



Journal of Nursing

Revista de Enfermagem

UFPE On Line

ISSN: 1981-8963

ORIGINAL ARTICLE

ESTIMATING THE TIME OF ABANDONMENT OF PATIENTS IN TREATMENT OF TUBERCULOSIS

ESTIMAÇÃO DO TEMPO DE ABANDONO DE PACIENTES EM TRATAMENTO DA TUBERCULOSE ESTIMACIÓN DEL TIEMPO DE ABANDONO DE PACIENTES EN EL TRATAMIENTO DE LA TUBERCULOSIS

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ABSTRACT

Objective: verifying the determinant factors for patients in treatment of tuberculosis abandonment. **Method:** a quantitative and inductive study through secondary registration data. It was used the Information System of Reportable Diseases, Joao Pessoa, Paraiba, from January 2001 to December 2008. For descriptive analysis and estimation of the survival model it was used the software R. The study was approved by the Research Ethics Committee under No. 498/10. **Results:** the incidence of new cases was 88.3%. The average time for the start of treatment until the abandonment of patients with tuberculosis was of six months. **Conclusion:** the decision making process should be directed to the best fit model for the identification of individuals who will leave the treatment to direct the observed therapy. **Descriptors:** Treatment; Abandonment; Tuberculosis.

RESUMO

Objetivo: verificar os fatores determinantes do abandono dos pacientes em tratamento da tuberculose. **Método:** estudo quantitativo e indutivo por meio de dados cadastrais secundários. Foi utilizado o Sistema de Informação de Agravos de Notificação, de João Pessoa, Paraíba, no período entre janeiro de 2001 a dezembro de 2008. Para análise descritiva e estimação do modelo de sobrevivência foi utilizado o software R. O estudo teve o projeto aprovado pelo Comitê de Ética em Pesquisa sob nº 498/10. **Resultados:** a incidência de casos novos foi de 88,3%. O tempo médio do início do tratamento até o abandono de pacientes com Tuberculose foi de seis meses. **Conclusão:** a tomada de decisão deverá ser direcionada ao modelo de melhor adequação para identificação dos indivíduos que irão abandonar o tratamento para direcionar o tratamento supervisionado. **Descritores:** Tratamento; Abandono; Tuberculose.

RESUMEN

Objetivo: identificar los factores determinantes de la deserción de los pacientes en tratamiento para la tuberculosis. **Método:** estudio cuantitativo e inductivo a través de los datos de registro secundarios. Se utilizó el Sistema de Información de Enfermedades de Notificación Obligatoria, Joao Pessoa, Paraíba, en el período comprendido entre enero de 2001 a diciembre de 2008. Para el análisis descriptivo y la estimación del modelo de supervivencia se utilizó el software R. El estudio tuvo el proyecto aprobado por el Comité de Ética de Investigación, bajo el número 498/10. **Resultados:** la incidencia de nuevos casos fue de 88,3%. El tiempo medio fue de seis meses, desde el inicio del tratamiento hasta el abandono de los pacientes con tuberculosis. **Conclusión:** el proceso de toma de decisiones debe ser dirigido al modelo de mejor ajuste para la identificación de individuos que dejarán el tratamiento para dirigir la terapia observada. **Descriptor:** Tratamiento; Abandono; Tuberculosis.

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INTRODUCTION

Tuberculosis (TB) is an injury associated with conditions of poverty and inadequate health care, with an increase in indicators of morbidity and mortality in underdeveloped or developing countries where these conditions are unfavorable.

Brazil occupies the 19th place among the 22 countries that account for 80% of TB cases, and the 14th place when it comes to cases with positive bacilloscopy, and is responsible for 31% of all TB cases in Latin America.¹ In 2009, 73.395 cases were reported, with incidence of 46 and prevalence of 29 cases per 100,000 inhabitants, respectively. The cure rate reached 77% and the dropout rate was 9%.² Despite being curable, TB still causes death in 3,8% of cases diagnosed in Brazil. The biggest problem identified in the treatment of TB is the failure to comply with the therapy, considered one of the most serious problems related to the disease in the country.

According to the state secretary of Paraíba³, considering the year 2008, according to data from SINAN, the percentage of cure, abandonment and death were respectively 59,79%, 7,26% and 2,25%. In João Pessoa, the state capital, in 2009, 399 new cases were reported. Among whom there was 56% cure rate and 8,5% dropout. For positive pulmonary cases the dropout rate reached 11%.

