. *Transferred out:* This is the patient that was referred to another clinical unit for treatment and information on the outcome is not available.

7. *Not evaluated:* A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.

8. *Failure/unsuccessful treatment*: treatment failure, loss to follow-up, death and not being evaluated are considered unsuccessful TB treatment outcomes.

9. *Distance to facility in minutes:* Participants' residence to facility in minutes

10. *Gender:* Male or female

11. *Marital status:* Refers to married, single or widow

12. *Age*: <15yrs, ≥ 15yrs

13. *Literacy:* Patients above 15 years can read or write.

14. *Post-primary disease:* Occurs when the immune response is exaggerated, most commonly within two years after exposure.

15. *Primary disease:* MTB infection will often lead to a relatively mild self-limiting disease.

16. *Lifestyle:* Whether the participant takes alcohol or smokes cigarettes or none.

17. *Source of income:* Current occupation for income generation such as salary job, farming, mining or none of the listed.

18. *Number in household:* Number of people living under the same roof with participants and also

eating from the same pot.

19. *Death of family member from TB or lung diseases within 2 years:* refers to any death within the period that was diagnosed or suspected of being a pulmonary TB by a licensed health practitioner.

5.2 Quality Control

There were trainings and rehearsals facilitated before the team moved to the field for pilot testing of data collection after which the actual data collection started although it did not take long as the team had previously collected data in some of the facilities for TB study. The pilot test ensured better and uniform data collection among workers. Supportive supervision was continuous to the team to ensure quality data collection.

5.3 Bias and Confounding

To minimize data collection bias and confounding study data collection and collation staff retention and support/continuous training was ensured. Experienced data officers employed previously were contracted again as the variables on which data were collected were just added to the previous ones in a bid to reduce errors in data collection.

5.4 Ethical Considerations Records Retention and Confidentiality

Approval from the ethics and scientific research committee was received. Ministry of Health and Sanitation representative in the TB and Leprosy department at the district also consented before collecting as can be seen in the annex.

Data collection was void of variables that could identify individual patients. Data usage is restricted only for the purpose of the study and not for other uses. Any future use of the data will trigger a new consent or assent of authorization from the same ethical committee that gave the clearance. Even though the data was such that it cannot be used to identify individuals, password protection was even made for more security and this shall be maintained until the data is destroyed after work is done. Patients' unique IDs were used and not names in addition to other variables such as age, sex, geo-origin, type of outcome, etc.

## 5.5 Ethical Clearance of Protocol Number

The standard protocol number used to identify the study is the version of 29 May 2023 and SLESRC no: 019/06/2023 of ethical grants and scientific approval of the Sierra Leone Ethics and Scientific Committee of the Ministry of Health and Sanitation as clearance to go ahead with the study. Clearance was also granted for the research data collection by the programme

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manager of the National Leprosy and Tuberculosis Control Program as the requirement for approval by the Ethics and Scientific Committee approval.

6. RESULTS

Data was processed from the 2176 participants and the results were analyzed as seen in the results below.

Figure 1: The inter-rater reliability analysis graph dependent samples of exit code
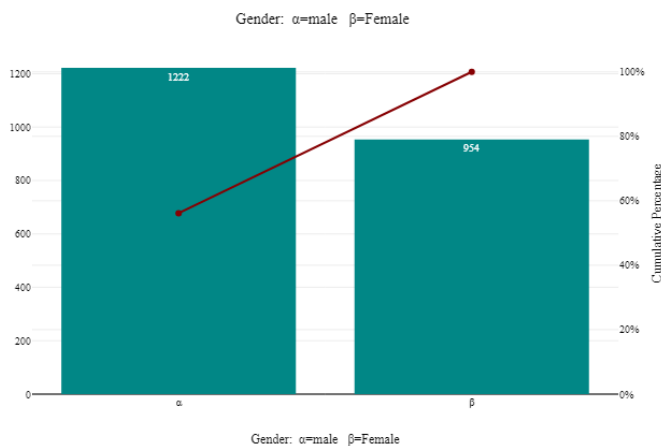
An inter-rater reliability analysis was performed between the dependent samples of exit code: α= cured, β= completed treatment γ= LTFP ε= died π= transferred out, ç=unknown information ψ=failure and marital status: α=married β=single γ=widow. For this purpose, Cohen's Kappa was calculated, which is a measure of the agreement between two dependent categorical samples. Cohen's Kappa showed that there was a slight agreement between samples; exit code and marital status with κ= 0.08. At the same time a Chi2 test was performed between marital status and exit which showed a statistically significant relationship between them, $\chi^2(8) = 94.04$, p = <0.001, Cramér's V = 0.15. The calculated p-value of <0.001 was lower than the defined significance level of 5%, that showed that Chi2 test is significant and therefore null hypothesis was rejected.

