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Cross-cultural adaptation of the instrument "tool to estimate patient's costs" in priority municipalities of Brazil in tuberculosis control

Adaptação transcultural do instrumento "tool to estimate patient's costs" em municípios prioritários do Brasil no controle da tuberculose

Adaptación transcultural de la herramienta "tool to estimate patient's costs" en municipios prioritarios de Brasil en el control de la tuberculosis

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Abstract

Introduction: Tuberculosis is historically associated with poverty, generating costs that can influence treatment. Considering the impact of the costs of illness, the importance of adapting the instrument is highlighted. **Objective:** To adapt transculturally to Brazilian Portuguese the instrument Tool to Estimate Patient's Costs. **Methods:** Study of the type transcultural adaptation of instrument. The translation followed the criteria described by Herdman, 1998, in order to preserve functional equivalence as much as possible. The questionnaire with cross-cultural adaptation was applied to 77 patients, with at least one full month of treatment for the disease. **Results:** Instrument was shown with Cronbach Alpha above 0.71 constituting a good tool for measuring the costs of the disease, being necessary modifications. **Conclusions:** This study suggests the creation of an instrument adapted for the treatment of TB in Brazil, for the evaluation of costs with the illness by tuberculosis.

Keywords: Cross-cultural Adaptation; Tuberculosis; Cronabach's Alpha; Direct Costs; Indirect Costs.

Resumo

Introdução: A tuberculose é historicamente associada à pobreza, gerando despesas que podem influenciar no tratamento. Considerando o impacto dos custos do adoecimento, destaca-se a importância da adaptação do instrumento. **Objetivo:** Adaptar transculturalmente para o português brasileiro o instrumento "*Tool to Estimate Patient's Costs*". **Métodos:** Estudo do tipo adaptação transcultural de instrumento. A tradução seguiu os critérios descritos por Herdman (1998), de forma a preservar ao máximo a equivalência funcional. O questionário, com adaptação transcultural, foi aplicado em 77 pacientes, com pelo menos um mês completo de tratamento para a doença. **Resultados:** Instrumento mostrou-se com alfa de Cronbach acima de 0,71, constituindo-se em uma boa ferramenta para mensuração dos custos da doença, sendo necessárias modificações. **Conclusões:** Este estudo sugere a criação de um instrumento adaptado para o tratamento da TB no Brasil, para avaliação dos custos com o adoecimento por tuberculose.

Palavras-chave: Adaptação Transcultural; Alfa de Cronbach; Tuberculose; Custos Diretos; Custos Indiretos.

Resumen

Introducción: La tuberculosis está históricamente asociada con la pobreza, generando costes que pueden influir en el tratamiento. Considerando el impacto de estas cuantías de la enfermedad, se destaca la importancia de la adaptación del instrumento. **Objetivo:** Adaptar transculturalmente al portugués brasileño la herramienta "Tool to Estimate Patient's Costs". **Métodos:** Estudio del tipo adaptación transcultural del instrumento. La traducción siguió los criterios descritos por Herdman (1998), para preservar al máximo la equivalencia funcional. El cuestionario, con adaptación transcultural, fue aplicado en 77 pacientes, con al menos un mes completo de tratamiento para la enfermedad. **Resultados:** El instrumento presentó resultado de 0,71 con el alfa de Cronbach, constituyéndose en una buena herramienta para medir los costes de la enfermedad, siendo necesarias modificaciones. **Conclusiones:** Este estudio sugiere la creación de un instrumento adaptado para el tratamiento de la TB en Brasil, para la evaluación de los costes con la enfermedad por tuberculosis.

Palabras clave: Adaptación Transcultural; Alfa de Cronbach; Tuberculosis; Costos Directos; Costos Indirectos.