These data represent a challenge for Brazil in the population available for basic, affordable, equitable and better services. Since the last decade, with the aim of expanding efforts to control the disease, the National Tuberculosis Control Programme (NTCP) is establishing measures that integrate the spheres of government, recommending to their effectiveness that coordination activities, planning and assessment be held at the municipal level.

It proposes the adoption of the Directly Observed Treatment Short-Course (DOTS) for increasing case detection by smear among respiratory symptoms; ensuring regular supply of drugs and a registration system and efficient information; and for ensuring the completion of therapy diagnosed by treatment directly observable.¹

The commitment to the promotion of social services has increased the visibility of TB as a public health problem, and funding to control it. The DOTS strategy was proposed in 1998, primarily for tuberculosis control in order to increase patient compliance, increase cure rates and reduce risk of transmission in the community. The Directly Observed Treatment

(DOTS) was officially adopted by the Ministry of Health in 1999, bringing together five pillars: political commitment to ensure TB control, diagnosis and tracking of cases, regular supply of drugs, and supervised treatment, feeding and analysis of base data for decision making.⁴

As database systems for health information were structured to acquire, organize and analyze data, and are used in several ways: for diagnosis of the health situation, evaluation of actions and the impact of public policies on the health status of population.⁵

Among healthcare information systems (SIS), the space available for the National Tuberculosis Control Programme in Brazil, as for other diseases is the Information System for Notifiable Diseases (SINAN), adapted municipalization, in order to process data of diseases and injuries nationwide, to analyze the morbidity profile, contributing to decision making, whether at the municipal, state or federal level.

The database SINAN-Information System for Notifiable Diseases contains data required for the calculation of operational and epidemiological indicators considered essential for the evaluation of the endemic and control actions, requiring periodic evaluation of the fields filled in reporting and monitoring to detect and correct key field evaluation.⁶

Each local health team is responsible for the systematic data supply of bank SINAN, enabling reporting for managers who have the knowledge and to disseminate the epidemiological situation. Hence, the importance of the quality of the data record in order to have good performance. Some of the key indicators in the evaluation of interventions are: percentage of cure, default, death, bankruptcy and transfer. These will guide the adoption of measures to be implemented from the epidemiological perspective.⁷

SINAN is the main data source of epidemiological information about TB in federal, state and municipal systems. Basic Operational Norms regulated by the Unified Health System (SUS NOB- 01/96 of 11.06.96 and NOAS - UHS Ordinance No. 95/GM/MS, of 01.26.2001) with definitions of the structure and operation of the system information with regular feeding of databases. Existing ordinances as standard on the 1882/GM of 18/12/1997 and 933 of 04.09.2000, is the suspension of Floor Care basically PAB, in the absence of information in the supply SINAN for two months consecutive.⁶

Among the goals of SINAN's to collect, transmit and disseminate data over a computer network, routinely generated by the Epidemiological Surveillance System of the three spheres of government, to support the research process and give subsidies to analyze the information of notifiable diseases, thus enabling quick search of information of cases.⁸ The set of actions to which information systems are equipped on the collection and processing of data flow and dissemination of a compulsory notification of national interest. In the case of tuberculosis, this case study in this research, the Ministerial Ordinance standards and manuals of rules and routines of SINAN must be met.

Abandonment of tuberculosis treatment should arouse the interest of professionals involved on health policy and health systems developed for a reality that has not yet been reached. There are several factors that influence non-adherence to treatment: improved symptoms, believing it is no longer sick; how the individual patient controls and articulates its body; demographic and socioeconomic variables (age, sex, race, occupation, marital status, income and education); interaction between doctors and patients; Patients who do not trust the health system or the physician; the effect of drugs and reactions to treatment.⁹

It will be relevant showing the paths and analyzing sociodemographic variables, as well as the type of treatment to which the individual has undergone, in order to recognizing which treatment would be appropriate for every individual in its phase of the disease.⁴ It is notorious the complexity of the fact that Brazilian population is, but specifically the Northeast region, the State of Paraíba. Persists the importance of the profile of patients who discontinue treatment because, even with the strategies and measures adopted, patients may continue to drop, the irregular use of the drug may occur allowing bacterial resistance, which emanate a major public health problem. From these statements aimed to:

- Checking the determinants of dropout by patients being treated for tuberculosis;
- Estimating the time of abandonment by patients on TB treatment.

