

Factors predictive of adherence to tuberculosis treatment, Valle del Cauca, Colombia

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SUMMARY

BACKGROUND: Early diagnosis and treatment are fundamental to tuberculosis (TB) control. Nevertheless, the effectiveness of TB management continues to be influenced by treatment adherence.

OBJECTIVE: To determine which factors are predictive of adherence to TB treatment at the time of diagnosis in Colombia.

METHODS: A cohort of 300 patients newly diagnosed with TB was followed up over 26 weeks. Treatment adherence was measured by determining whether the patient took all or part of the 84 doses in the 26 weeks of treatment. A logistic analysis was carried out and the predictive power of the final variables was determined by means of a receiving operator curve analysis.

RESULT: A high incidence of partial completion of treatment (65.6%) was found. Significant associated factors were 1) living away from the family, 2) overcrowding at home (≥ 2 persons per bedroom), 3) lack of family support, 4) living > 10 min away from the treatment facility and 5) not having used the services of the treatment facility before.

CONCLUSION: Several factors can be measured on PTB diagnosis that would help identify those patients at higher risk for treatment non-adherence. The predictive value of each of these factors alone was weak, but if associated their predictive value was high.

KEY WORDS: pulmonary tuberculosis; treatment; adherence; predictors

PULMONARY TUBERCULOSIS (PTB) remains an important public health problem and a major cause of mortality in low-income countries.¹⁻³ Early diagnosis and treatment are fundamental to controlling tuberculosis (TB) transmission.³ The lack of adherence to TB treatment is one of the main factors determining its effectiveness, especially in low-income countries.⁴ Despite the introduction of short-course treatment in the 1990s,³ poor adherence to TB treatment has led to falls in cure rates, increased transmission in the population, a 5.6 times higher risk of acquiring multidrug resistance (MDR), increases in mortality⁵ and a 100-fold increase in the cost of treatment for a patient with MDR.⁶

The policies used to improve adherence to TB treatment in different regions of the world offer a number of alternatives for treatment administration and supervision. The results obtained with these alternatives have been variable and seem to depend on individual and community characteristics, the characteristics of the health services, the relationship between health provider and patient and the degree of transmission of the disease.⁷⁻¹²

Adherence, or completion of long-term treatment, is an aspect of individual behaviour that is determined by individual, interpersonal and environmental fac-

tors.¹³⁻¹⁵ Factors associated with treatment adherence include cultural, economic and socio-demographic factors, the type of relationship with the health services, the knowledge, attitudes and behaviour of the patient, the patient's family and the health care workers, the efficacy of the medications and adverse drug effects.^{5,15-18} As a result, factors that affect patient behaviour in a specific community should be kept in mind when attempting to strengthen treatment adherence. For example, the health services should be able to identify those persons at risk for non-adherence and should be flexible enough to be able to offer different alternatives for treatment administration and supervision according to their needs.

The aim of this study is to contribute to the search for effective alternatives for the administration and supervision of TB treatment in Colombia by determining individual, family and health service factors predictive of adherence to anti-tuberculosis treatment at the time of diagnosis.

METHODS

We studied a fixed cohort of 300 patients aged > 15 years with newly diagnosed PTB between September 2003 and November 2005 in the municipalities of

Cali, Buenaventura, Palmira and Tuluá in Valle del Cauca, Colombia. The diagnosis was based on sputum bacilloscopy following the criteria established by the Colombian Ministry of Social Protection (MPS) and in accordance with the recommendations of the World Health Organization (WHO).¹⁹

Standard TB treatment is given in two phases. During the initial phase, patients receive four drugs 6 days per week for 8 weeks (isoniazid [INH] 150 mg, rifampicin [RMP] 300 mg, pyrazinamide [PZA] 500 mg orally and streptomycin [SM] 1 g intramuscularly). During the continuation phase, patients receive two doses per week of INH 250 mg and RMP 300 mg for 18 weeks.

Patients were recruited into the study at 41 health care facilities that provide diagnosis and treatment for TB in the municipalities included in the study. The patients were interviewed about individual characteristics and those of their family and the health care services at the time of diagnosis and before initiating TB treatment. The face-to-face questionnaire used had previously been validated in a cognitive interview.²⁰ The application of the questionnaire was standardised by theoretical and practical training of the interviewers.