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INTRODUCTION

Tuberculosis (TB) is historically associated with poverty[1-5] and, although it is a neglected disease, it represents a major global public health problem with deep social roots.[6] The World Bank estimates that there are approximately 1.2 billion people in the world living with less than US$ 1 a day. Globally, low or middle-income countries (gross national product per capita less than US$ 2.995) account for more than 90% of TB cases and deaths, with 76% of the world's population living in these countries.[7]

Thus, poverty not only leads to vulnerability to TB infection and disease development, but also represents extensive economic barriers to access to health services. This generates costs that negatively influence the treatment of TB contributing to its resurgence.[8-11]

Considering the impact of sickness costs on the treatment of the disease, the need to estimate them in their entirety in a unified way, with information that subsidizes interventions in reducing their link with poverty, in 2008, the KNCV Tuberculosis Foundation, the World Health Organization (WHO) and the Japan Anti-Tuberculosis Association developed the "Tool to Estimate Patients' Costs" questionnaire, an instrument that assesses the costs of TB treatment to patients and their families. This questionnaire allows identifying the types of costs and their magnitude, classifying them as direct and indirect, taking into account specific costs such as: food, transportation, accommodation, medication, fees and hospitalization.[12,9]

In 2008, Aspler and colleagues conducted a study in Lusaka, Zambia, on the costs of diagnosis and assistance for 103 patients between the first and third month of treatment. The costs of treating the disease for the first two months of treatment were US$ 24.78 per patient, representing 47.8% of their average monthly income.[13] This type of study in Brazil, however, has not yet been performed with the use of this questionnaire, in addition to the fact that there is no evidence base on these specific expenditures, which assists in planning interventions related to illness, tuberculosis, patients and their family members, and that allows to prepare a situational diagnosis, as well as advances and effective strategies to combat the transmission of the disease.

For the use of original instruments from other cultures, however, its translation and suitability for the local particularities where it is proposed to apply the research tool should be carried out. This process is called cross-cultural adaptation (CCA) and aims to ensure consistency in content between the original and translated versions of an instrument.[14,15]

In this context, this study intends to adapt the Tool to Estimate Patients' Costs instrument cross-culturally to Brazilian Portuguese using three priority municipalities to combat of the disease: Cachoeiro de Itapemirim, Manaus and Vitória.

METHODS

A cross-cultural adaptation study with a questionnaire of costs of illness with a structured and closed questionnaire for cross-cultural adaptation, carried out in individuals with TB between the first and sixth month of treatment in the Basic Health Units that had Control Programs of TB - CPT's. Participated in the study 77 patients with at least one month of treatment for the disease, from September 2014 to May 2015. As exclusion criteria, were considered: to have less than one month of complete treatment at the interview date; having completed the treatment during the research; deaths; and patients with a history of psychiatric disorders.

Tool to Estimate Patient's Costs - Instrument to estimate the costs of tuberculosis patients and Corss-Cultural Adaptation process.

The questionnaire originally consists of 88 items, divided into 13 domains: patient information; previous treatment; pre-diagnosis delay and costs of diagnosis; treatment costs; cost of follow-up; hospitalization; costs related to food supplements; costs related to others diseases; insurance; financed costs; socioeconomic information; family income and expenditures; and socioeconomic indicators.[12]

