Original Article

Development and validation of a questionnaire on tuberculosis among foreign-born individuals in a province of northern Italy

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Abstract

Introduction: In low tuberculosis (TB) incidence countries, foreign-born individuals represent a population at risk. Knowledge, Attitude and Practice (KAP) surveys use standardized and structured questionnaires to collect information by a specific population in relation to a particular topic. As primary objective, we developed and validated a questionnaire exploring TB knowledge among foreign-born individuals from high TB incidence countries living in Ferrara's province, a low TB incidence province of northern Italy. As secondary objective, we investigated respondents' demographic and social determinants of health data.

Methodology: Questionnaire items were developed based on World Health Organization (WHO) "A guide to develop KAP surveys" questionnaire sample and literature review. Questionnaire underwent Delphi technique evaluation, back and forward translation, health literacy review, and two pilot tests. Internal consitency and validity were computed through Cronbach's alpha, content validity index, and principal component analysis (PCA). Descriptive statistics were used to summarize demographic and social determinants of health data.

Results: We initially proposed a 38-item questionnaire. After Delphi technique, performed with seven experts, a 17-items questionnaire was obtained. Cronbach's alpha coefficient, used to assess internal consistency, was 0.65. Content validity index was > 0.80. One factor was extracted by PCA, with a cumulative contribution of 50%. The population investigated was similar to the immigrant population settled in Ferrara's province, according to age, gender and TB risk factors.

Conclusions: The questionnaire we developed and validated can contribute to measure foreign-born individuals' TB knowledge.

Key words: Questionnaire validation; tuberculosis knowledge; foreign-born individuals.

Introduction

TB is still a major public health problem worldwide. In low tuberculosis (TB) incidence countries, such as Italy, it clusters among vulnerable groups, such as foreign-born individuals from high TB incidence countries [1]. According to the Global plan to end TB 2016-2020 and the global fund, foreign-born individuals from high TB incidence countries are a key and vulnerable population for TB [2-3]. In Ferrara's province, a low TB incidence province of northern Italy, foreign-born individuals represented 10.7% of total population [4], and 60% of notified TB cases [5]. Knowledge, Attitude and Practice (KAP) surveys are cross-sectional studies that use standardized and structured questionnaires to collect information on what is known, believed, and done by a specific population in relation to a particular topic [6]. The attractiveness of KAP surveys is attributable to characteristics such as an easy design, quantifiable data, ease of interpretation and concise presentation of results, generalisability of small sample results to a wider population, speed of implementation [6]. There are studies that link higher KAP level with efficient management of illness, response to medical treatment, and promotion of one's own health, and lower KAP level with poor health, inefficient health care use, decrease of disease screening rate [7-9].

In 2008 the World Health Organization (WHO) published a guide to developing KAP surveys, and a TB KAP survey questionnaire sample within the guide [6]. As primary objective, based on WHO's sample [6], we developed and validated a questionnaire exploring TB knowledge among foreign-born individuals from high TB incidence countries living in Ferrara's province, a low TB incidence province of northern Italy. We decided to focus our questionnaire on TB knowledge, and not to investigate TB attitude and practice, because of the complexity of all these issues [7]. As secondary objective, we analyzed demographic and social

determinants of health data of the population investigated.

Methodology

Participants and settings

Participants were recruited from five settings of Ferrara's province (the city of Ferrara and a town called Cento): Ferrara's hospital, an adult schooling centre for foreign-born individuals, two charity centres, an immigrant facility centre. Participants were recruited from November 2019 until February 2020. Inclusion criteria were: individuals aged 16 and over from a high TB incidence country (TB incidence rate > 50/100000 people according to Italian TB guidelines), with no medical education, and without active TB or history of active TB.

Questionnaire development

Phase 1: Item construction

Items were developed based on WHO KAP questionnaire sample [6] and literature review [10]. Literature review was conducted searching in PUBMED database for relevant articles (in English and Italian) using the following terms: "Tuberculosis knowledge questionnaire" (1116 articles), and "Tuberculosis knowledge attitude and practice" (1172 articles). A total of 22 articles were considered relevant to this topic and were reviewed.

Phase 2: Item screening

Items were screened through Delphi technique (two-round expert consultation) [11]. Experts were recruited according to the following inclusion criteria: be engaged in TB prevention and control, TB clinical diagnosis and treatment, global health, migrants' health. Delphi technique was conducted via e-mail. In Delphi round one, experts were asked to rate the items on a five-point Likert scale (0 to 4, where 0 = very unimportant and 4 = very important), showing to which extent they thought each item should be included in our questionnaire. Experts could add suggestions and comments. After Delphi round one, the central tendency was evaluated by item selection rate (the number of experts who rated items with a score of 3 = important, or 4 = very important /the total number of experts × 100%). Items scored < 80%, were deleted or amended according to experts' comments. This amended questionnaire was assessed from the same expert panel in Delphi round two. Experts were asked to re-rate the amended items on the same five-point Likert scale. Thereafter, central tendency and discrete degree were computed. Discrete degree was measured using the coefficient of variation (the ratio of standard deviation and arithmetic average of the item importance score). Items with item selection rate <80% and item coefficient of variation >0.2, were deleted [12].