METHOD

This is an observational, exploratory, descriptive and inferential research undergone with patients with tuberculosis reported in the database of the Notifiable Diseases Information System (SINAN), referring

to the city of João Pessoa, Paraíba, in the period from January 2001 to December 2008. Upon learning of errors and inconsistencies in this data source, screening was performed on the database (SINAN) aiming to qualify him to follow through with the subsequent analyzes, so that the end results offer plausible.

The database consisted of 5.164 observations; first duplicate records were removed and missing yielding 4.763 observations. These 4763 records a description was made of comorbidities considering the situation of foreclosure and abandonment healing, thus consolidating a total of 3405 records. After this first treatment and description of data in the study were only 2706 records containing the variables gender, age, race, education, type of treatment and foreclosure situation. And also because the choice of survival time is given in months, records of time spent in therapy less than 30 days were excluded, leaving only 2635 records to follow the analysis.

For purposes of analysis, the variables were redefined considering the needs of stratification. The age was set at: childhood, adolescence, adult and elder. The race was stratified into white, brown, and black, yellow, indigenous. The educational level was defined as illiterate, primary, secondary and higher education. The type of treatment was categorized into new case, relapse, and return after default and transfer.

The method of survival analysis is a statistical technique known as survival analysis used when trying to analyze a phenomenon in relation to a period of time, ie the time between an initial event in which a subject or has been used an object enters a particular state and a final event that modifies this state, thus describes dichotomous outcomes.¹⁰

In this research outcome is represented by the abandonment or cure of TB treatment. This time (dependent or response variable) was defined in months between notification of the grievance by SINAN and the abandonment of TB. Survival curves and median time to abandonment were estimated by the Kaplan-Meier (KM) method. Time in months until the abandonment, among the categories of each variable was compared using the log-rank test statistic.

Age, sex, race, educational level and type of treatment: the semi-parametric proportional hazards model of Cox for estimating rates and hazard ratios for the set of variables was used. Variables that reached a descriptive level of statistically significant p value ($<0,05$) were retained in the model. The

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evaluation of the assumption of proportional hazards for the Cox model was verified graphically from the analysis of Schoenfeld residuals and the overall fit of the model was verified from waste Martingale and deviance.

All information collected was entered into Excel and then transferred to the R software version 2.15.0,¹¹ where procedures of statistical analyzes of the data were performed. This study was approved by the Ethics Committee in Research of the University Hospital Lauro Wanderley - CEP / HULW No. 498/10, Cover No. 368.778, of the Federal University of Paraiba in 28th September, 2010.

RESULTS

The sample analyzed was of 2635 records of TB, where the majority was composed of

Table 1. Log-rank tests for equality testing of survival curves obtained for the variables considered in the study.

Variable	P-value
Gender	0,957
Age	0,008**
Race	0,979
Schooling	0,302
Treatment	0,0002**
**p<0,01	

To evaluate jointly the variables for the outcome of abandonment was used the parametric analysis of survival analysis. Initially, the probability distribution in a more appropriate for the study data from the use of statistical methods is found. In the survival curve method the points that came closest

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males (62,8), adults (75,1%), considering the brown race (59,4%), with schooling elementary school (41,7%) and treatment situation considered as a new case (87,0%).

The mean time to dropout was six months between the years 2001 to 2008, ie, up to six months at least 50% of patients had discontinued treatment for TB.

Aiming to evaluate which variables influence the abandonment of TB treatment was applied to Kapla-Meier test stratified for each variable of the study tested the hypothesis of equality of survival curves using the log-rank test, as shown in table 1.

was the straight log-normal; method still in the survival curve that is closer to the Kaplan-Meier estimator was also the curve of the log-normal distribution. Leaving for the analysis method that analyzes the linearity of the model, the model appears more upright is the log-normal (Figure 1).