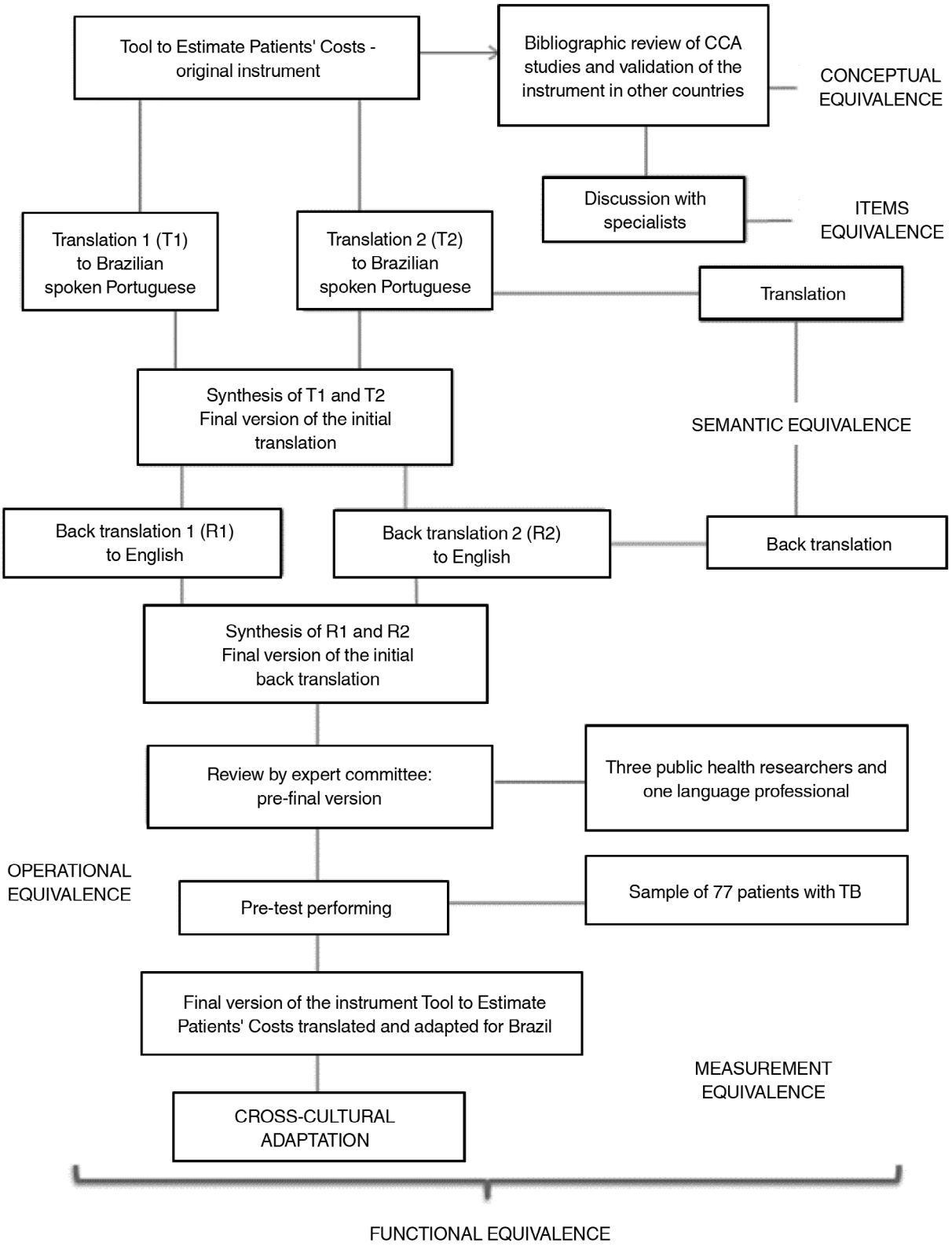
The study was developed in stages for cross-cultural adaptation following the model proposed in 1998 by Herdman et al.,[16] based on the verification of six types of equivalence between the original instrument and its adaptation: conceptual, item, semantic, operational, measurement and functional equivalence, as shown in the picture below (Figure 1):

The initial translation of the instrument was made from English (Annex A - English version) into Portuguese by two translators, being: one of them sworn bilingual whose mother tongue is Portuguese (T1), had no knowledge about the objectives of the instrument and the concepts involved, not being from the health area; and by a bilingual masters student translator (T2) of the health area. The translators received the original version of the instrument via email and had a deadline of 15 days to translate. The translations were done in independent ways. The unawareness of T1 facilitated the literal and conceptual translation, while the knowledge of T2 facilitated cultural and idiomatic equivalence. Two researchers synthesized the results of the translations in face-to-face meetings. After clearing the discrepancies, a final version of the initial translation of the instrument translated by T1 and T2 was reached.

The translated instrument was re-translated into the original language by two translators from the health area whose native language was English and were fluent in Portuguese (R1 and R2). Both didn't know the original version, unaware of goals and concepts. They received the version via email and had 15 days to perform the retranslation. Sequentially, a committee of experts reviewed the entire translation process until this moment.

Figure 1. Logistics of the process of Cross-Cultural Adaptation of the instrument "Tool to Estimate Patient's Costs". CCA - Cross-Cultural Adaptation.

Source: Own elaboration, 2016.



The group was composed by three researchers in public health and a language professional, with the purpose of consolidating the versions of the instrument - translated and retranslated - in meetings, to obtain a final consensus on the version to be applied to the instrument and the equivalence between the two instruments - the original and the translated. There was consensus between the two on the translated version for the instrument. In this phase, it obtained the pre-final version of the instrument to be used in the pre-test.

