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## Abstract

**Background**: Tuberculosis (TB) represents a major health problem having serious financial impact on a substantial proportion of patients. This has necessitated the development of a valid tool for measuring TB-related expenditure by patients and their households so that appropriate measures can be taken to reduce the financial burden.

**Aims**: To translate and culturally validate the generic WHO tuberculosis patient cost survey within the Egyptian context.

**Methods**: The instrument was translated and culturally adapted using forward-translation, back-translation, expert panel assessment, pretesting, cognitive interviewing, and appraisal by the developer.

**Results**: A final Arabic version with modifications to 35 descriptors of the original tool was produced after review by an expert committee and cognitive interviews with patients. Twelve questions were modified, 13 response options were changed, 6 questions were added, and 4 questions were removed. Pretesting of the tool ensured that the final version is culturally sensitive and fit for assessing the costs incurred by TB patients in an Egyptian context.

**Conclusion**: Policymakers are encouraged to use the WHO tuberculosis patient cost survey tool for assessing the expenditure of TB patients with a view to developing appropriate policies to reduce the financial burden of patients.

Keywords: Tuberculosis, Egypt, catastrophic health expenditure, WHO, cost survey, cultural adaptation.

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## Introduction

Tuberculosis (TB) represents a major public health problem worldwide (1). In 2019, there were an estimated 10 million new cases of TB and 1.4 million deaths and more than 90% of these cases and deaths occurred in developing countries (2). The incidence of TB in Egypt was 12 per 100 000 people according to the World Health Organization (WHO) global tuberculosis report in 2020 (1).

TB is estimated to have cost the world economy US$616 billion from 2000 to 2015 (3). A considerable proportion of the economic burden is shouldered by patients within

the low-income quartiles. Three studies conducted in South Africa and Malawi stratified TB costs by income status and revealed that poorer patients incurred higher costs for treating TB than those who were richer (4–6). Accordingly, WHO set a target of zero TB-affected families facing catastrophic costs as 1 of 3 aims of the End TB Strategy (7). Catastrophic costs are defined as those that account for ≥ 20% of patients' annual household income (including direct medical expenses, nonmedical expenses, and overall indirect costs, which include lost wages and time off work due to symptoms and treatment seeking) (8,9). In a meta-analysis of 29 studies, the aggregated proportion of catastrophic costs at a cutoff point of 20% for the 29 studies was 43% (10).

To reduce the risk of TB-related poverty, it is critical to have a valid tool to measure TB-related patient and household expenditure so that relevant policies can be implemented (11). A tool for measuring the direct and indirect costs for TB patients and their households was developed in 2015. This tool measures the proportion of patients who experience catastrophic payments due to TB. This generic tool was expanded into a handbook in 2017 after field testing in 9 countries and consultation with a WHO-led TB patient cost task force (12). By March 2020, 17 countries had completed the survey, with another 30 planning to do so by the end of 2020. According to the countries that have completed the survey evaluations, 27–83% of people with any kind of TB faced catastrophic expenditures. Those with drug-resistant TB had a substantially higher rate, ranging from 67% to 100% (13).

The tool has been cross-culturally adapted in many countries, including Indonesia (14), Ethiopia, Kazakhstan (15), South Africa, Mozambique, United Republic of Tanzania, and Gambia (11). Cross-cultural adaptation is a process in which a questionnaire is translated into a language other than that with which it was developed and adapted to the local context where it will be applied (16). Based on the measurements of catastrophic costs, several countries have applied TB-specific strategies such as cash transfer to TB patients in India and Nigeria, and medical insurance coverage, food support and cash transfer in Kenya (17). Other countries have applied TB-sensitive strategies such as conditional cash transfers based on income in Brazil and Universal Health Coverage (UHC) in Indonesia (18,19).

In Egypt, the national TB control programme offers free treatment; however, there is no social support to help patients cope with indirect and out-of-pocket payments. Few studies have been conducted to measure the financial burden on TB patients. In a recent study in Cairo Governorate, 33% of patients encountered catastrophic payment with the highest proportion during the prediagnostic stage (20). In Egypt a UHC law was approved in 2017 and will be applied gradually between 2018 and 2032. The law will extend insurance to 30% of the population who are not currently covered by any form of insurance (21). UHC is a social solidarity-based compulsory system that exempts individuals who cannot afford to pay contributions. In the new system, the family is the primary insurance coverage unit, as opposed to the current system, which provides separate coverage to each family member, leaving some uninsured (22). The law aims to reduce catastrophic payments due to medical care and it is considered a TB-sensitive strategy. The current study aimed to adapt the WHO cost tool to an Egyptian context. It assessed the catastrophic payments due to TB before and after applying UHC; thus enabling policy-makers to determine whether this strategy is sufficient to protect TB patients against improvisation, or whether additional social protection measures are needed.