Phase 3: Questionnaire translation and health literacy review

After Delphi technique, the questionnaire underwent forward and back translation from English to Italian. The translation process was carried out according to methods described by Beaton [13]. Thereafter, Ferrara's hospital health literacy committee reviewed the translated questionnaire, aiming to make it understandable to foreign-born individuals without medical education.

Phase 4: Pre-testing: focus group and pilot study

A focus group with four foreign-born individuals was performed to evaluate linguistic and cultural barriers within the questionnaire. To test clarity and intelligibility, the questionnaire underwent two pilot tests. A sample of 11 individuals participated in the first pilot test, whereas 40 individuals participated in the second one. Individuals were asked to vote on a three-point Likert scale (0 to 2, where 0= totally not understandable, 1= partially understandable, and 2= totally understandable) how much understandable was each item. After each pilot test, items scored less than 2 (2= totally understandable) by more than 80% of individuals were deleted. During pilot tests, the mean time to complete the interview was calculated.

Questionnaire validation
- Internal consistency was assessed by calculating Cronbach's α coefficient [14].
- Content validity was assessed by content validity index (CVI). CVI represents the proportion of experts that consider each item relevant (the extent to which they thought each item should be included in the questionnaire). A CVI >0.8 was accepted. In our case CVI corresponded to item selection rate of Delphi technique, and it was calculated based on the result of Delphi round two.
- Construct validity was assessed by principal component analysis (PCA). PCA explores the inter-relationship of variables [15]. Bartlett's test of Sphericity which assesses the equality of variance in different populations, and Kaiser-Meyer-Olkin (KMO) test, which is a measure of sampling adequacy, were conducted to confirm the suitability of data [10,15].

To determine underlying factor structure of the questionnaire, eigenvalue >1 and scree plot of eigenvalues were determined. The number of factors to be extracted was determined by inspecting the scree plot.

An eigenvalue is an estimate of variance explained by a factor in a data set, and a value >1 indicates greater than average variance. A screen plot is the graphic representation of this [10].

P-value < 0.05 was considered statistically significant.

Descriptive statistics were used to summarize demographic and social determinants of health data.

Results

A total of 96 foreign-born individuals were interviewed, 10.4 % were interviewed at Ferrara's hospital, 44.8% at the adult schooling centre, 40.6% at the two charity centres, 4.2% at immigrant facility centre.

Demographic and social determinants of health data of the population investigated are summarized in Table 1.

Questionnaire development
Phase 1: Item construction

Based on the WHO guide [6], and literature review, we realized a 38-item questionnaire divided into seven sections [Appendix 1]. The tool we developed was a face-to-face questionnaire.

Phase 2: Item screening

Seven out of the eleven experts (63.6%) who were e-mailed, participated in the study (four epidemiologists, two pneumologists, one infectious disease specialist). Areas of expertise were: TB prevention and control, TB clinical diagnosis and treatment, global health, migrants' health. After Delphi round one, 14 items were deleted and 7 were amended according to experts' comments. After Delphi round two, 7 items were deleted, and one item amended. The result was a 17-item questionnaire divided into six sections [Appendix 1].

Phase 3: Questionnaire translation and health literacy review

After items were screened by the expert-panel, the questionnaire underwent forward translation from English to Italian by an English native speaker with good Italian knowledge, and back translation from Italian to English by an Italian native speaker. The initial and final English versions were compared [12]

and we found no substantial difference. Thereafter, the final Italian version of the translated questionnaire underwent health literacy review.

Phase 4: Pre-testing: focus group and pilot study

In the focus group participated four men, one from Morocco, one from Gabon, and two from Ivory Coast. All of them had an excellent Italian language knowledge. After the focus group, two items were deleted, one concerning HIV status, one concerning alcohol use and illicit drug use, because both these items were perceived as too personal and uncomfortable. Other two items were rephrased according to the group suggestions. The result was a 16-item questionnaire. Thereafter the questionnaire underwent two pilot tests, in pilot test one no item was deleted and two were amended; in pilot test two, only one item was rephrased [Appendix 1]. Mean time to complete the questionnaire was 7.2 minutes. The questionnaire development process is shown in Figure 1.