The independent variables studied are framed in the Integrated Mental Health (IMH) Information-Motivation-Behavioural skills model (Figure).¹⁴ The information variables measured patients' knowledge and beliefs about their illness and treatment. The motivation variables explored the perception of risk of disease, the importance of treatment adherence, the perception of the benefits of treatment, identification of barriers to attending the clinic for treatment, evaluation of the efficacy and self-efficacy in adhering to treatment and perceptions of social pressure to complete treatment. The behavioural skills variables assessed the existence of individual, familial and health care service factors that would facilitate treatment completion.

Follow-up was initiated for each patient at the start of treatment. Verification of treatment adherence was based on weekly review of the forms used to record the supervision of treatment and the patient's

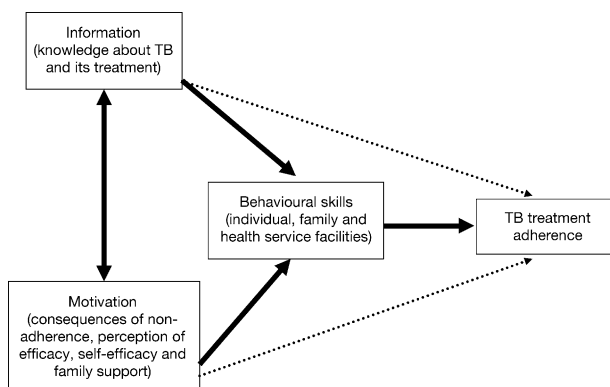


Figure Information-motivation-behavioural skills model for completion of TB treatment.

assiduity in attending for treatment. These standardised forms are filled out by National TB Programme (NTP) personnel. Adherence was evaluated by completion of treatment. The subjects studied were classified into two categories of treatment completion: full completion when the patients took all prescribed doses in 26 weeks, or partial completion when the patients did not take the drugs within the required treatment period.

Patients for whom partial completion was caused by transfer to a different health care facility, a change of address, hospitalisation or surgery, an illness other than TB or death were excluded from the study.

Ethical considerations

The objectives and procedures of the study were explained to all patients, and informed consent was obtained for their participation in the study. The study was evaluated by two institutional review committees of the Fundación FES Social and the Comité de ética de Comfenalco EPS Valle del Cauca. Both classified the study as at lower than minimal risk, according to national and international standards.²¹

Analysis

Correlations were established between treatment adherence and the information, motivation and behavioural skills variables through logistic analysis.²² Once the factors related to treatment completion were identified, the capacity to predict partial completion was examined using receiver operating characteristic (ROC) analysis.²³

RESULTS

Of the 300 patients studied, 12 (4%) died before finishing treatment and 18 (6%) were lost to follow-up. Of the 270 subjects followed up, only 104 (38.5%) completed treatment. The median age was 34.5 years (95% confidence interval [CI] 30–39, range 15–84). The majority of the patients were men, mestizos and single, with a low level of education and low income (Table 1). The majority of the study subjects lived with their families, reported good relationships with their children and other relatives and expected family support in case of disease. The results show that the majority of the patients considered that the treatment schedule was adequate. Most of them did not consume alcohol or other psychoactive substances. The majority of the patients knew that TB was curable but did not know how it was transmitted, reported being satisfied with their health care and knew how long the treatment took, and approximately 50% of the patients took 10 min to reach the clinic where they received treatment (Table 2).

Patient age, type of coverage by the health care system, contact with and perception of relationship with relatives and the nature of family support expected by the patient were variables associated with poor

Table 1 Socio-demographic characteristics of study subjects, Valle del Cauca, Colombia