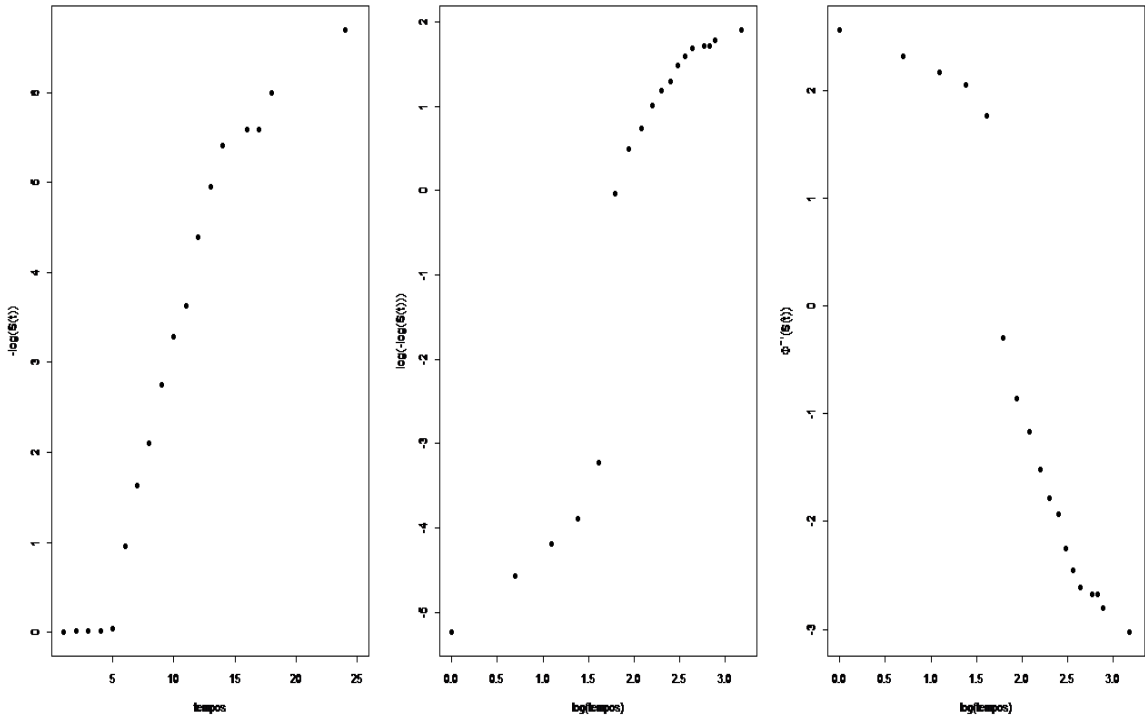


Figure 1. Linearized graphs for exponential models, Weibull and log-normal.

According to these results, one can observe that the log-normal distribution is the best suited to adjust the treatment time until the

abandonment of TB treatment. It was later verify which variables explain the variable outcome. In the final model were the only

variables that had the statistical significance level of 5%, as shown in Table 2.

Table 2. Estimates of the parameters and Wald test of the lognormal regression model adjusted to the data of the study.

Variable	Estimate	Wald test (p-value)
Intercept	1,87	0,000
Treatment 2	0,082	0,003**
Treatment 3	0,062	0,019*
Treatment 4	0,048	0,099

*p<0,05, **p<0,01.

From the graph of survivals of waste estimated by Kaplan-Meier and the lognormal model standard, as well as the chart of their respective survival curves estimated, it might be noted that the model was not well adjusted. From the Wald statistic to check the overall fit of the model, the p-value adjustment was significant (p-value <0.05), which tells us that this model was not appropriate.

The Cox regression model was used to measuring the effects of variables on the rate function fails or risks. A model with all categorical variables, however the 5% level of significance, it was noted that gender, race and education variables did not serve to explain the independent variable (p>0,05), being removed from the model was adjusted. Getting the final model only the variables age and treatment (Table 3).

Table 3. Result of the adjustment of the Cox regression model to the data.

Variable	P-VALUE	ODDS	IC (95%)	ODDS
Gender	0,948	-0,0028	[0,91; 1,08]	
Age	0,040*	-0,0827	[0,85; 0,99]	
Race	0,884	0,0022	[0,97; 1,03]	
Schooling	0,848	0,0033	[0,85; 0,99]	
Treatment	0,0005**	-0,1120	[0,83; 0,95]	

*p<0,05, **p<0,001.

Then proceeded with an initial assessment of the proportionality of risk variables in time through the construction of Kaplan-Meier curves stratified. And the assumption of

proportionality over time has been violated, since there was cross between the survival curves of the categories of variables (Figure 2).