When Chi2 test was performed between literacy and exit there was no statistically significant relationship between the two, $\chi^2(4) = 4.11$, p = 0.391, Cramér's V = 0.04. Also, the calculated p-value of 0.391 is above the defined significance level of 5%. The Chi2 test is therefore not significant and the null hypothesis is not rejected. Similarly, when an inter-rater reliability analysis was performed between the dependent samples of exit code and literacy using Cohen's Kappa which showed no agreement between samples with κ= 0.

Logistic regression analysis was performed to examine the influence of gender: α=male β=female β, lifestyle: α=alcoholic β= cigarette smoker γ=none γ, lifestyle on variable exit code to predict the value "α". Logistic regression analysis showed that the model is not significant (Chi2(3) = 4.58, p 0.205, n = 2176).

Logistic regression analysis was performed to examine the influence of lifestyle: α=alcoholic β= cigarette smoker γ=none α and lifestyle: α=alcoholic β= cigarette smoker γ=none β on variable exit code: α= cured , β= completed treatment γ= LTFP ε= died π= transferred out, ç=unknown information ψ=failure to predict the value "α". Logistic regression analysis shows that the model is not significant (Chi2(2) = 4.03, p .133, n = 2176). The coefficient of the variable lifestyle: α=alcoholic β= cigarette smoker γ=none α is b = 0.12, which is positive. That implies if the value of the variable is lifestyle: α=alcoholic β= cigarette smoker γ=none α, the probability of the dependent variable being "α" increases. However, the p-value of 0.548 indicates that this influence is not statistically significant. The odds ratio of 1.13 means that if the variable is lifestyle: α=alcoholic β= cigarette smoker γ=none α, the probability that the dependent variable is "α" increases by 1.13 times. The coefficient of the variable lifestyle: α=alcoholic β= cigarette smoker γ=none β is b = 0.48, which is positive. However, the p-value of 0.063 indicates that this influence is not statistically significant. An inter-rater reliability analysis was performed between the dependent samples of exit code and lifestyle and for this purpose, Cohen's Kappa was calculated, which is a measure of the agreement between two dependent categorical samples. Cohen's Kappa showed that there was a slight agreement between samples exit code and lifestyle with κ= 0.01. The coefficient of the variable lifestyle: α=alcoholic β= cigarette smoker γ=none γ is b = -0.09, which is negative. This means that if the value of the variable is lifestyle: α=alcoholic β= cigarette smoker γ=none γ, the probability of the dependent variable being "α" decreases. However, the p-value of 0.682 indicates that this influence is not statistically significant. The odds ratio of 0.92 means that if the variable is lifestyle: α=alcoholic β= cigarette smoker γ=none γ, the probability that the dependent variable is "α" increases by 0.92 times. The coefficient of the variable lifestyle: α=alcoholic β= cigarette smoker γ=none β is b = 0.36, which is positive. However, the p-value of 0.258 indicates that this influence is not statistically significant.

The coefficient of the variable gender: α=male β=female β is b = -0.09, which is negative which means that if the value of the variable is gender, the probability of the dependent variable being "α" decreases. However, the p-value of 0.457 indicated that this influence is not statistically significant. The odds ratio of 0.91 means that if the variable is gender: α=male β=female β, the probability that the dependent variable is "α" increases by 0.91 times.

The Chi2 test performed between distance to facility in minutes: α=<30 β=>30 and exit: α= cured, β= completed treatment γ= LTFP ε= died π= transferred out, ç=unknown information ψ=failure. At least one of the expected cell frequencies were less than 5. The assumptions for the Chi2 test were not met. There was no statistically significant relationship between distance to facility in minutes and exit, $\chi^2(4) = 1.67$, $p = 0.796$, Cramér's V = 0.03. The p-value of 0.796 is above than the defined significance level of 5% and the Chi2 test is therefore not significant and the null hypothesis is not rejected.