The pre-test was performed with the application of the questionnaire in the form of an interview, in which each interview lasted approximately 15 to 30 minutes. After this step, a synthetic was originated with 87 closed questions and one open question, ten domains and one item excluded from the original instrument.

The project was approved by the Research Ethics Committee of the Health Sciences Center (*Centro de Ciências da Saúde* - CCS) of the Universidade Federal do Espírito Santo, under the number 925.230.

All variables studied were categorical. The data was entered into an Excel for Windows program spreadsheet version 2010. The descriptive analysis methods used were the STATA 13.0 software. For the reliability analysis of the research instrument, Cronbach's alpha was used.

RESULTS

After all the translation (T1 and T2) and retranslation (R1 and R2) stages, a final translated version of the instrument was elaborated and, afterwards, the pre-test was carried out. Some questions were inconsistent, so a synthetic version of the questionnaire was created. For most questions no changes were required. The final translated version remained the same in the synthetic version.

In the questionnaire header, the interview options were adequate to the existing health centers in Brazil, with the following options: 1 - Surgeries; 2 - Health Unit; 3 - Local Hospital; 4 - Reference Hospital; and 5 - PCT (Figure 2).

Questions number 2, 3, 4, 5, 7 and 8 of the "patient information" domain were completed with the help of the patient's medical record and/or of the summarized fact sheet of the Brazilian Notification of Disease Information System (*Sistema de Informação de Agravos de Notificação* - SINAN), as they were of questions that patients did not know how to answer or, for the most part, did not remember.

In question 11, the response options were adequate to the Brazilian health system. Thus, they were arranged in: 1 - Local Hospital; 2 - TCP; 3 - Health Unit; 4 - Mission/Campaign/Regional Hospital; 5 - Pharmacy or Drugstore; 6 - Phytotherapy; 7 - Private Hospital/Clinic; 8 - Others. In this option, in its entirety answered, the patients referred to the Emergency Room, then, being replaced "other" by the same. The item response corresponding to the dispensary/pharmacy item, and was excluded and replaced for pharmacy or drugstore, since dispensary no longer exists in Brazil, in addition to the term being unknown to the patients.

In question 14, the last item is about reimbursement insurance and cost assistance, still in the pre-diagnosis phase. The index of answers was zero for both questions, since to the Brazilian health reality these do not apply. Thus, both were removed from the instrument (Annex B).

In question 43, letter "c" - "financed costs" domain - the interest rates were chosen according to the ones practiced in

Figure 2. Original, translated and synthetic versions of the instrument "Tool to Estimate Patients' Costs", respectively. TCP - Tuberculosis Control Program.

Date of Interview (dd/mm/yy)	**Name of Province**	**Name of District**	**Place of interview (household/facility name)**	**Interviewer Name**
Category of Facility	1. Dispensary 2. Health Centre 3. District Hospital 4. Mission Hospital			
Data da entrevista (dd/mm/aa)	**Estado**	**Cidade**	**Local da Entrevista (domicílio/instituição)**	**Nome do Entrevistador**
Categoria da instituição	1. Dispensário 2. Unidade de Saúde 3. Hospital local 4. Hospital missionário			
Data da entrevista (dd/mm/aa)	**Estado**	**Cidade**	**Local da Entrevista (domicílio/instituição)**	**Nome do Entrevistador**
Categoria de especialidades	1. Cirurgias 2. Unidade de Saúde 3. Hospital local 4. Hospital de referência 5. PCT			

the country, by banks and financial institutions, with the following options being: a - less than 5%; b - between 5% and 10%; c - more than 10%; and d - I do not pay any interest.

In questions 47, 48, 49 and 50 - "socioeconomic information" domain - the response options used did not satisfactorily serve the category of education, regarding the classification of individuals in the pre-test, since most patients had up to eight years of study or less. In the synthetic version of the questionnaire, the following categories were inserted as answers: according to IBGE of 2010: 1 - not literate; 2 - only literate; 3 - elementary incomplete or 1st to 3rd grade of the basic education; 4 - elementary school or up to the 4th grade of the basic education; 5 - high school 1st cycle or 5th to 8th grade of the basic education; 6 - high school 2nd cycle or secondary school; 7 - higher education; 8 - Masters or PhD; 9 - do not know/without declaration[17] (Annex C).

