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Original Research Article

An evidence-based tuberculosis patient's nutrition assessment tool and intervention guidelines for DOTS providers: a modified Delphi study

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ABSTRACT

Background: An individual's nutritional state is an indicator of their overall health. Poor nutrition, under nutrition, vitamin deficiency and protein energy malnutrition a form of nutritional problems. In low and middle-income countries, the linkage between infectious diseases such as tuberculosis and under nutrition is critical to public health. Thus, the current study aims to explore the DOTS Providers' concerns and develop evidence-based tuberculosis patient's nutrition assessment tool and intervention guidelines for DOTS providers, which can be quick and easy to assess.

Methods: A modified Delphi process was used to develop the nutrition assessment tool and intervention guidelines through mixed-method approach. Three rounds of the Delphi process were carried out via email, with a letter requesting to participate in the Delphi process.

Result: An in-depth interview schedule was conducted to extract themes and subthemes generating an item pool in the initial phase. The main themes identified were Perception of disease, TB cure, Association of under nutrition and TB management, Problems or difficulties encountered, Counsel, Assessment and intervention. Quantitative data analysis was performed manually by calculating the content validity index (CVI). The CVI was found to be >80% for all the items with I-CVI≥0.8 and S-CVI≥0.9. All the items were considered very essential with a score of 1.

Conclusions: The assessment tool should be subjected to other levels of evaluation that measures the suitability of the tool and interventional guidelines for the intended field.

Keywords: Nutrition assessment tool, TB patients, Health workers

INTRODUCTION

Tuberculosis (TB) is a top infectious killer disease worldwide, claiming a total of 1.5 million deaths in 2020 and an estimated 10 million people sick. Nearly 2 billion people are infected with tuberculosis, approximately 1/4th of the world's population and the second leading infectious killer disease after COVID-19. Tuberculosis spreads from person to person and can move across borders. Overcrowding, bad ventilation and malnutrition are the known factors in disease transmission. TB is present in almost all the countries in the world and can affect all the age groups.[1,2] Almost one-fourth of the world's population is infected with M. tuberculosis agent. TB is curable and preventable. About 85% of people who develop TB can be successfully treated with suitable drug regimens. Risk factors such as unhealthy diet, substance abuse namely alcohol, tobacco, weed, and sedentary lifestyle are the bridge to sickness among healthy individuals.[3]

In addition to all this, nutritional problem is also a major public health problem in developing countries. Nutritional status is a measure of the health condition of the individual. Poor nutrition, under nutrition, vitamin deficiency and protein energy malnutrition a form of nutritional problems under a broad term called malnutrition. Those at highest risk for under nutrition are older people who are hospitalized or living in care homes, people on a low income or who are socially isolated, people with chronic disorders, and those recovering from serious illness or condition, particularly a condition that affects their ability to eat and digest. The linkage between under nutrition and infectious diseases like tuberculosis is of crucial importance to public health in low-middle-income countries. These linkages were noted more than a century ago and have been strengthened by evidence from ecologic, observational, and experimental studies. Nevertheless, every country in the world witnesses a level of nutritional issues that constitute a serious public health risk. The government of India has been making efforts through multiple programmes and policies to improve the health situation of the people, but the result review has limited acceptance as more milestones to be attained.[4]

Malnutrition should be considered and treated as an additional disease, as it has been shown to worsen clinical outcomes and to increase morbidity, mortality and complication rates causing additional expenditure to every individual. Nutritional problems are preventable and mostly reversible with early assessment, diagnosis, and intervention. It often remains undetected due to a lack of knowledge, awareness, and clinical protocols to identify and treat the problem.[5] The identification of malnutrition has typically been based on anthropometric, biochemical, and physical parameters among others. However, there is currently no universally accepted gold standard for assessing or evaluating the nutrition status of people. A nutritional screening tool plays an important role in identifying the nutritional condition, systematically through a direct approach. A health professional establishes a special plan as a nutritional care plan in diagnosing, monitoring, and implementing the necessary need-based care to overcome the nutritional deficiencies among patients with chronic illness.[6,7] To improve the overall outcomes from nutritional treatment it is necessary to select patients with overt malnutrition and those at most risk of developing nutritional deficiencies. An approach to address under nutrition should start with the screening of all patients on admission, proceeding to a detailed assessment of nutritional status in those found to be at increased risk. Patients who are identified as malnourished or at nutritional risk should undergo periodic assessments with suitable tools to plot improvement or worsening conditions. Appropriate nutritional intervention is to be administered to the individual patients depending on the condition categorised.[8,9] The majority of studies show that there is a bidirectional relationship between nutrition and tuberculosis by which both are risk factors for each other. Hence the researcher felt to explore the DOTS Providers' concerns & develop evidence-based tuberculosis patient's nutrition assessment tools and intervention guidelines.