## Methods

### Original WHO survey

The WHO generic TB patient cost survey gathers data from patients about their current treatment and the costs incurred during the treatment phase in which they are interviewed (12).

### Translation adaptation

Guidelines for translation and cross-cultural adaptation were followed (16,23). The tool was translated through the following 5 stages:

#### Stage 1: forward translation

Two bilingual translators whose mother tongue is Arabic translated the WHO tool. The translators were health professionals who were aware of the concepts examined by the

questionnaire. The translation aimed at conceptual equivalence between the generic and translated tools rather than literal translation. The tool was translated into the written Arabic language with the goal of ensuring that the terms in the target language conveyed the same or similar meanings as the source language.

### Stage 2: back translation

Two bilingual, native English-speaking translators translated the tool backwards to English. The translators were unaware of the concepts being explored in order to avoid information bias and to point out unexpected meanings of terms in the translated tool (24). Back-translation provided validity checks and uncovered inconsistencies in the translation process. Discrepancies between the original and the back-translated versions were discussed. The forward-translated tool was iterated as many times as needed by the bilingual expert panel until a satisfactory version was achieved.

### Stage 3: expert committee (content validity and cross-cultural adaptation)

Content validity is defined as the extent to which the element of an assessment instrument is relevant and representative of the targeted structure for a particular assessment goal (25). Content validity was achieved in several steps. First, the content validation form was prepared to ensure that the review panel had clear expectations and understanding of the task. Second, the group responsible for reviewing the questionnaire was selected based on individual expertise on catastrophic costs incurred by TB patients. The panel consisted of 8 reviewers with specialties in tropical and infectious diseases, TB and pulmonary diseases, health economics, clinical pharmacy, and epidemiology . In a face-to-face discussion, the experts critically reviewed the field and its components before assigning a score to each. They provided verbal feedback to improve the relevance of each item to the focus area. All comments were taken into consideration to refine the domain and its items. Upon completing the review of the domain and items, the experts were requested to provide a score on each item independently based on the relevant scale (26). The conceptualized equivalence between the generic and translated tools was evaluated. The content validity index was 0.8. As recommended by the WHO task force (11), questions on income and household assets were adapted for the local context using the same wording as in the Demographic Health Survey and the Household Income and Expenditure Survey available in Egypt (27,28).

### Stage 4: pretesting and cognitive interviewing

Cognitive interviewing is a research-based qualitative method for determining whether a survey question fulfils its intended purpose (29,30). The lead investigator trained a physician and a pharmacist to conduct the cognitive interview through role play. Fifteen participants were recruited for the interview (5 physicians and 10 TB patients aged > 18 years at the TB Department of El Mamora Chest Hospital, Alexandria at least 2 weeks after initiation of the intensive phase, and after signing informed consent). Recruitment of subjects for cognitive

interviewing aimed to include variation of subjects rather than statistical representation. The interview was conducted in a quiet place and notes were taken by trained cognitive interviewers. The interviewers prepared the draft form of the questionnaire together with probe questions to be asked (30).

The interviewer used concurrent probing, which is a verbal probing approach in which the interviewer asked the probe question just after the respondent had read aloud and answered each survey item (29). The following types of cognitive probes were used: (1) comprehension/interpretation: respondents were asked what they thought was meant by each questionnaire item and the chosen response; (2) paraphrasing: respondents were asked whether they could repeat the question in their own words; (3) recall: respondents were asked to explain how they came up with their answer; and (4) general: respondents were asked about any word they did not understand and any word or expression that they found unacceptable or offensive.

Stage 5: submission of the final version to the developer for appraisal of the adaptation process

All forms, reports and the final culturally adapted and pretested questionnaire were sent to the WHO expert panel, which audited the process of translation and adaptation and assessed whether the constructs measured the catastrophic costs.

### Analysis

The raw data were coded and entered using Microsoft Excel software an the data were described using frequency distribution tables. Qualitative data were described using number and percentage and the variable “age” was described using arithmetic mean and standard deviation. Analysis of the cognitive interviews was based on text summarization (30); the interviewers’ written notes were summarized and the consistent themes were identified, and the questions modified based on results of the analysis.

