

# Development, Translation and Validation of COPD Awareness Questionnaire (COPD-AQ): A Pilot Study

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## ABSTRACT

**Background:** The current study sought to create, translate, and pilot a culturally relevant COPD Awareness Questionnaire (COPD-AQ) to measure awareness of the disease among Indian patients in the Nilgiris district. **Materials and Methods:** It developed a 20-item questionnaire through a four-stage process: item creation through literature review, expert validation, translation into Tamil and back-translation, and field testing. The final questionnaire measured two constructs - understanding and managing COPD. 60 participants were included in the pilot. **Results:** Item-level and scale-level content validity was established with CVI  $\geq$  0.83 and CVI/Ave  $\geq$  0.90, respectively. The questionnaire had internal consistency of  $\alpha = 0.860$ . Test-retest reliability was determined based on Pearson's correlation coefficient ( $r = 0.932$ ), Cohen's kappa ( $\kappa = 0.714$ ), and Intra-Class Correlation (ICC = 0.894), all of which showed good reliability. **Conclusion:** COPD-AQ is valid, reliable, culturally important, simple to use, and good for raising COPD awareness among Tamil-speaking people.

**Keywords:** Community health research, COPD, Patient awareness, Psychometric evaluation, Validity and reliability.

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## INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a heterogenous lung condition which is characterized by persistent respiratory symptoms and airflow limitation, due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases (Venkatesan, 2025). At a global level, the prevalence of COPD in 2020 across both males and females was estimated to be 10.6%, which translates to 480 million cases. Epidemiology models have estimated that the number of COPD cases are to increase by 112 million to a total of 592 million by 2050 (9.5% of the total population aged  $\geq 25$  years), a relative increase of 23.3% from 2020 to 2050 (Boers *et al.*, 2023). Evidence from India suggested that COPD prevalence increases with age and exponentially after 30 years of age (Verma *et al.*, 2021).

Studies have shown that patient education about their condition and patient self-management are key elements to successful treatment of COPD as they can reduce hospitalizations and

improve overall quality of life (Omachi *et al.*, 2010; Thakrar *et al.*, 2014). A Swedish study concluded that patients with COPD required more knowledge about their condition in order to take an active role in their care, which led to better adherence to treatment plans and improved health outcomes (Sandelowsky *et al.*, 2019). Poor knowledge about COPD has also been shown to be a significant risk factor for anxiety and depression in COPD patients (Zhang *et al.*, 2014). A number of instruments are available to assess disease-specific health status which are reliable, valid and widely used in clinical practice, but they fail to focus on aspects that are unique to our study population such as exposure to biomass fuels and tea dust. Instruments such as COPD-Q and BCKQ lack components that address emotional aspects and adherence to inhaler therapy (Maples *et al.*, 2010; White *et al.*, 2006). The reliability and validation results of COPD Assessment Test are derived from the USA alone due to the availability of the data at the moment (Jones *et al.*, 2009). To the best of our knowledge, no previous studies have evaluated the level of awareness of COPD in the Nilgiris population which has a high number of COPD cases.

The objective of our study was to develop, translate and validate a questionnaire to evaluate the disease awareness in patients with COPD in our setting. The developed questionnaire was to be translated to Tamil and back-translated as it is intended to be self-administered, making it more comprehensible to the Nilgiris



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population. Our ultimate goal was to understand if people in Nilgiris district of India were aware of their illness, risk factors and its management.

## MATERIALS AND METHODS

### Sample

The study employed convenience sampling and recruited 72 participants diagnosed with COPD from GMCH, Ooty. This study was approved by Institutional Ethics Committee (IEC) of Government Medical College and Hospital, Nilgiris (Ref. No.: 12/IEC/ICMR; Approval No.: IRBGMC0072). Patients of either sex aged > 18 yrs diagnosed with COPD with/without other comorbidities were included and those with history of psychiatric illness were excluded from the study. Pre-testing and cognitive interview were conducted in 12 participants and 60 participants were included to conduct the pilot study after consent was obtained. Various academic experts and physicians were approached for validation.