In question 62, items frequently cited by patients as occupation categories were education and health, related to category 6 (others). In the synthetic version of the questionnaire, these two items were included.

In the domain of "socioeconomic indicators", question 86, were included as answers the options according to the IBGE (Brazilian Institute of Geography and Statistics), in 2010, for the Brazilian standard of goods and consumption: car, refrigerator, television, microwave, stove and computer with internet.

Concerning question 87, "If the government could offer you some service to relieve the burden of TB on you and your family, what would you rather receive?" 48% of patients chose to receive the "food stamps", referring to the basic food basket, as response.

In question 88, "How much would you be willing to pay to not get sick with TB in the first place?", 80.5% of patients chose item "d" in response to "others", mentioning the words "would pay all the money in the world"; "Would pay a lot"; "Would pay all that I had" and "A lot of money", without being able to stipulate an exact and quantifiable cash value for the suffering caused by the burden of the disease, suggesting a qualitative evaluation of the question.

In other questions, the translated version was similar or very similar to the final version of the instrument and was answered without semantic problems. Patients who were in the intensive phase of treatment for the disease responded more accurately to the questions, mainly regarding pre-diagnosis. Patients in the continuation stage, especially those more advanced in the treatment, such as in the 5th or 6th months, were more prone to memory bias, regarding the issues related to the pre-treatment phase and diagnosis.

The alpha for each domain of the questionnaire was calculated separately after the pre-test, so that a very large variability of items did not influence its value. The domain "Socioeconomic Indicators", with nine items, had the highest value for alpha 0.90 and an IC of 0.34, while the lowest alpha was observed in the domain "family income and expenses", with 26 items, 0.71 and an IC of 0.21. The item referring to "reimbursement" in question 14 was excluded, as it did not apply. There are four domains with only one item (previous treatment, cost of follow-up, other costs and insurance), these domains were included in a larger domain of related content, in order to become one, to justify the reliability of the items of the questionnaire.

The united domains showed an improvement in the alpha value, 0.80 for the domain Previous Treatment and Delay, Pre-Diagnosis and Costs of Diagnosis; 0.76 for Costs of treatment, Follow-up and hospitalization; and 0.88 for Insurance and financed Costs (Tables 1 and 2).

Table 1. Cronbach's α value for the domains of the instrument.

Domains	Cronbach's α	Items
Patient Information	0.72	8
Previous Treatment	0.72	1
Delay, Pre-Diagnosis and Costs of Diagnosis	0.80	5
Treatment Costs	0.89	13
Follow-up Costs	0.88	1
Hospitalization	0.89	9
Other Costs	0.83	1
Other Diseases	0.87	3
Insurance	0.88	1
Financed Costs	0.88	3
Family income and Expenses	0.71	26
Socioeconomic Information	0.84	8
Socioeconomic Indicators	0.90	9
Total		88

Table 2. Cronbach's α value for the domains of the instrument after unification.

Domains	Cronbach's α	Items
Previous Treatment and Delay, Pre-Diagnosis and Costs of Diagnosis	0.80	6
Costs of Treatment, Follow-up and Hospitalization	0.76	10
Other Costs and other Diseases	0.87	4
Insurance and Financed Costs	0.88	4

DISCUSSION

Considering the need to measure the impact of the costs generated to patients and their families due to TB illness, and the lack of a specific instrument that allows comparison with studies in Brazil, it was decided to adapt an instrument developed in another culture. Its adaptation becomes of fundamental relevance, since the adapted questionnaire was developed in English and applied in another contextual reality.[18] Thus, after the application of the questionnaire, it was necessary to perform the exclusion and inclusion of some items in order to better fit the actual health situation of the patients and of the control programs for the disease.

In relation to the questions of the instrument that were completed with the help of documents corresponding to the patient's card in Brazil, as recommended by the World Health Organization (WHO), the patient's medical record and/or summarized fact sheet of the SINAN were used. Despite the availability of these extra documents, the incompleteness or erroneous filling of some patient data in SINAN was visible.