A Chi2 test was performed between No. of rooms in the house: α=<3 β=>3 and exit : α= cured , β= completed treatment γ= LTFP ε= Died π= Transferred out, ç=Unknown information ψ=failure with one of the expected cell frequencies were less than 5. The assumptions for the Chi2 test were not met and there no statistically significant relationship between number of rooms in the house and exit code, $\chi^2(4) = 1.43$, $p = 0.839$, Cramér's V = 0.03. The calculated p-value of 0.839 is above than the defined significance level of 5%. The Chi2 test is therefore not significant and the null hypothesis is not rejected.

A Chi2 test was performed between source of income: α=salary β=subsistence farming γ=mining ε= none and exit code. Their frequencies were less than 5 and a statistically significant relationship between source of income and exit, $\chi^2(12) = 94.57$, $p = {<0.001}$, Cramér's V = 0.12. The calculated p-value of <0.001 is lower than the defined significance level of 5%. The Chi2 test is therefore significant and the null hypothesis is rejected.

A Chi2 test was performed between patient being family bread winner: α= Yes β= No and exit showing at least one of the expected cell frequencies were less than 5. That means that the assumptions for the Chi2 test were not met and was a statistically significant relationship between the two variables bread winner and exit code, $\chi^2(4) = 13.64$, $p = 0.009$, Cramér's V = 0.08, p-value of 0.009 was lower than the defined significance level of 5%. The Chi2 test is therefore significant and the null hypothesis is rejected. An inter-rater reliability analysis was performed between the dependent samples of exit and patient being the family bread winner: α= Yes β= No. For this purpose, Cohen's Kappa was calculated, which is a measure of the agreement between two dependent categorical samples. Cohen's Kappa showed that there was a slight agreement between samples exit patient as family bread winner with $\kappa = 0.02$.

A Chi2 test was performed between food security - meal/day: α=3m/d β= < 3m and exit. At least one of the expected cell frequencies were less than 5. There was a statistically significant relationship between food security and exit, $\chi^2(4) = 15.32$, $p = 0.004$, Cramér's V = 0.08. The calculated p-value of 0.004 is lower than the defined significance level of 5%. The Chi2 test is

therefore significant and the null hypothesis is rejected.

An inter-rater reliability analysis was performed between the dependent samples of exit and HIV status: α=negative β=positive. For this purpose, Cohen's Kappa was calculated, which is a measure of the agreement between two dependent categorical samples. Cohen's Kappa showed that there was a slight agreement between samples exit and HIV status with κ= 0. A Chi2 test was performed between HIV status and exit. At least one of the expected cell frequencies were less than 5. Therefore, the assumptions for the Chi2 test were not met. There was no statistically significant relationship between HIV status and exit, $\chi^2(4) = 1.66$, p = .797, Cramér's V = 0.03. The calculated p-value of .797 is above than the defined significance level of 5%. The Chi2 test is therefore not significant and the null hypothesis is not rejected.

A Chi2 test was performed between age: α= <15 yrs β= ≥15yrs and exit. At least one of the expected cell frequencies were less than 5. Therefore, the assumptions for the Chi2 test were not met. There was a statistically significant relationship between age and exit, $\chi^2(4) = 188.32$, p = <0.001, Cramér's V = 0.29. The calculated p-value of <0.001 is lower than the defined significance level of 5%. The Chi2 test is therefore significant and the null hypothesis is rejected.