Objectives

Objectives of current study were; to explore the DOTS providers concerns involved in nutritional assessment and interventional guidelines for tuberculosis patients and to develop evidence-based tuberculosis patient's nutrition assessment tool and intervention guidelines for the DOTS providers.

METHODS

Study design and setting

A mixed method approach with a modified Delphi process was used to develop the evidence-based tuberculosis patient's nutrition assessment tool and intervention guidelines at the urban primary health centre (UPHC), Rishikesh, Dehradun dist. Study was conducted during September 2021 to March 2022, after obtaining prior permission from concerned authority. The qualitative phase was conducted first, followed by a modified Delphi process.

Study participants

Health workers trained under RNTCP/NTEP to administer DOTS for TB patients. It includes (ASHA, Anganwadi workers, TB Health visitor, Community health officer, Male and female health workers) were included as study participants.

Data collection and analysis

Face-to-face in-depth interviews were conducted among 20 Health workers selected with a purposive sampling technique. Permission was obtained from the medical officer, UPHC, Rishikesh, for conducting data collection of the phase-I Qualitative approach with a validated semi-structured questionnaire. The inclusion criteria for the participants included health workers involved in DOTS therapy, trained under RNTCP/NTEP, administering DOTS therapy on a day-to-day basis, and consented to participate in the study. However, health workers not willing to participate and not directly involved in DOTS therapy were excluded.

Phase I: qualitative approach

In this step, the researcher first developed a semi-structured interview schedule for DOTS providers to explore the concerns involved in nutritional assessment for tuberculosis patients. The in-depth interview schedule included the experiences of the DOTS providers about their thoughts on nutrition and tuberculosis (TB), the importance of nutrition status in TB cure, witnessing digestive problems after beginning a DOTS regimen, challenges faced when examining TB patients, and

counselling patients to improve nutrition status and continue the treatment regimen. Each participant's session lasted roughly 30 to 35 minutes, with previous permission obtained from the medical officer. Twenty healthcare professionals were interviewed after obtaining written consent from the research setting and DOTS providers. Participants denied having their words recorded, thus the textual versions are preserved verbatim. The verbatim was recorded on an A4 sheet. Key data summarization was done with each DOTS provider followed by 1st and 2nd order coding. In the current study, the researcher has maintained and assured the rigor and trustworthiness according to Lincoln and Guba's framework.[11] Some probing was also used during interviews to clarify whether the interpretation was correct. Theme extraction was done by read-reread method to extract the themes and sub-themes under expert guidance, and no software was used (Table 2). The extracted themes were further helpful in the development of evidence-based tuberculosis patients' nutritional assessment for the DOTS providers.

Phase II: quantitative approach

The next phase entailed developing an evidenced based tuberculosis patient's nutrition assessment tool and intervention guidelines for the DOTS providers. The nutrition assessment tool was developed from the ideations of the explored content gathered from the in-depth interview schedule. The tool was developed with the understanding that, prompt nutritional assessments and high-quality care were essential for TB patient classification and health promotion. The initial step of tool designing, and development was the preparation of content based on an exploration of the DOTS provider's concerns related to nutritional assessment and interventional needs for TB patients. DOTS providers were interviewed in depth related to their concerns and then the rough draft was prepared.

Literature review and item pool generation

An extensive review of literature is an important component of the tool in the research process. Approximately 120 studies were explored, but after reading the titles and abstract, most of the studies were rejected based on required criteria. Finally, 23 articles reached saturation. Various research articles associated with the prevalence of Tuberculosis, the importance of nutrition in tuberculosis, the perception of DOTS providers on nutrition needs and assessment among tuberculosis patients were searched to gather data. An item pool was generated based on a review of the literature in order to construct a research tool. National and international online and offline journals and available nutrition assessment tools for chronically ill patients, nutritional care, and support for TB patients: guidance document (MOHFW) and malnutrition assessment tools were used to collect and construct the items for evidence-based tuberculosis patients' nutrition assessment tool and intervention guidelines.[1] Based on this literature, an initial item pool was constructed, and the first draft of the tool was prepared for validation.