### Procedure

The development of the questionnaire occurred in four steps:

#### Step 1: Item generation

After extensive review, the following two areas of knowledge were generated: 1. Understanding COPD with 14 items and 2. Management of COPD with 6 items. Validated tools assessing knowledge regarding a broader context of COPD were also reviewed (Hyland *et al.*, 2006; White *et al.*, 2006). Three questions (Q4, Q10 & Q12) were included with the correct answer being 'No', which allowed us to assess the accuracy of patient responses, as a validity check. Participants received a score of 1 for each correct answer, and 0 for each incorrect answer. A self-administered data collection form was designed with basic demographics and socioeconomic status (Modified Kuppusamy scale (Mandal & Hossain, 2024)).

#### Step 2: Construction and Validity of Questionnaire

The instrument is developed with 20 items in total. The instrument was subjected to content experts (4 senior academic experts with >20 years of experience in pulmonary research; 3 General Physicians; 1 Consultant Pulmonologist and 1 Senior Nurse) to rate the instrument. The experts were asked to rate the relevancy of each item to the respective domain in the questionnaire using a Likert Scale (1- Not relevant; 2- Somewhat relevant; 3- Quite relevant; 4- Highly relevant) and were asked to review each domain and independently to score the relevancy level of each item.

#### Step 3: Translation of the Questionnaire

The questionnaire was subjected to translation by implementing a multi-step methodology developed by Valmi D Sousa – forward

translation and backward translation (Sousa & Rojjanasrirat, 2011). Expert panel review (Perinetti, 2018) with two subject experts & healthcare experts followed by pre-testing.

#### Step 4: Field testing of the questionnaire

A total of 60 participants were recruited and administered with COPD-AQ during their first visit. This data was used for assessing the validity and internal consistency ( $\alpha$ ). Following the first visit, COPD-AQ was again administered to the same set of participants after a time period of three weeks (second visit). 13 participants out of 60 failed to complete their second visit. So, data from 47 participants were taken up for evaluation of test reliability.

### Statistical Analysis

Demographic information of the patients was collected and entered in Excel. Data analysis was conducted using SPSS, Version 27. To evaluate the internal consistency of the questionnaire, Cronbach's alpha was calculated, with a threshold of  $\alpha \geq 0.70$  considered acceptable (Vishwas *et al.*, 2017). For test-retest repeatability, Cohen's Kappa ( $\kappa$ ), Pearson's correlation coefficient ( $r$ ) and Intra-Class Correlation (ICC) were employed. A  $\kappa \geq 0.60$  was considered acceptable for reliability, while a  $r > 0.70$  was taken as an acceptable level of test-retest reliability (Mishra & Nitika, 2016; Sedgwick, 2012). ICC value  $> 0.75$  was regarded to be acceptable.

## RESULTS

### Phase I: Content Validity Analysis:

The Content Validity Index (CVI) was determined both at the Item-level (I-CVI) and the Scale-level (S-CVI) (Department of Medical Education, School of Medical Sciences, Universiti Sains Malaysia, MALAYSIA & Yusoff, 2019). The I-CVI was calculated based on the ratio of experts (out of 9 total) who rated each item a 3 or 4 to the total number of experts (Polit *et al.*, 2007). The CVI cutoff is 0.83 (Lynn, 1986). CVI analysis on understanding and management of COPD domains are described in Tables 1 and 2, and demographic characteristics of the study participants are listed in Table 3. Responses for the individual items in COPD-AQ attained mean score values ranging between 0.05-0.88 with the Standard Deviation (SD) 0.22-0.54 and the median values from 0 to 1. The detailed descriptive statistics of COPD-AQ scores are listed in Table 4.

### Phase II: Validity & Internal Consistency

The Validity was analysed using Cronbach alpha ( $\alpha=0.860$ ) and Internal Consistency using Pearson's correlation coefficient ( $r=0.932$ ) & Cohen's Kappa ( $\kappa=0.714$ ). The individual items and domains are provided in detail from Tables 5 and 6.

## Intra-Class Correlation (ICC)

Test-Retest reliability was estimated using ICC, based on two-way mixed effect model for absolute agreement. The ICC obtained for total score was 0.894 (95% CI 0.494-0.962)  $p < 0.001$ , suggesting good reliability.