The underreporting of cases in this information system does not allow an analysis of the real epidemiological situation of TB, hampering the planning of actions aimed at the control and elimination of the disease. It is still made difficult to estimate the number of cases that are lost in the system, but it is highly relevant to recover these missing data so that the routine retrieval of data from different sources of information used by TCPs can minimize the occurrence of the problem.[19]

When asked about the possibility of choosing a service to alleviate the burden of poverty during TB treatment, both patients preferred to receive the "food stamps", referring to this item as "*Bolsa Família*", a Brazilian government program that provides financial aid to poor families in the country. Only in the municipality of Vitoria does this incentive exist to improve adherence to treatment, as well as a social voucher to cover the costs of transportation of the patient to the unit during visits, and which is assured by a Municipal Law, No. 6,466 dated May 30, 2005. In other municipalities, this incentive does not exist, since the initiative came from the municipal sphere. These initiatives contribute to a higher rate of adherence to the treatment of the patient and decrease the rate of abandonment.[20]

A study carried out on the impact of *Bolsa Família* on TB treatment compared a group of people diagnosed with the disease and beneficiaries of the *Bolsa Família* with another group of beneficiaries enrolled in the program after the end of treatment. The rate of cure among beneficiaries of *Bolsa Família* was 86%, 5.4% above the group not exposed to the benefit during treatment (those who receive the income transfer have a 5.4% greater chance of improving from the disease).[20]

Regarding what the patient would be willing to pay to not get sick with TB, the majority chose the "other" category in the two phases of the study, mentioning to the sentence "would pay all possible money". It is not feasible to quantify the suffering that the patient had due to the burden of the disease only contemplating the financial aspect. Questions like these are subject to very subjective responses and are influenced by a number of factors, such as: individuals are distinct, have dimensions, characteristics, values and personal experiences that each individual brings with them as a human being. Thus, it is suggested that this question be opened, for a more qualitative analysis, that takes into account all dimensions of the disease, not only the economic one.

In the performing of the instrument CCA, there are two measurement characteristics that should be considered in the development of questionnaires: validity and reliability.[21] Reliability is used to determine the consistency of the results of the evaluation of items of a survey, which can be estimated by the alpha of Cronbach, and the validity refers to the precision of the characteristic to be measured.[22] Our results for the alpha and its respective domains reveal internal consistency between moderate to high, confirming the reliability of the research instrument. Only one domain, "Family Income and Expenses" had moderate reliability, with an alpha value of 0.71.

In relation to the domains with only one item each, they were joined with other related domains and thus increasing the value of alpha 0.80 for the domain "Previous Treatment and Delay, Pre-Diagnosis and Costs of Diagnosis"; 0.76 for "Costs of Treatment, Follow-up and Hospitalization"; and 0.88 for "Insurance and Financed Costs". According to the literature, the alpha value is considered for domains with at least three items, which would not justify the calculation of the same according to the original instrument.[23] Thus, the instrument would have eight domains and no longer 13, and the minimum number of items per domain would be 4 questions.

The main limitation of this type of study is memory bias when selecting patients for interviews. Patients who were in the attack phase for treatment of the disease, that is, after the first month and until the end of the second full month, remembered better about the expenses due to TB when questioned. Patients after the third month tend not to remember the costs before the diagnosis, which could compromise the estimates aimed at the study's objective.[13]

CONCLUSION

The "Tool to Estimate Patients' Costs" questionnaire proved to be very reliable and useful in accomplishing this goal of estimating measures and values for the calculation of the costs of tuberculosis illness. However, there is a need to make more changes, in addition to the structural adjustments already made, so that it can better meet the Brazilian reality and reach its goal of accurately measuring TB costs. These results may lead to joint actions among the TB care team actors, mainly in medical and nursing care, in the planning of actions with these patients and in the referrals that are necessary for the social assistance services. Thus, it is suggested to interview patients who are between the 2nd and 3rd month, in order to avoid and minimize this type of bias in future studies.

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SUPPLEMENTARY MATERIAL

The following online material is available for this article:

Annex A. English version.
Annex B. Questionnaire "tool to estimate patients' costs" – sworn translation. (KNCV Tuberculosis Foundation, Tool to Estimate Patients' Costs Literature Review, 2008, 33p.).
Annex C. Questionnaire "tool to estimate patients' costs" – synthesized version.