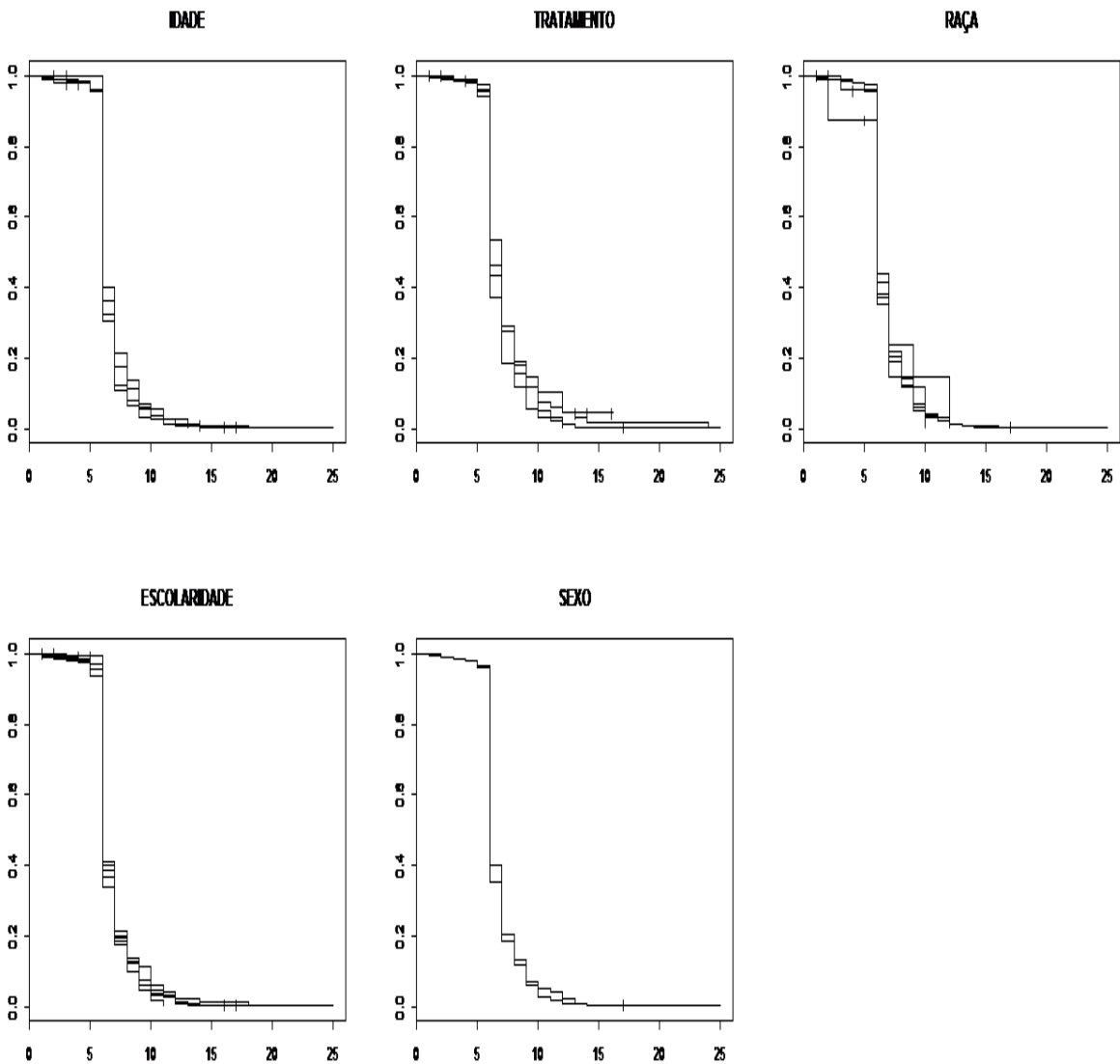


Figure 2. Assumption of risks are proportionate to the significant covariates using Kaplan-Meier's storied.

Even the graphical method showing that the proportional hazards were violated, the statistical proportionality test revealed that there is proportionality for the variables: age and treatment ($p > 0,05$).