Figure 2: A one-factor analysis of variance showing difference between the categorical variable exit and serial # F
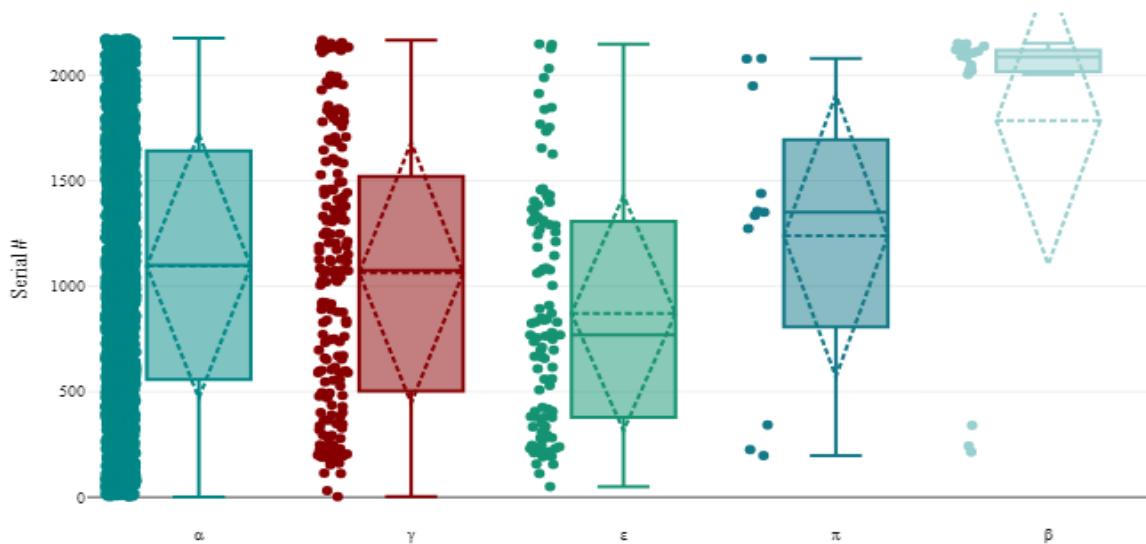
Exit code: α= cured , β= completed treatment γ= LTFP ε= Died π= Transferred out, ç=Unknown information ψ=failure

In an analysis of variance a one-factor analysis of variance has shown that there is a significant difference between the categorical variable exit: α= cured , β= completed treatment γ= LTFP ε= died π= transferred out, ç=unknown information ψ=failure and the serial # F = 9.11, p = <.001 Thus, with the available data, the null hypothesis is rejected. There is significant interaction between exit and lifestyle, and two-factor analysis of variance interaction is used for the further calculations.

**Table 1: Cohen's Kappa interrater reliability of exit**

Table 2: Effect size

η^2	η_p^2	Cohen's f^2
0.02	0.02	0.02

f	Classification according to Cohen (1988)
0.2	weak effect
0.15	moderate effect
0.35	strong effect

The post hoc Test of ANOVA showed that there was a significant difference. A Bonferroni Post hoc test was used to compare the groups in pairs to find out which was significantly different. The Bonferroni post-hoc test revealed that the pairwise group comparisons of α - ε, α - β, γ - β and ε - β have a p-value less than 0.05 and thus, based on the available data, it can be assumed that these groups are each significantly different pairwise.

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Figure 3: The one-factor analysis of marital status for treatment outcome
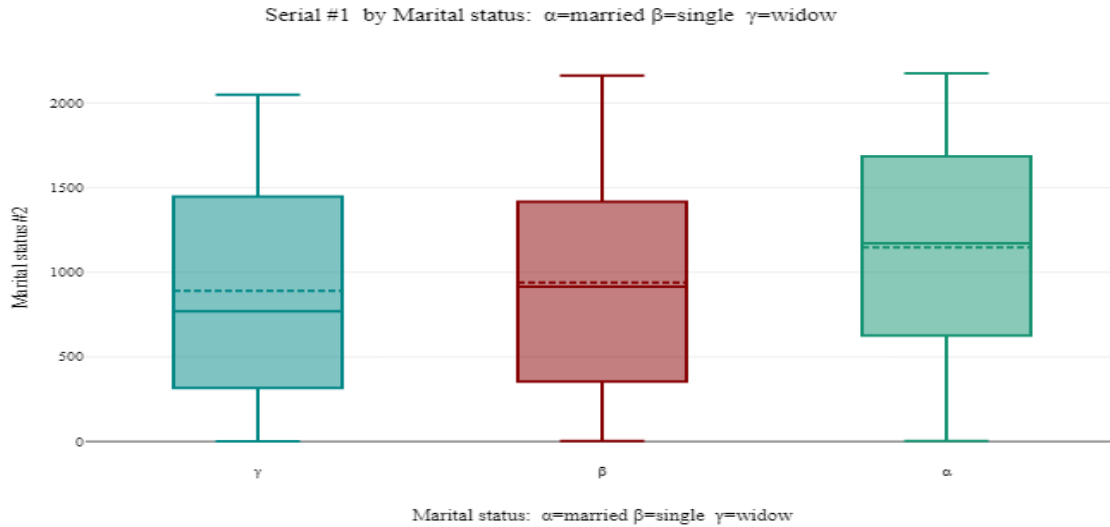
Serial #1 by Marital status: α=married β=single γ=widow

Marital status: α=married β=single γ=widow

A one-factor analysis of variance has shown that there is a significant difference between the categorical variable Marital status: α=married β=single γ=widow and the variable Serial # F = 25.74, p = <.001 Thus, with the available data, the null hypothesis is rejected.