Questionnaire validation

Cronbach's alpha, used to assess internal consistency, was computed on four items (items 10-13) because it was possible to rate the answers on a Likert scale (0= no knowledge, 5= very good knowledge). The Cronbach's alpha coefficient was 0.65. Content validity was assessed during Delphi round two. Four items

Table 1. Demographic data and social determinants of health among foreign-born respondents.

Demographic data and social determinants of health	Foreign-born individuals (Tot = 96)
Gender, female (n.,%)	54 (56.2)
Age, mean (range)	31.1 (16-64)
Country of origin	
Subsaharan Africa (n.,%)	54 (56.2)
North Africa (n.,%)	20 (20.8)
East Europe (n.,%)	13 (13.5)
Asia (n.,%)	6 (6.2)
South America (n.,%)	3 (3.1)
Other (n.,%)	0 (0)
Years from migration/spent in Italy (mean, range)	7.01 (0.25-30)
Years from migration/spent in Italy (median, IQR)	3 (2.25-10)
Refugee/asylum seeker (n.,%)	39 (40.6)
Homeless (n.,%)	6 (6.25)
Unemployed, yes (n.,%)	70 (73.0)
Education	
No education (n.,%)	3 (3.1)
Primary (n.,%)	18 (18.7)
Secondary (n.,%)	59 (61.4)
University (n.,%)	15 (15.6)
Not reported (n.,%)	1 (1.0)

Tot: total; n: number; IQR: interquartile range.

presented CVI < 0.8 and were deleted. After Delphi round two, the CVI of the questionnaire was > 0.8.

PCA was performed to assess construct validity. Kaiser-Meyer-Olkin (KMO) was computed on the same four items (items 10-13). KMO value was 0.68, and the result of Bartlett's test was statistically significant ($p < 0.001$), which indicated that data were suitable for factor analysis. Since eigenvalue was 1.99, only one factor was determined, that accounted for 50% of items' variance [Figure 1]. Table 2 shows factor loading results. Factor scores were around 0.5, and only one factor was identified. It was interpreted as "TB symptoms and transmission".

Discussion

TB knowledge is essential for successful prevention and treatment among vulnerable groups, such as foreign-born individuals from high TB incidence countries. [1,2,6] and TB knowledge is an important issue to address for successful prevention and treatment. Therefore, having a valid tool to assess TB knowledge among this population is necessary to better control the disease. In this study, we developed a 16-item questionnaire and validated it. To our knowledge this is the first questionnaire exploring TB knowledge among foreign-born individuals from high TB incidence countries, validated in a low TB incidence setting, with high immigrant flow and TB cases clustering among foreign-born individuals. Because of the whole validation process, we think that the present questionnaire is more consistent with real-world conditions in assessing TB knowledge among foreign-born individuals in our setting. Our questionnaire was not validated in other low TB incidence settings, but it might be useful in those settings that present characteristics comparable to Ferrara's province. Because of the validation process the primary objective, we evaluated psychometric variable that presented good values. Internal consistency was evaluated with Cronbach'α coefficient. In literature is reported that Cronbach' alpha coefficient should score at least between 0.65—0.70. In our study, four items underwent Cronbach' α calculation, and the coefficient scored 0.65. We considered this coefficient the minimum

Table 2. Factor loading results of PCA.

Items	Factor loading score
Item 10	0.5261
Item 11	0.5403
Item 12	0.4605
Item 13	0.4683

PCA: principal component analysis.

acceptable value to validate the internal consistency of the items investigated [12]. To assess content validity, we used Delphi technique and CVI. Delphi technique involved seven subjects with expertise in different disciplines. According to literature, this is a good panel to investigate our topic [11, 15, 16]. Our results showed that CVI was >0.80, consistent with the requirement of a CVI of at least 0.8. To assess construct validity, our study adopted the PCA method, and one factor was extracted. It was interpreted as "TB symptoms and transmission". Another strength of this study is represented by the translation according to Beaton's guidelines, the health literacy review, and the focus group's cultural acceptability assessment, that contribute to provide an adequate instrument to be administered to foreign-born individuals. Our study presented some limitations: first, internal consistency and construct validity were computed only on four items; secondly, the population sampled partially represented the foreign-born individuals settled in Ferrara's province. In particular, the study population was comparable with the foreign-born population living in Ferrara's province according to age and gender (in our study mean age was 31.1 years and 56.2% was female, while among foreign-born individuals settled in Ferrara's province mean age in 2019 was 34.2 years and 54.9% was female [4]). According to country of origin, the study population did not reflect those of foreign-born individuals in Ferrara's province: in our study, more than 50% of individuals were from North Africa and Subsaharan Africa, and only 13% from East Europe, while in Ferrara's province most individuals were from East Europe, and secondly from Subsaharan and North Africa (2019 data [4]). Risk factors for TB [2] were well represented in the study population: 73.0% were unemployed, 40.6% were refugee/asylum seeker, 6.25% were homeless, and they were mostly