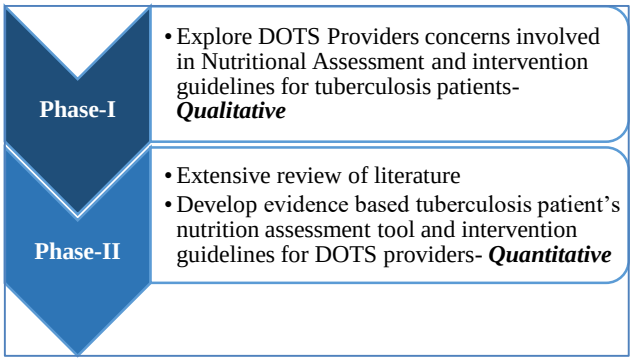

Figure 1: Study methodology.

Modified Delphi process

After developing the first draft of the item pool it was given for expert validation. An expert is considered as a person who possesses expertise and knowledge in the field, and who has time and willingness to participate in study. Initially request was sent to 18 experts from the multidisciplinary field of Community health and family medicine, TB nodal officer, nursing experts, dietician, and senior treatment supervisor via email. The first contact with the selected experts was made through mail in which a request letter was sent inviting for Delphi method along with the study title. Twelve experts agreed to be on the panel and guide for developing a tool. The multiround survey technique that structures group communication to achieve consensus among a panel of experts was used for the validation process, since the initial pool of items was already prepared by the researcher, the first round of unstructured open-ended questionnaire feedback similar to that of a classic Delphi process was omitted. After confirmation mail, a preliminary draft of the tool and evaluation criteria for validation was shared with experts. The panel members were requested to evaluate the items with degree of relevance and essential of items collected. 11 Experts were asked to give their ratings as 1= not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant followed by 1= not essential, 2=essential, 3=very essential. The first round was completed in three weeks of time duration and all the 12 experts gave their valuable feedback. There was maximum modification required as per experts' opinion in the domains and items constructed. Experts suggested adding a few essential items which may be important for the nutrition assessment tool. During the second round, all the modification was done, and the tool was reconstructed as per panel suggestion and resubmitted to experts at the same time for the second round of Delphi. Among 12 experts in the panel, 9 experts gave their feedback in 3 weeks, but the remaining 3 experts delayed due to their busy schedules. A constant requisition and reminder were sent via email for their valuable feedback. In response to the remainder of the

mail and telephonic conversation, one expert replied after 2 weeks. The evaluation criteria were similar to the first round of Delphi, in which the degree of relevance and essential should be scored. Feedback was to modify some of the items and replace them with simple verbs, which participants felt were easy to understand while doing the assessment. Since the items are to be finalized after all modifications and the final draft of the assessment tool, a last round of Delphi was conducted via E-mail as per expert's opinion. Following with same evaluation criteria, in the last round of Delphi, there were not many comments given by the expert panel, however only 4 experts replied by mail rest responded with "no more suggestion, comments remain same as previous evaluation".

Statistical analysis

Quantitative data analysis was performed manually by calculating the content validity index (CVI).[15] Items with highly relevant and quite relevant agreement scores by the experts were coded as 1, and items having somewhat relevant and not relevant agreement scores were coded as 0. Item level content validity (I-CVI) and scale level content validity (S-CVI) were calculated based on relevance rating of expert's values of I-CVI higher than 0.8 and S-CVI higher than 0.9 were having good content validity.

RESULTS

Qualitative phase

The basic demographics are shown in (Table 1). There were 20 DOTS providers in this study to explore the concerns in nutritional assessment and interventional guidelines for TB patients. Among them 100.0% were female and 40.0% and 20.0% of them completed their diploma, 12th and 10th education respectively.

40.0% and 20.0% of DOTS providers were ANM (SC), ASHA workers, and Anganwadi workers. 60.0% of them were aged less than 30 years. Out of 20 DOTS providers, 40.0% were from rural areas and 60.0% were from urban areas. All DOTS providers have been appointed as DOTS providers under RNTCP and have more than 2 years of experience as active DOTS Providers respectively. 40.0% of our DOTS providers have attended training programs under TB management. The average income of DOTS providers was less than 15.000 which is 40.0%, 15000-16000 is 40% and above 16000 is 20% respectively.

Quantitative phase

Major findings from modified Delphi process: Items were selected from the content and pooled together, and a preliminary draft was prepared for the first round of Delphi. There were 2-3 rounds of the modified Delphi process.[10] Maximum correction from the expert panel was for the first 2 rounds. since the initial pool of items was already prepared.

Table 1: Socio-demographic characteristic of DOTS providers (n=20).