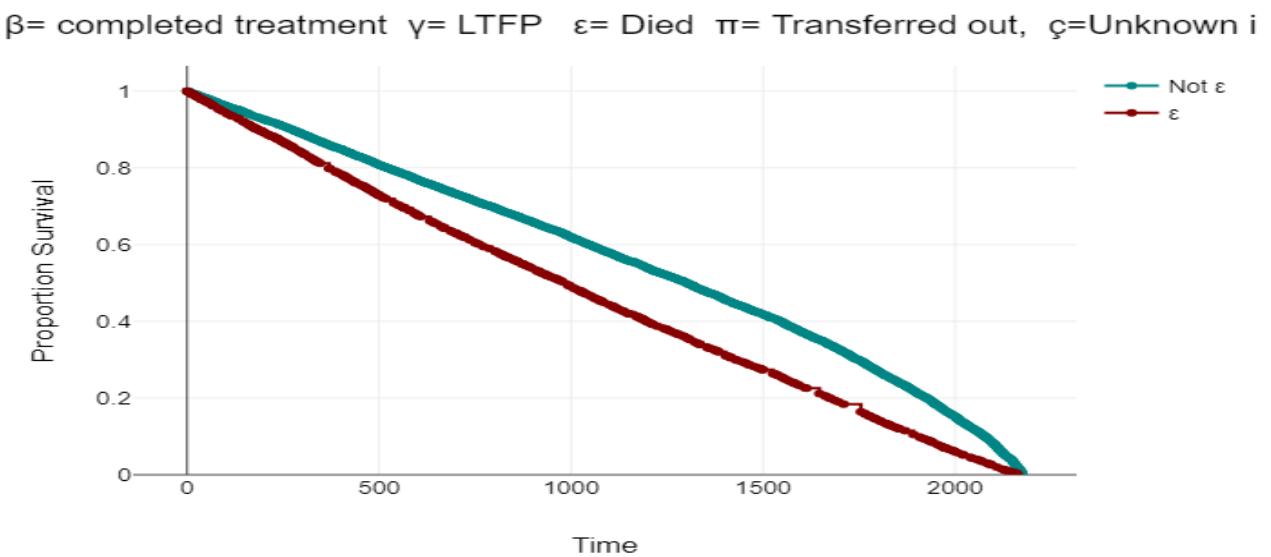**Fig 4: Survival Analysis of favorable and non-favorable outcomes**

β= completed treatment γ= LTFP ε= Died π= Transferred out, ç=Unknown i

Table 3: Size of individual treatment Outcomes.

Exit Code: A= Cured, B= Completed Treatment Γ= LTFP E= Died Π= Transferred Out, Ç=Unknown Information Ψ=Failure	Amount
α	1851
γ	190
ε	106
π	11
β	18

The effect size was measured using Post hoc test and ANOVA showed that there was a significant difference. A Bonferroni Post hoc test was used to compare the groups in pairs to find out which was significantly different. The Bonferroni post-hoc test revealed that the pairwise group comparisons of γ - α and β - α have a p-value less than 0.05 and thus, based on the available data, it can be assumed that these groups are each significantly different pairwise.

7.   DISCUSSION

In the study of 2176, the data reflected 56.16% (1222) of the recorded participants to be males and 43.84% (954) being females. The data even though lower is consistent with the data from many nations that the greater percentage of TB cases are females. In Sierra Leone too, the demographics of TB cases are like that of this study (Kangbai. 2013).

Of the 2176 participants, 95.04% (2068) were ≥15 years of age while the tiny 4.5% were below 14 years of age. Dong, et al. 2022 had similar results and explained that the young (20–24 years old) and the elderly (70–74 years old) were equally at high risk which could be some of the reasons why the low number of children affected by TB. According to the reliability analysis between exit and marital status showed a statistically significant relationship even though slight between the two like Adeyeye (2010) stated the effects of treatment outcome of the treatment of pulmonary

tuberculosis at the Lagos State University Teaching Hospital. Several factors which include age, gender, marital status, income as well and educational levels, influence the quality of life of patients with tuberculosis.