Figure 1. Flowchart of the study.

| Item Construction:
Literature review | ⇨ | Item screening:
Delphi technique | ⇨ | Translation and health
literacy review | ⇨ | Pre-testing:
- focus group
- pilot test | ⇨ | Validation:
- Cronbach's alpha
- CVI
- PCA |

CVI: Content validity index; PCA: principal component analysis.

recently migrated [Table 1]. Over the years, limitations of KAP surveys are emerged, and authors consider that KAP survey alone do not provide a complete panorama concerning a particular health issue in a specific population [7]. However, KAP surveys can be useful as a part of the whole investigation [7]. Moreover, even if TB knowledge without accessibility to diagnosis and treatment, and social support cannot improve TB control, TB knowledge is an essential element to tackle TB epidemic [1,6].

Conclusions

In the present study, we developed and validated an instrument, which may be useful as a measure of foreign-born individuals' TB knowledge. The analyses of internal consistency and validity demonstrated the good psychometric properties of the questionnaire. To our knowledge, currently, our questionnaire is the only validated tool available to assess TB knowledge among foreign-born individuals from high TB incidence countries living in low TB incidence settings. Therefore, we propose the questionnaire we developed as a valid tool for the assessment of TB knowledge among foreign-born individuals, and a contribution to improve TB prevention and control.

References
1. World Health Organization (2020) Global Tuberculosis Report 2020. Geneva: World Health Organization
2. StopTB Partnership/ World Health Organization (2015) Global plan to end TB. The paradigm shift 2016-2020. StopTB Partnership. Geneva: World Health Organization
3. Global fund advocates network (2018) TB key population and the Global Fund's sixth replenishment: why key populations need a fully funded Global Fund and why the Global Fund needs fully engaged tb communities. Available: https://www.globalfundadvocatesnetwork.org/tb-key-populations-and-the-global-funds-sixth-replenishment/. Accessed 12 September 2021.
4. Comune di Ferrara (2019) Available: https://servizi.comune.fe.it/234/gli-stranieri-nel-comune-di-ferrara. Accessed 30 May 2020.
5. Di Nuzzo M, Trentini A, Grilli A, Massoli L, Biagi E, Maritati M, Contini C (2018). Extrapulmonary tuberculosis among immigrants in a low-TB burden and high immigrant receiving city of northern Italy. J Infect Dev Ctries 12: 73-79.
6. World Health Organization (2008) Advocacy, communication and social mobilization for TB control: a guide to developing knowledge, attitude and practice surveys. Geneva: World Health Organization
7. Launiala A (2009) How Much Can a KAP Survey Tell Us about People Knowledge, Attitude, and Practice? Some Observations from Medical Anthropology Research on Malaria in Pregnancy in Malawi. Anthropol Mat J 11: 1-13.
8. Matsumoto-Takahashi EL, Tongol-Rivera P, Villacorte EA, Angluben RU, Jimba M, Kano S (2015) Patient Knowledge on Malaria Symptoms Is a Key to Promoting Universal Access of Patients to Effective Malaria Treatment in Palawan, the Philippines. PloS one 10: e0127858.
9. Rana M, Sayem A, Karim R, Islam N, Islam R, Zaman TK,Hossain G (2015) Assessment of knowledge regarding tuberculosis among non-medical university students in Bangladesh: a cross-sectional study. BMC Public Health 15: 716.
10. Rattray J, Jones MC (2007) Essential elements of questionnaire design and development. J Clin Nurs 16: 234-243.
11. Shakila Thangaratinam MRCOG, Charles WE, Redman MD FRCOG FRCS (2005) The Delphi technique. TOG 7: 120–125.
12. Fan Y, Zhang S, Li Y, Li Y, Zhang T, Liu W, Jiang H (2018) Development and psychometric testing of the Knowledge, Attitudes and Practices (KAP) questionnaire among student Tuberculosis (TB) Patients (STBP-KAPQ) in China. BMC Infect Dis 18: 213.
13. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 25: 3186-3191.
14. Tavakol M, Dennick R (2011) Making sense of Cronbach's alpha. Int J Med Educ 2: 53–55.
15. Jolliffe IT, Cadima J (2016) Principal component analysis: a review and recent developments. Philos Trans A Math Phys Eng Sci 374: 20150202.
16. Linstone HA (1978) The Delphi technique. Handbook of Futures Research. In J Fowlers edition. Westport, CT: Greenwood Press 271–300 p.
17. Niederberger M, Spranger J (2020) Delphi Technique in Health Sciences: A Map. Front Public Health 8: 457.

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