Socio-demographic characteristics		N	%
Age (years)	Less than 30	12	60
	More than 30	8	40
Gender	Female	20	100
	Male	0	0
Education	10th	4	20
	12th	8	40
	Diploma	8	40
	Graduate	0	0
	Postgraduate	0	0
	Others	0	0
Income (Rs.)	<15000	8	40
	15000-16000	8	40
	>16000	4	20
Occupation	Anganwadi worker	4	20
	ASHA	8	40
	CHO	0	0
	ANM (CHC)	0	0
	LHV	0	0
	ANM (SC)	8	40
	TB supervisor	0	0
Type of family	Nuclear	16	80
	Joint	4	20
	Extended	0	0
Religion	Hindu	20	100
	Muslim	0	0
	Christian	0	0
	Other	0	0
Marital status	Unmarried	4	2
	Married	16	8
	Separated/divorced	0	0
	Widow/ widower	0	0
Habitat	Urban	12	60
	Rural	8	40
	Hilly areas	0	0
Have you been appointed as DOTS provider under RNTCP	Yes	20	100
	No	0	0
What is your experience as active DOTS provider?	6-12 months	0	0
	12-24 months	0	0
	More than 24 months	20	100
Have you attended any training program regarding nutritional needs and TB management?	Yes	8	40
	No	12	60

During the first round of Delphi feedback expert's suggestion was to remove the main domains and make it simple with a direct heading (sub-domain) considering the study participants as basic health workers (ASHA, Anganwadi worker, ANM, Sub centre worker).

Table 2: Thematic analysis of findings from face-to-face interview.

Themes	Sub-themes
Perception of disease	Major social health problem, Spreads from person to person, High mortality rate.
TB cure	Suppressed immune system, Treatment and follow-up, Effective strategy, Malnutrition-A major role in TB cure, Essential nutrition-As supportive treatment of TB.
Association of under nutrition and TB management	Under nutrition worsen TB symptoms, improve drug absorption and reduce drug complication, Food digestive issues, Balance diet, Protein and calories rich diet, Effectiveness of pre-meal and post-meal.
Problems or difficulties encountered	Negative emotional distress, Patient psychological problems, Lack of co-operation-patient, co-health worker, social stigma, discontinue medication and fail to follow up, feeling of over burden, Lack of resources, Recording and reporting
Counsel	TB-patients, Family, Patient attender, Health worker
Assessment and intervention	Easy and quick to use, Recognizing and treatment complication, Simple and basic information, Oriented language, Accessible and approachable, Less time consumable.

Table 3: Agreement of the experts concerning items and domains of nutritional assessment tool and interventional guidelines based on the CVI (round 1).

Main domain	Sub-domain	Item no.	I-CVI	S-CVI	Essential
Subjective parameters	Disease and treatment related history	1	1	-	1
		2	0.727273		1
		3	1		1
		4	1		1
		5	0.545455		0.63
		6	0.545455		0.63
	Nutritional oriented history	7	0.727273	0.736842	1
		8	1		1
		9	0.545455		1
		10	1		1
		11	0.636364		0.63
		12	0.818182		1
Objective Parameters	Anthropometric measurement	13	0.818182	-	1
		14	1		1
		15	0.818182		1
		16	0.727273		1
		17	0.636364		1
		18	0.545455		0.81
		19	0.454545		0.45
		20	0.646587		0.72

Regarding intervention guidelines as educating material, experts' opinion was not to separate from tool, and complex information does not benefit the DOTS provider while educating TB patients.

Considering their qualification and knowledge level items were rephrased and restructured to make it simple to understand. Most of the responses from experts on I-CVI needed modification. Hardly items no 1, 3, 4, 8, 10, 14 was highly relevant followed by 12, 13, 15 quite relevant and 2, 5, 6, 7, 9, 11, 16, 17, 18, 19, 20 items were somewhat and not relevant in the context of experts hence reformulated as per suggestion. The overall S-CVI was 0.73. As per experts, items no 1, 2, 3, 4, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17 was very essential followed by essential and not essential. During the second round (Table 4) of Delphi feedback, the major correction was to change the wordings and use simple verbs for language understanding and for scoring to be made direct (as the present tool made).

No item was deleted or excluded but instead modified as per the expert's suggestion. All the items n=20 was ≥0.8 in I-CVI except three items 17, 19, and 20 and overall S-CVI was=0.9. Most of the items were very essential and only a few belonged to the essential category which was ≥0.8 and none was in the not essential category. Since there was little more modification required with some items hence researcher wanted to proceed with one more round of surveys with experts.

For the third round of Delphi feedback, the expert's comments were nil apart from 2 experts suggested to add more socio-demographical factors (Table 5).

Minor corrections were required in a few items to make it highly relevant and essential, hence modification was made. All the items were made highly relevant in I CVI with an overall S-CVI of 0.98 and very essential with 1.