Sequence was found in the overall fit of the fitted model from waste Martingale and deviance. It was found that waste Martingale suggest the existence of points that may be considered atypical (outlier), and the random behavior of Deviance around zero waste, provides evidence that the fitted model is appropriate to the data of this study, however checking the quality measure of adjustment for linear models, R^2 (6%), it was noted that the model very wrong.

DISCUSSION

Regarding sociodemographic data of this study, a study conducted in São Paulo-SP,¹² the male gender had 66% percentage, and average age of 39.1 years old. In a study conducted in Bage - RS,¹³ with males (74%), adulthood (55,8%), and education between 1-7 years of study with 62,6% percentage; another study,¹⁴ with findings that males predominate with 74,2%, and adult age group with 70%. When it comes to race in two studies¹³⁻⁴ the

predominance of white color with 63,4% and 80.7%, respectively, explaining that fact is both have been developed in the southern region, data that resemble the demographics of the region.

According to IBGE,¹⁵ data corroborate to the demographics of the city of João Pessoa, where most people belong to the brown race, followed by the white race. The predominance of male gender confirms the profile observed in other studies of TB, those are more exposed to associated factors such as drug abuse and alcoholism, so getting the lowest percentage for females, confirming that these commonly used health services especially programs targeting women's health.¹⁶

The low percentage in the range of childhood/adolescent confirms the findings, explained by greater care both from the services of the charge to children.¹⁷ The lower prevalence of occurrence of TB was elderly, with a percentage of 10,6%, despite this group presents natural physiological disadvantages of the aging process in relation to others. The aging process presents with morphological, functional, biochemical and psychological changes leading to increased vulnerability to

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disease processes, thus associated demographic transition which Brazil is going to increase in this vulnerable population, there has been increasing numbers of cases of tuberculosis.¹⁸

Explanations are mentioned as the percentage increase of the disease in young adults indicating occurrence of recent transmission, epidemiological pattern that differs from that found in countries where this disease under better control at this age and the elderly being the most affected as a result of past exposure, to deserve greater attention to this productive and working class, with greater representation of young adults affected by TB because when they turn away from work, or even die prematurely.¹⁷

In hospital and primary health in São Paulo, there was checked for 85% of new cases,¹² similar to the approximate percentage of new cases of the present study was 88,3%. This high percentage was found to be tuberculosis of the most prevalent diseases in the world and can affect all organs and systems, which are prevalent in developing countries where the population reaches with less access to environmental sanitation, health services and low level socioeconomic.

The National TB Control Programme aims to find 70% of cases, curing at least 85% of diagnosed cases, and keep the dropout percentage below 5%. These percentage rates confronted with the data reported from 2001 to 2008, he presented 59,3% cure and 12,2% of neglect, abandonment and is below the average of 12,9% appointed by the Ministry of Health in Brazil in 2001.¹⁷

To analyze the average time from start of treatment until the abandonment of patients with TB, we used the Kapla-Meier estimator that eliminates the need to assume that the censored observations occur uniformly during a break, if only assume that the censored observations future would have the same experience that those who are still observed.¹⁰

According to the Log-rank test, only the variables age and treatment were statistically significant for the time of abandonment in TB treatment, unlike what happened to the other study variables. TB affects individuals of working age, 60% of women represent aged 15-34 years old, while in males 53,41% are aged 25-44 years old. In females the infection is contracted in reproductive age, making them likely to become severely ill, as well as increased risk of HIV infection. The fact that involvement in productive age limits therapy, once they leave the treatment needs to return

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to work, but also reduce the side effects of drugs.¹⁹

Better results are expected in the supervised treatment strategy, because this way it is guaranteed to take the drug, and this improves the adhesion, reducing disease transmission and thus prevent the emergence of resistant strains.¹⁹⁻²⁰

CONCLUSION

The average time for abandonment of TB treatment was of 6 months and the various influencing this abandonment are age and treatment. A parametric analysis of survival contacted only to treatment situation with patients in relapse and readmission after abandonment were important to estimate the time of abandonment, however, after examining the model fit it was found that this misses a lot and cannot be taken decision as to promotion and prevention strategies to abandonment of TB treatment.

It is noteworthy that the inconsistencies of database records of SINAN constitute a difficulty for visualization of strategies, requiring precision and reliability update on the primary data, since they constitute an important tool for strategic decision of the intervention.

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Submission: 2014/06/09

Accepted: 2014/08/20

Publishing: 2014/12/01

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