## Results

A total of 35 modifications were made to the original WHO cost survey. Twelve questions were modified, 13 response options were changed, 6 questions were added and 4 questions were removed. Examples of the changes in questions were replacing “patient registration number” with “patient ID number” and “province” with “governorate” ( Table 1 ). Thirteen sociodemographic questions had their response options altered, including education, employment and occupation, so that the answers represented the local categories. Other

examples of alterations were questions on health insurance and social protection schemes, to reflect the schemes in Egypt (e.g. government insurance, private insurance and donors), and types of facilities for diagnosis and treatment, to reflect the health facilities in Egypt (e.g. chest hospital and chest clinics) (
Table 2
). Six questions were added, including questions about savings in the cost of TB treatment; cost of accommodation because sometimes patients received treatment in remote facilities that required an overnight stay in a governorate other than their home governorate; and nonessential jobs in the informal sector for additional income (
Table 3
). Four questions were removed, such as “Was a fee paid to pick up medications?” TB medications are subsidized by the National Tuberculosis Control Program and dispensed free to patients. Questions on vouchers were removed because such a system does not exist in Egypt (
Table 4
).

For cognitive interviews, 10 patients and 5 physicians were interviewed [10 male, 5 female, mean age 34.56 (12.32) years]. All patients were living in Alexandria and recruited from Mamora Chest Hospital. All patients were drug sensitive, and 8 of them were in the continuation phase (
Table 5
). After the interviews, subjects declared that questions were clear and understandable and suggested minor changes. The date of presentation of symptoms and initiation of treatment could not be recalled precisely, especially for patients in the continuation phase. One of the confusing items was the cost of drugs other than anti-TB treatment (nutritional supplementation and vitamins) because these 2 items were inseparable in the prescription. Therefore, a question was added about the total cost of other medication if the patient could not report the cost of each item; patients usually receive a hospital bill with the total cost of hospitalization without itemization. Thus, we added an item that reported the total cost of hospitalization if the patient did not know the cost of each subcategory.

Some words were confusing, such as ambulatory treatment, consultation fee, and biopsy. These words were adapted to suit the local context; for example, energy drinks were replaced with milk and consultation fee with examination fee. We added a question that asked for other national forms of transportation, such as toktok (in Egypt, a 2-wheeled pulled rickshaw with a seat for 1 or 2 people). A question was added about household monthly expenditure on rent. We also asked about the cost of utilities, the estimated monthly net income from work-related activities, the methods of rubbish and municipal waste disposal, and other fixed sources of income.

## Discussion

A final Arabic version of the original WHO tuberculosis patient cost survey was developed with modifications to 35 descriptors. Twelve questions were modified, 13 response options were changed, 6 questions were added and 4 questions were removed. We encountered some challenges during translation. First, the Arabic language has a rich vocabulary, with many terms used to convey the same meaning. One description in English may have multiple Arabic equivalents, necessitating a lengthy translation procedure to select the most acceptable and accurate equivalent word for the Arabic version (31). The disparity between the spoken (colloquial) and written (classical) versions of the language was another challenge. It is worth mentioning that, while written Arabic is the same across the 22 countries of the Middle East, spoken Arabic varies (31). Thus, a decision was taken to translate the tool into written Arabic. This resulted in a translated version that could be valid for use in all Arab-speaking countries with some cultural adaptation.

The research team made the following changes to adapt the generic WHO survey to the Egyptian context: changing wording of the questions, changing the response options, and adding and omitting questions. For example, we omitted questions about transportation or accommodation vouchers for TB patients because the voucher system does not exist in Egypt. Similarly, we omitted a question about fees paid to collect TB medications because patients receive TB medications at no charge under the National Tuberculosis Control Program. We added 6 questions. For example, the accommodation costs for the patients and their caregivers because some patients receive treatment in a governorate other than the one they resided. We added a question about nonessential jobs because it is common for Egyptians to take up informal private employment in addition to their main employment as a means to increase their income (32). We changed questions about type of healthcare facilities, education, employment, facilities for dispensing TB medications…etc. to make them appropriate for the Egyptian context.