The reason is that if the male patient is married and likely the breadwinner, there is the probability of LTFP or even other unpleasant outcomes as he will prioritise finding food for the family over the illness except for the very sick. On the other hand, if the patient is female and there is no socio-economic support for patients in facilities, there may be a delay in decision-making by the breadwinner to let her go for medical care as he has to weigh the expenditure involved in getting the patient to the hospital versus food on the table for the rest of the family, especially in poor countries like Sierra Leone. Widows are even more severely impacted by the unfavourable outcomes due to either lack of care or bankruptcy.

There was no statistically significant relationship between literacy and the treatment outcome of treatment. It is likely because the facilities are community-owned and community health workers do a lot of health promotion and information, education and communication activities which is patient education which makes formal education a bit redundant. This cadre of workers in the Ministry of Health is responsible for mass drug distribution and is trusted by communities. Olayemi, et al. 2022 stated that the health information literacy of the respondents can be enhanced in order to have good treatment outcomes. The need for a high level of health information literacy to identify specific health information needs, access information sources and use information is never enough. In their study, Arif, et al. 2021, noted that empirical findings show that formal education and selection of treatment arm do not significantly affect the outcome of the cure. However, health literacy provided by the NTP plays a vital role in improving treatment outcomes.

There was also no significant relationship between treatment lifestyle and gender. This may be related to the fact that other than alcohol there is less addiction to other substances. It might also be related to the firm grip females have on the day-to-day activities of society. There are female chiefs who can stand for the weaklings so they will not take to substance abuse because of stress but choice which is not more than those of males.

According to Date & Okita. 2005, the illiterate patients had a longer diagnostic delay than literate patients ($P = 0.006$, univariate logistic regression analysis). They also maintained their traditional view of illness, not the illness 'TB'. More females than males completed treatment ($P = 0.046$, univariate logistic regression analysis). Supervision by male relatives contributed to the completion of treatment among female patients.

Cohen's Kappa analysis showed that there was a slight agreement between lifestyle and treatment

outcomes however, logistic regression analysis shows that the relationship between lifestyle and treatment outcome although not significant likely for the same reason just mentioned above. However, Gillani, et al. 2010 stated that of this, 250 (47.7%) were never smokers while ever-smoking TB patients accounted for 274 (52.3%), there were significant relationships between the smoking status of TB patients and outcomes, that smokers of TB patients were four times more likely to have slower smear conversion at two months compared to non-smoker tuberculosis patients.

There was also no statistically significant relationship between distance to facility in minutes and treatment outcomes. Robsky, et al. 2020, associated unfavourable treatment outcomes at a distance of >2Km to the treatment facility with have increased risk of death (aRR 1.42 [95%CI 0.99, 2.03]) but decreased risk for loss to follow-up (aRR 0.57 [95%CI 0.41, 0.78]) than those living within 2 km.

There is no statistically significant relationship between the number of rooms in the house and treatment outcome (regarding treatment outcome, 89% were cured and/or completed treatment (93% among prisoners vs 88% among the general population), 0.2% were treatment failures, 8% died (5% among prisoners vs 8% among the general population) and 3% were not evaluated (1% among prisoners vs 4% among the general population). Unsuccessful TB treatment outcomes were associated with age greater than 35 years (aOR = 0.68: 95% C.I: 0.58-0.80), Extra-Pulmonary TB (aOR = 1.69: 95% C.I: 1.08-2.63) and HIV positive status (aOR = 0.63: 95% C.I: 0.42-0.94).) (Singano, et al. 2020).

There was a statistically significant relationship between source of income and treatment outcome. We demonstrated that TB patients in Georgia with lower household incomes were at greater risk of poor TB treatment outcomes. Providing targeted social assistance to TB patients and their households may improve clinical response to anti-TB therapy (Djibouti, 2014).

There was a statistically significant relationship between the two variables breadwinner and treatment outcome. After six months of TB therapy, treatment outcome was available for 193 of 202 enrolled patients, of these 155 (80.3%) had a favorable TB treatment outcome. Compared to TB patients with poor treatment outcomes, those with favourable treatment outcomes were younger (median 33.0 vs. 42.5 years), reported higher household monthly income (median $137 USD vs. $85 USD), were less likely to be unemployed (38.7 vs. 47.4%), and had a higher level of education (38.7% vs. 31.6% with a college education or greater). In a multivariable analysis adjusted for age, sex, and socio-economic indicators, only low household income remained statistically significantly associated with poor TB treatment outcomes.