Characteristic	n (%)
Sex	
Male	170 (56.7)
Female	130 (43.3)
Ethnicity	
Mestizo	135 (45.0)
Indigenous	13 (4.3)
Black	109 (36.3)
White	43 (14.3)
Marital status	
Single	129 (43.0)
Married	42 (14.0)
Common-law union	83 (27.7)
Separated/divorced	34 (11.3)
Widowed	12 (4.0)
Formal education, years	
None	19 (6.3)
≤3	61 (20.3)
4–5	74 (24.7)
6–10	72 (24.0)
>10	74 (24.7)
Occupation	
Home	78 (26.0)
Work	102 (34.0)
Home/work/study	38 (12.7)
Unemployed	82 (27.3)
Monthly wage (minimum)*	
<1	94 (31.3)
1–2	22 (7.3)
2–3	5 (1.7)
>3	2 (0.7)
Not reported	177 (59.0)
Type of health coverage [†]	
Contributor	56 (18.7)
Subsidised	105 (35.0)
Non-affiliated	139 (46.3)

* <1 = <US\$217; 1–2 = US\$218–434; 2–3 = US\$435–651; >3 = >US\$652.

[†] Contributor: a registered worker who pays into the public health system. Subsidised: poor population whose health system affiliation is subsidised by health system resources. Non-affiliated: poor population not covered by health system resources, and health care is provided by public health institutions.

adherence, as were previous use of services at the clinic, the consumption of alcohol and other substances, and having planned to work, study or travel before receiving the diagnosis (Table 3). The association of each of these variables with partial completion of treatment was adjusted for other variables with a statistically significant association (between 0.06 and 0.25) by means of a multiple logistic analysis using the backward stepwise method (Table 4).

According to the multiple logistic model obtained, age was the only socio-demographic variable that helped to predict partial completion of treatment. Family variables that helped predict the risk of partial completion were living with family, number of persons sharing a bedroom and type of family support. With regard to the health care services, variables predictive of the risk of partial completion were the time taken to travel to the clinic and whether the patient had previously used the services of the clinic. The perception of the type of relationship with their children, alcohol consumption in the last 30 days and having

Table 2 Frequency of individual, family and health service variables in the study population, Valle del Cauca, Colombia

Variable	n (%)
Lives with relatives	
Yes	262 (87.3)
No	38 (12.7)
Poor/average relationship with children*	
Yes	27 (13.0)
No	180 (87.0)
Persons sharing bedroom	
<2	134 (49.6)
≥2	136 (50.4)
Expects family support	
Yes	274 (91.3)
No	26 (8.7)
Previous use of services in the health facility [†]	
Yes	126 (41.8)
No	174 (58.2)
Believes treatment schedule is adequate [‡]	
Yes	291 (97.0)
No	9 (3.0)
Consumes alcohol [§]	
Yes	70 (23.3)
No	230 (76.7)
Consumes psychoactive substances [¶]	
Yes	72 (24.0)
No	228 (76.0)
Believes TB is curable	
Yes	274 (91.3)
No	26 (8.7)
Had study/work/travel plans before diagnosis	
Yes	265 (88.3)
No	35 (11.7)
Has children and lives with them	
Yes	157 (52.3)
No	143 (47.7)
Good relationship with family	
Yes	243 (81)
No	57 (19)
Family income less than minimum wage	
Yes	192 (64.0)
No	108 (36.0)
Expects full family support [#]	
Yes	102 (34.0)
No	198 (66.0)
Satisfaction with health care ^{**}	
Good	280 (93.3)
Average/poor	20 (6.7)
Wishes to receive treatment at home	
Yes	128 (42.7)
No	172 (57.3)
Smokes tobacco ^{¶¶}	
Yes	161 (53.7)
No	139 (46.3)
Knows how TB is transmitted	
Yes	65 (21.7)
No	235 (78.3)
Knows duration of treatment	
Yes	228 (76.0)
No	72 (24.0)
Time to reach health care facility, min	
≤10	137 (50.7)
>10	133 (49.3)

* Of the 207 with children.

[†] Before current episode.

[‡] The schedule set by the facility allows the patient to receive treatment.

[§] In last 30 days.

[¶] In his/her lifetime.

[#] Of the 274 who expected family support. Full family support = economic, emotional and nutritional.

^{**} Including current episode.