As per experts' suggestions and review of the literature, with various modifications, the tool was developed with 20 items, listed alphabetically with reference and socio-demographical factors of TB patients.

Table 4: Agreement of the experts concerning items and domains of nutritional assessment tool and interventional guidelines based on the CVI (round 2).

Domain	Item no.	.Item	I-CVI	S-CVI	Essential
Nutritional assessment tool	1	a	1	0.9042	1
	2	b	1		1
	3	c	1		1
	4	d	1		1
	5	e	0.909091		1
	6	f	1		1
	7	g	1		1
	8	h	1		1
	9	I	1		1
	10	j	1		1
	11	k	1		1
	12	l	0.818182		0.81
	13	m	1		1
	14	n	1		1
	15	o	1		1
	16	p	1		1
	17	q	0.727273		0.81
	18	r	0.818182		0.81
	19	s	0.727273		0.81
	20	t	0.727273		0.81

Table 5: Agreement of the experts concerning items and domains of nutritional assessment tool and interventional guidelines based on the CVI (round 3).

Domain	Item no.	Item	I-CVI	S-CVI	Essential
Nutritional assessment tool	1	a	1	0.9854	1
	2	b	1		1
	3	c	1		1
	4	d	1		1
	5	e	1		1
	6	f	1		1
	7	g	1		1
	8	h	1		1
	9	I	1		1
	10	j	1		1
	11	k	1		1
	12	l	0.909091		1
	13	m	1		1
	14	n	1		1
	15	o	1		1
	16	p	1		1
	17	q	0.909091		1
	18	r	1		1
	19	s	0.909091		1
	20	t	0.909091		1

DISCUSSION

The quality of patient care can be improved by the readily available evidence-based tuberculosis patient's nutritional assessment tool and interventional guidelines. The present study has been conducted for the development and validation of a nutrition assessment tool to measure the nutritional status of TB patients in selected health centres. The study was carried out in two different phases' qualitative and quantitative approaches to explore the DOTS Providers' concerns & develop evidence-based tuberculosis patient nutrition assessment tools and intervention guidelines. The qualitative phase was carried out to Exploration of the DOTS Provider's concerns involved in Nutritional Assessment and intervention guidelines for tuberculosis patients and an Extensive review of literature to develop an evidence-based tuberculosis patient nutrition assessment tool and intervention guidelines for DOTS providers. A similar study was conducted using a mixed-methods approach combining qualitative and quantitative techniques. The goal of the study was to develop and validate palliative care nursing theory standards so that patients with advanced cancer might receive better palliative care.[12]

An extensive review of the literature was conducted for item pool generation and construction of research tools followed after in-depth interview schedule with DOTS providers in selected health centres. A study was conducted in a tertiary care hospital in Uttarakhand with similar material and method. Eight oncology nurses participated in a focus group discussion to extract the themes, and a thorough literature analysis was then done on these themes to explore the most recent pieces of evidence for item pool development.[13] The modified Delphi technique was used for the tool validation process among the selected expert panel since the initial pool of items was already prepared by the researcher after an extensive review of the literature was performed. A similar study, utilizing a modified Delphi technique to reach consensus, a study was done to determine the critical structures, processes, outcomes, and difficulties of nursing practice in foetal care.[14] The findings from the present study demonstrated that the nutritional assessment tool consists of 20 items with I-CVI ≥0.8 and overall S-CVI ≥0.9 which is considered to be valid. Most of the items were very essential and only a few belonged to the essential category which was ≥0.8. A study was conducted in the tertiary care hospital of Uttarakhand, to develop and validate neutropenic nursing care (NNC) bundles with similar findings. The I-CVI was found to be >0.8 and S-CVI >0.9 for the final NNC bundle.[13,14]

Implications

The tool can be used to evaluate TB patients' nutritional status in clinical setting or in the community area. All healthcare professionals, including physicians, community health workers, dieticians, ASHA employees, sub centre staff, and Anganwadi workers, may find the tool beneficial. The assessment tool should be subjected to other levels of evaluation, such as the psychometric aspect of the validation, reliability that measures the suitability of the tool and interventional guidelines for the intended field.

Limitations

In the present study the combination of search strategies employed to maximize finding eligible articles for literature review (keywords, Boolean operators, and manual search) some relevant studies could have been missed. The study selection criteria of including only those articles that are published in English may also have limited the search.

CONCLUSION

This study focused on developing a tool to measure the nutritional status of TB patients which can be quick and easy to assess along with additional demographic and medical variables. The topic chosen for the study is of great significance, interest, and relevance to the nursing profession.

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