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The evidence available suggests that patients in low- and middle-income countries receiving cash during treatment for active pulmonary tuberculosis are more likely to have a positive clinical outcome. These findings support the incorporation of cash transfer interventions into social protection schemes within tuberculosis treatment programmes (Richterman, et al. 2018)

There was a statistically significant relationship between food security and treatment outcomes with a statistically significant relationship between age and treatment outcomes. Of 2209 patients included in the study, 133 (6%) were children (aged <10 years), 132 (6%) were adolescents (10-19 years), 1782 (81%) were adults (20-59 years) and 162 (7%) were aged ⩾60 years, defined as elderly. The highest proportion of smear-negative pulmonary TB cases was among the elderly (40%). Unfavourable outcomes, mainly deaths, increased proportionately with age and were highest among the elderly (adjusted relative risk 3.8, 95%CI 1.3-10.7). Having previous TB, being human immunodeficiency virus-positive and not on antiretroviral treatment or cotrimoxazole preventive therapy were associated with an increased risk of unfavourable outcomes (Ncube, et al. 2017)

We identified 28 studies with a comparator group for the impact assessment and added 19 non-comparative studies to a qualitative analysis of care delivery approaches. Approaches included strengthening capacity in primary-level facilities, providing services in communities, screening for tuberculosis in other health services, co-locating tuberculosis and human immunodeficiency virus treatment, offering a choice of treatment location and providing social or economic support. Strengthening both decentralized diagnostic services and community linkages led to one-to-sevenfold increases in case detection across nine studies and improved prevention outcomes. We identified only five comparative studies on integrated or family-centred care, but 11 non-comparative studies reported successful treatment outcomes for at least 71% of children and adolescents (Yuen, et al. 2022)

8. STUDY LIMITATIONS

1.   There were some of the LTFP cases that were not traced and was difficult to know if they really died in the program or were truly the former exit variable.

2.   Since even numbers were only used to include participants, patient exits might have been confounded with this.

3.   It is likely that some patients did not disclose their true lifestyle when information was been recorded from them because of cultural reasons, for example, women and cigarette smoking even though that will not significantly influence the population-level result.

4.   Since the analyses are done based on population-level figures there is a likelihood that the impact of other variables on exit for specific geographical locations will be masked by the large data.

9.   CONCLUSION

The major determinants that have a high degree of impact on the treatment outcome of TB are lack of economic support, poor health literacy, socio-cultural challenges such as decision-making in time, certain lifestyles, some marital status such as a widow or young married women who will be decided for, distance to treatment facility and the family breadwinner being the patient.

We suggest more support to community health workers and awareness-raising on the need to tailor their activities to special care for cases to increase favourable treatment outcomes such as health literacy training. There should also be an improvement of strategy to tailor the directly observed therapy approach for higher risk groups; establishment of a flexible referral scheme to handle technical and psychosocial problems, including alcoholism; and increased collaboration with the HIV/AIDS program.

We also suggest that health literacy should be introduced in formal education for the improvement of the health status nationwide. Lack of education does not hinder women from receiving TB diagnosis and treatment but the concept of traditional illness, causes a longer diagnostic delay among illiterate patients, and the role of male relatives positively influences treatment outcomes for female patients.

Distance from home residence to TB treatment facility is associated with an increased risk of death but decreased risk of loss to follow-up, those who seek care further from home may have advanced disease, but once enrolled may be more likely to remain in treatment. Therefore, facilities should be within the distance approved by WHO for peripheral healthcare.

Maximum prisons provide a stable population that can be easily monitored throughout the course of TB treatment. Good TB treatment outcomes which are comparable to the general population can be achieved among prisoners despite the challenging prison conditions. If the prison term ends before the completion of the treatment, the treating facility should ensure that the patient stays in the cohort until treatment is completed through socio-economic support.

Cigarette smoking is significantly linked with poor tuberculosis treatment outcomes and the patient can be continually educated on the dangers of smoking and benefits when there is abstinence until treatment is completed.

Older persons need better adapted TB management and more sensitive diagnostic tools, such as

the use of Ultra-cartridges in GeneXpert® MTB/RIF investigations. If the adult's respiratory muscles are too wasted to produce sputum, gastric lavage or stool can be used as both have similar sensitivity.

Strengthening decentralized services in facilities and communities can improve tuberculosis outcomes for patients.

Above all cash transfers to patients, supply of family dry food, abstinence from risky lifestyle, health literacy, bringing the healthcare closer to the population.

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