Table 3 Relationship between treatment completion and individual, family and health service variables, Valle del Cauca, Colombia

Variables*	Crude OR (95%CI)	P value
Occupation		
Home	1	
Work/home/study	1.72 (0.96–3.11)	0.07
Unemployed/retired	1.81 (0.92–3.58)	0.09
Age, years		
>50	1	
≤50	2.50 (1.39–4.51)	0.02
Type of health system coverage†		
Contributor	1	
Subsidised	2.69 (1.34–5.39)	0.005
Not affiliated	3.14 (1.60–6.15)	0.001
Has children and lives with them		
Yes	1	
No	1.99 (1.21–3.28)	0.007
Perceived relationship with children		
Good	1	
Average/poor	4.03 (1.31–12.30)	0.014
Patient lives with family		
Yes	1	
No	5.74 (1.96–16.78)	0.001
Persons sharing bedroom		
<2	1	
≥2	2.62 (1.61–4.44)	0.000
Perceived relationship with relatives		
Good	1	
Average/poor	2.96 (1.45–6.04)	0.003
Type of family support expected		
Full‡	1	
Partial/no support	2.50 (1.48–4.23)	0.001
Time required to reach TB clinic, min		
≤10	1	
>10	1.48 (0.90–2.42)	0.120
Previous use of services in the health facility		
Yes	1	
No	1.78 (1.08–2.93)	0.024
Previously received treatment for ≥2 weeks		
Yes	1	
No	2.06 (1.18–3.57)	0.011
Consumption of alcohol in last 30 days		
No	1	
Yes	2.37 (1.27–4.44)	0.007
Consumption of psychoactive substances		
No	1	
Yes	2.62 (1.36–5.04)	0.004
Planned to study/work/travel before diagnosis		
No	1	
Yes	2.46 (1.15–5.27)	0.020
Sex		
Female	1	
Male	1.51 (0.92–2.48)	0.099

* Only variables with $P < 0.25$ on bivariate analysis are presented.

† Contributor: registered worker who pays into the public health system. Subsidised: poor population whose health coverage is subsidised by the health system. Non-affiliated: poor population not covered by health system resources; health care is provided by public health institutions.

‡ Full family support = economic, emotional and nutritional. OR = odds ratio; CI = confidence interval; TB = tuberculosis.

Table 4 Crude and adjusted associations between completion of treatment and individual, family and health service variables, Valle del Cauca, Colombia

Variable	Crude OR (95%CI)	Adjusted OR (95%CI)	P value
Age, years			
>50	1		
≤50	2.50 (1.39–4.51)	2.46 (1.00–6.06)	0.049
Perceived nature of relationship with children			
Good	1		
Average/poor	4.03 (1.31–12.30)	3.26 (0.78–13.62)	0.105
Patient lives with family			
Yes	1		
No	5.74 (1.96–16.78)	16.01 (2.60–98.66)	0.003
Persons sharing bedroom			
<2	1		
≥2	2.67 (1.61–4.44)	3.86 (1.79–8.53)	0.001
Type of family support expected by patient			
Full*	1		
Partial/no support	2.50 (1.48–4.23)	3.41 (1.56–7.47)	0.002
Time taken to reach clinic, min			
≤10	1		
>10	1.48 (0.90–2.42)	2.70 (1.25–5.84)	0.012
Previous use of clinic services			
Yes	1		
No	1.78 (0.90–2.42)	2.46 (1.16–5.22)	0.019
Alcohol consumption in last 30 days			
No	1		
Yes	2.37 (1.27–4.44)	2.42 (0.96–6.10)	0.061
Had study/work/travel plans before diagnosis			
No	1		
Yes	2.46 (1.15–5.27)	2.53 (0.78–8.26)	0.124

* Full family support = economic, emotional and nutritional. OR = odds ratio; CI = confidence interval.

planned to travel, study or work before receiving the diagnosis were not significantly associated with adherence, but helped in predicting the individual's adherence to treatment.

Among the final variables, no modification of effects was shown and the final adjusted model was acceptable (Hosmer-Lemeshow test 61.76, $P = 0.9815$).