## DISCUSSION

Due to a greater cultural diversity, existing validated tools DACQ and BCKQ might not be suitable for use in our population, as a result of limited resources and linguistic barrier (Banville *et al.*, 2000). Hence the need for this study is to develop, translate and validate a culturally appropriate COPD awareness questionnaire

**Table 1: CVI on Understanding of COPD Relevance.**

	R1	R2	R3	R4	R5	R6	R7	R8	R9	Experts in agreement	Items CVI	U/A
Under Standing of COPD												
Item1	1	1	1	1	1	1	1	1	1	9	1.00	1
Item2	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 3	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 4	1	0	1	1	1	1	1	1	1	8	0.88	1
Item 5	1	1	1	1	0	1	1	1	1	8	0.88	1
Item 6	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 7	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 8	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 9	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 10	1	1	1	1	1	0	1	1	1	8	0.88	1
Item 11	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 12	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 13	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 14	1	1	1	1	1	1	1	0	1	8	0.88	1
										S-CVI/Ave	0.96	1
Proportion	1.00	0.92	1.00	1.00	0.92	0.92	1.00	0.92	1.00	S-CVI/U/A		1

**Table 2: CVI on Management of COPD Relevance.**

	R1	R2	R3	R4	R5	R6	R7	R8	R9	Experts in agreement	Items CVI	U/A
Management of COPD												
Item 15	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 16	1	1	1	1	1	1	1	1	1	9	1.00	1
Item 17	0	1	1	1	1	1	1	1	1	8	0.88	1
Item 18	1	1	1	1	1	1	1	0	1	8	0.88	1
Item 19	1	0	1	1	1	1	1	1	1	8	0.88	1
Item 20	1	1	1	1	1	1	1	1	1	9	1.00	1
										S-CVI/Ave	0.94	
Proportion	0.83	0.83	1.00	1.00	1.00	1.00	1.00	0.83	1.00	S-CVI/U/A		1

\*R: Rater.

**Table 3: Demographic distribution of the participants.**

Parameter	Classification	N	%
Age	< 50 years	6	10
	50-59 years	15	25
	60-69 years	31	51.7
	≥ 70 years	8	13.3
Gender	Male	42	70
	Female	18	30
Living condition	Own Home	21	35
	Rental Home	39	65
Marital status	Married	47	78.3
	Widowed	13	21.7
BMI	<18.5	14	23.3
	18.5-24.9	16	26.7
	25.0-29.9	23	38.3
	30.0-34.9	7	11.7
Sleep disturbance	Yes	57	95
	No	3	5
Family history of respiratory disease	Yes	23	38.3
	No	37	61.7
Smoking history	Never smoked	21	35
	Ex smoker	14	23.3
	Current smoker	25	41.7
Smoking product*	Beedi	28	46.7
	Cigarette	11	18.3
Pack years*	10-20 pack years	1	1.7
	21-30 pack years	11	18.3
	31-40 pack years	23	38.3
	41-50 pack years	4	6.7
Smokeless tobacco product	Yes	36	60
	No	24	40
Education	Primary school	33	55
	Middle school	19	31.7
	High school	8	13.3
Occupation	Elementary occupation	31	51.7
	Plant and machine operators	14	23.3
	Craft and related trade workers	7	11.7
	Skilled workers and shop and market sales workers	8	13.3
Monthly Income	≤10702	46	76.7
	10,703-31977	14	23.3
Socio-economic	Upper Lower	47	78.3
	Lower Middle	13	21.7
Alcoholic history	Non alcoholic	22	36.7

Parameter	Classification	N	%
	Past alcoholic	7	11.6
	Current alcoholic	31	51.7
Exacerbation history (in last 6 months)	0 to 1	24	40
	>1 or >2	36	60

\*Applicable only for current and former smokers.

**Table 4: Descriptive statistics for individual items of COPD-AQ.**

Item	Mean	Median	Std deviation	Item-total correlation
Q1	0.68	1.00	0.469	0.273**
Q2	0.60	1.00	0.494	0.672**
Q3	0.58	1.00	0.497	0.799**
Q4	0.60	1.00	0.494	0.795**
Q5	0.52	1.00	0.504	0.355**
Q6	0.62	1.00	0.490	0.741**
Q7	0.58	1.00	0.497	0.799**
Q8	0.52	1.00	0.504	0.355**
Q9	0.58	1.00	0.497	0.799**
Q10	0.50	0.50	0.504	0.190**
Q11	0.58	1.00	0.497	0.799**
Q12	0.73	1.00	0.446	0.489**
Q13	0.57	1.00	0.500	0.457**
Q14	0.52	1.00	0.504	0.238**
Q15	0.33	0.00	0.475	0.342**
Q16	0.43	0.00	0.500	0.299**
Q17	0.25	0.00	0.437	0.042**
Q18	0.05	0.00	0.220	0.271**
Q19	0.88	1.00	0.324	0.069**
Q20	0.23	0.00	0.427	0.116**