The WHO patient cost survey adapted in our study has a cross-sectional design in which the patient is interviewed only once. Expenditure incurred after treatment completion is not included, and costs cannot be linked to treatment outcomes, which are sometimes unavailable at the time of the survey. This is likely to underestimate the economic impact of TB because costs incurred after treatment for TB sequelae or loss of job or income due to disability would be overlooked (11). Accordingly, several TB cost studies have drawn attention to the necessity for longitudinal studies, including the costs incurred by patients after recovery, including economic recovery (e.g. ability to repay debts or regain production), and the ability to build resilience against future shocks after completion of TB treatment (11). In one study, the WHO generic cost survey was adapted for longitudinal use in African countries: at enrolment (start of TB therapy at day 0), and at 2, 6, 12 and 24 months after enrolment. The periods were designed to determine expenditure for diagnosis, treatment and long-term follow-up once treatment was concluded. Repeated measurements allowed for comparison of costs over time, measuring the economic impact after concluding TB treatment, and linking the cost survey to treatment outcomes. Thus, further studies adapting the current tool for use in longitudinal studies is recommended.

The income provided by patients in the generic WHO survey is self-reported income. This can be challenging in an informal economy setting (4,33). For example, it would not be possible to measure lost income due to illness for patients who report a zero income (11). A report by the World Bank estimated that income from informal private employment accounted for 62% of the overall income (32). In the current study, questions about the monetary value of all items consumed by households were added, using the Demographic Health Survey and the Household Income and Expenditure Survey available in Egypt (27,28). Estimating the income based on possession of assets, such as televisions, refrigerators and mobile phones, is more accurate than self-reported income. This was illustrated in a study in South Africa that used 6 different approaches for estimating catastrophic expenditure. Depending on the estimation method, the total proportion of households experiencing catastrophic costs ranged from 0% to 36%, with the self-reported income significantly lower than the estimated income based on asset linking (34). The South African study highlighted the difficulty of accurate assessment of income when estimating disease-specific catastrophic costs. A consumer expenditure questionnaire is the gold standard for estimating permanent income.

The current study had some limitations. The Demographic Health Survey and Household Income and Expenditure Survey provided accurate estimates of the respondents' income. However, these surveys are specific to the Egyptian context and will be difficult to use in other countries. If the survey is to be replicated in an Arab country, the local context should be taken into consideration when estimating income. Another limitation was that the tool did not account for expenditure incurred after treatment completion. Further adaptation of the tool for use in longitudinal studies is recommended.

## Conclusion

This study has resulted in the availability of an Arabic version of the WHO TB patient cost survey that could be used to estimate the catastrophic health expenditure among TB patients in Arab countries. With the use of the adapted tool, focused interventions could be applied to reduce the financial burden on TB patients.

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**WHO EMRO | Translation and cultural adaptation of the WHO generic tuberculosis patient cost survey to**

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## Traduction et adaptation culturelle de l'enquête générique de l'OMS sur les coûts de la tuberculose pour les patients dans un contexte égyptien

## Résumé

**Contexte** : La tuberculose représente un problème de santé majeur qui a de graves répercussions financières sur une proportion importante des patients. Il a donc été nécessaire de mettre au point un outil valable pour mesurer les dépenses liées à la tuberculose par les patients et les membres de leur foyer afin de prendre les mesures appropriées pour réduire la charge financière.

**Objectifs** : Traduire et valider culturellement l'enquête générique de l'OMS sur les coûts de la tuberculose pour les patients dans le contexte égyptien.

**Méthodes** : L'instrument a été traduit et adapté culturellement à l'aide de la traduction initiale, de la rétrotraduction, de l'évaluation par un groupe d'experts, du prétest, de l'entretien cognitif et de l'évaluation par le développeur.

**Résultats** : Après avoir été examinée par un comité d'experts et après des entretiens cognitifs avec les patients, une version finale en arabe a été produite avec des modifications apportées à 35 descripteurs de l'outil original. Douze questions ont été modifiées, 13 options de réponse ont été changées, six questions ont été ajoutées et quatre questions ont été supprimées. Le prétest de l'outil a permis de s'assurer que la version finale tient compte des différences culturelles et qu'elle est adaptée pour l'évaluation des coûts supportés par les patients tuberculeux dans un contexte égyptien.

**Conclusion** : Les responsables politiques sont incités à utiliser l'outil d'enquête de l'OMS sur les coûts de la tuberculose pour les patients afin d'évaluer les dépenses de ces derniers en vue d'élaborer des politiques appropriées pour réduire leur charge financière.

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