ROC analysis

There was a high probability of 0.8452 (84.5%) of partial completion of TB treatment when a patient presented with all of the following criteria: age ≤50 years, average or poor relationship with his/her children, not living with family, sharing a bedroom with ≥2 other people, belief that only partial support would be provided by his/her family, more than 10 min needed to reach the clinic, no previous use of the clinic's services, consumption of alcohol in the last 30 days and

Table 5 Capacity of variables studied to predict tuberculosis treatment adherence, Valle del Cauca, Colombia

	Age ≤50 years	Average/ poor relation- ship with children	Does not live with family	≥2 persons sharing bedroom	Expects partial family support	>10 min from clinic	No previous use of clinic services	No alcohol consump- tion in last 30 days	Had plans to work/ study/ travel before diagnosis	Model without variable
Age ≤50 years		0.6517	0.6496	0.6474	0.6372	0.6074	0.6116	0.6161	0.5925	0.8423
Relationship with children perceived as average/poor			0.6131	0.6691	0.6712	0.6265	0.6305	0.6299	0.6138	0.7854
Does not live with family				0.6793	0.6379	0.6118	0.631	0.6425	0.6124	0.8228
≥2 persons sharing bedroom					0.6648	0.6451	0.6558	0.6512	0.64	0.8070
Expects partial family support						0.6247	0.6436	0.636	0.6207	0.8464
>10 min to reach clinic							0.5945	0.6025	0.594	0.8337
Has not used clinic services before								0.6191	0.5839	0.8131
No alcohol consumption in last 30 days									0.5992	0.8205
Had plans to work/study/travel before diagnosis										0.8266

plans to travel, study or work before receiving the diagnosis. Alone, these variables have a low predictive capacity of partial treatment completion. However, if the individual presents more than one of these variables, the predictive capacity increases (Table 5). We observed that the probability of partial completion was respectively <50%, 50–75%, and 75–84.5% if the patient presented none of these variables, 1–6, and 7–9 variables.

DISCUSSION

Several family, individual and health service variables can be used to predict treatment adherence. As these variables are present before patients start treatment, they may be used to identify patients at higher risk for poor adherence before the start of TB treatment. The identification of individuals at greater risk of poor adherence before initiating treatment offers clinics the possibility of adopting measures and training health personnel in new tools to reduce this risk. Furthermore, this strategy would facilitate studies designed to evaluate alternatives for provision of treatment to individuals at high risk of poor adherence.

The majority of the variables related to treatment adherence in this study are difficult to influence from a public health stand point. Their utility is therefore based on their predictive value and not on the design and content of an intervention designed to change these factors.

The half-life of the first-line drugs used in TB treatment in Colombia does not exceed 30 h,^{24,25} making the minimum inhibitory concentrations of the drugs even shorter. Consequently, the definitions of adherence based on default from treatment for several weeks can accept as correct that there has been no pharmaceutical action on the tubercle bacillus for long periods. Treatment completion as defined in this study would allow us to determine if a regimen was not cor-

rectly administered before the patient defaulted, and would therefore be a good indicator for measuring adherence. Treatment completion would also be a more sensitive indicator of adherence, as it detects those situations where patients have not taken drugs for a period that exceeds the half-life of these drugs.

Although the variables associated with treatment non-adherence in this study have already been identified in other settings,^{5,15–18,26} the significance of their association, their relative importance and the predictive value of these factors is different. These differences could be explained by the different contexts in which the studies have been conducted, differences in the definitions of adherence¹⁵ and because different techniques were used to measure the variables studied.^{27–29}

The general lack of knowledge about the transmission mechanisms of the disease in almost all study subjects and the almost general expectation of a good treatment prognosis may be the reason why none of the factors related to individual knowledge about TB were associated with treatment completion.

Regarding patient motivation to complete treatment, the majority of the subjects were positive about the possibility of cure with the treatment they were receiving and had good family support. This may be why variables such as living with the family, number of persons per bedroom, nature of family support, time required to reach the clinic and previous use of the health care services of the clinic were associated with completion.

The relationship between health care provider and patient was not extensively evaluated during follow-up. We only investigated the perception of care when the patient had previously used the services of the facility, and thus this study could not assess the potential effects of health care provider-patient interaction. Similarly, the potential effects of patients' psychological characteristics on adherence were not evaluated.

With regard to the behavioural skills, the majority of

the subjects studied could rely on family support and mechanisms of self-efficacy, as few reported that they would not receive support or that they consumed alcohol or psychoactive drugs. The homogeneity of the frequency of these variables in relation to the behavioural skills in the study population therefore showed that there was no significant association with treatment completion. As a result, the effect of changes in family support during treatment was not evaluated.

The predictive capacity of partial treatment completion found with this model is higher than that reported elsewhere.^{15,30,31}

CONCLUSIONS

In the population studied, the definition of adherence used and supported in the IMH model sheds light on the understanding and prediction of adherence to TB treatment. The study findings suggest that motivational factors appear to have a greater impact on treatment completion, and that any public health intervention to improve adherence should target patient motivation.

Given the usefulness of the predictive capacity of the logistic model, it should be applied in the application of both health services and operational research. In the health services it could be used to identify patients at high risk of non-adherence at diagnosis, and offer alternatives for administering and supervising TB treatment. In operational research, it would also facilitate the selection of populations at high risk of non-adherence to study alternative methods of applying TB treatment.

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R É S U M É

CADRE : Un diagnostic précoce et un traitement adéquat sont les axes fondamentaux de la lutte contre la tuberculose. Néanmoins, l'efficacité de la prise en charge de la tuberculose continue à être influencée par l'adhésion au traitement.

OBJECTIFS : Déterminer quels sont les facteurs permettant au moment du diagnostic de prédire l'adhésion au traitement de la tuberculose pulmonaire.

SCHEMA : On a suivi pendant 26 semaines une cohorte de 300 patients chez qui le diagnostic de tuberculose pulmonaire avait été porté pour la première fois. L'adhésion au traitement a été mesurée en déterminant l'achèvement total ou partiel des 84 doses du traitement de 26 semaines en Colombie. On a mené une analyse logistique et déterminé la valeur prédictive des variables finales au moyen d'une analyse de la courbe des opérateurs.

RÉSULTATS : L'achèvement incomplet du traitement est très fréquente (65,6%). Les facteurs qui y sont associés sont 1) le fait de vivre en dehors de la famille, 2) la surpopulation des habitations (≥ 2 personnes par dortoir), 3) le manque de soutien familial, 4) un habitat à plus de 10 minutes d'une institution de traitement et 5) le fait de n'avoir pas utilisé antérieurement les services de l'institution de traitement.

CONCLUSION : Plusieurs facteurs peuvent être mesurés au moment du diagnostic de la tuberculose pulmonaire et pourraient aider à déceler les patients à risque plus élevé de non-adhésion au traitement. La valeur prédictive de chacun de ces facteurs seuls était faible, mais lorsqu'ils étaient associés la valeur prédictive était élevée.

R E S U M E N

INTRODUCCIÓN : El diagnóstico temprano y el tratamiento oportuno son los ejes fundamentales para controlar la tuberculosis (TB). Sin embargo, la efectividad del tratamiento continua siendo influenciada por la adherencia al mismo.

OBJETIVO : Determinar cuales factores presentes al momento del diagnóstico tienen capacidad para predecir la adherencia al tratamiento antituberculoso.

DISEÑO : Se siguió una cohorte de 300 pacientes con diagnóstico de TB pulmonar de primera vez durante 26 semanas. La adherencia se midió determinando el cumplimiento total o parcial de las 84 dosis en las 26 semanas que dura el tratamiento en Colombia. Se realizó un análisis logístico y se determinó el poder predictivo de las variables finales, mediante un análisis de la curva del operador característico.

RÉSULTADOS : Se encontró una alta incidencia de cumplimiento parcial al tratamiento antituberculoso (65,6%). Los factores asociados significativamente con esta incidencia fueron 1) no convivir con la familia, 2) vivir en un hogar que aloja 2 o más personas por dormitorio, 3) tener apoyo familiar deficiente, 4) tardar >10 min en llegar a la institución y 5) no haber usado previamente los servicios de la institución.

CONCLUSIONES : Existen varios factores que pueden ser medidos al momento del diagnóstico de la TB pulmonar que ayudan a identificar los pacientes con mayor riesgo de no-adherencia al tratamiento. La capacidad predictiva aislada de cada variable asociada fue baja, pero su capacidad predictiva conjunta fue alta.