\*\* Significance,  $p < 0.01$ .

considering the targeted population. The Questionnaire's conceptual framework identified the following two domains: (i) 14 items assessing the "Understanding of COPD" (ii) 6 items related to 'Management of COPD' and the final instrument included 20 questions. The inclusion of the first domain is essential as it captures awareness about the disease, its risk factors, symptoms and general misconceptions while the second domain deals with the practical aspects such as vaccination, self- management practices and smoking cessation.

CVI is classified into two types: Item-level CVI (I-CVI) and Scale-level CVI (S-CVI). All 20 items attained an I-CVI score  $\geq 0.83$  and S-CVI/Ave values  $\geq 0.90$ , indicating excellent content validity. Following this, the questionnaire was translated using a continuous multi-step process proposed by Valmi D. Sousa, along with WHO guidelines for translation and cultural adaptation (Hyland *et al.*, 2006; Younan *et al.*, 2019). It was then pilot tested among the Tamil speaking population to ensure its

reliability. Cronbach's alpha for COPD-AQ was found to be 0.860, suggesting good reliability (Tavakol & Dennick, 2011). Test-retest reliability was assessed using Pearson's correlation coefficient and Cohen's kappa (Vishwas *et al.*, 2017). The results demonstrated a high positive correlation ( $r=0.932$ ) with an overall kappa value ( $\kappa=0.714$ ) proving that the developed tool performs consistently with a good agreement between individual items.

The strengths of this study include expert panel involvement for content validation and adherence to standard translation and validation methodologies. Care was taken to avoid absolute qualifiers such as "always" and "never," which may encourage guessing. Compared to the BCKQ with 65 items, this 20-item questionnaire remains comprehensive while being concise, improving response rates, accessibility and ease of responding to questions (White *et al.*, 2006).

One limitation in the development of COPD-AQ is that, only "Yes/No" options were provided and "Don't know" option was

**Table 5: Reliability analysis of individual items of COPD-AQ.**

Item	Cronbach alpha if alpha deleted	Pearson's coefficient of Correlation	Kappa
Q1	0.861	0.894	0.887
Q2	0.845	0.827	0.812
Q3	0.839	0.785	0.762
Q4	0.839	0.821	0.806
Q5	0.858	0.841	0.829
Q6	0.842	0.778	0.754
Q7	0.839	0.912	0.908
Q8	0.858	0.805	0.786
Q9	0.839	0.820	0.816
Q10	0.865	0.807	0.789
Q11	0.839	0.785	0.762
Q12	0.853	0.787	0.765
Q13	0.854	0.826	0.826
Q14	0.863	0.843	0.830
Q15	0.858	0.914	0.910
Q16	0.860	0.771	0.746
Q17	0.868	0.899	0.894
Q18	0.860	0.700	0.657
Q19	0.865	0.902	0.897
Q20	0.865	0.849	0.837

**Table 6: Reliability analysis of individual domains of COPD-AQ.**

Domain	Cronbach alpha	Pearson's coefficient of Correlation	Kappa
Understanding COPD	0.892	0.968	0.745
Managing COPD	0.770	0.959	0.863

not included, which could lead to response bias and a reduced discrimination between lack of knowledge and wrong belief. Further, multi-centre studies would be essential to support wider application of the questionnaire, verifying its usefulness in different centres.

The more the patients are aware of their disease, the more they actively participate in the treatment leading to improved therapeutic outcomes. Hence, the developed 20 item COPD-AQ is a versatile and locally adoptable instrument for use in cross-sectional studies, public health campaigns and outreach programs to assess the level of COPD awareness and tailor interventions accordingly.

## CONCLUSION

The questionnaire was clear, easy to administer, and relevant to the target population. It covered culturally sensitive risk factors like exposure to biomass fuels and tea dust, which are usually missing in available tools. COPD-AQ is a valid, reliable, and

locally applicable instrument appropriate for cross-sectional surveys and public health projects to enhance disease awareness and management in COPD patients among Tamil-speaking populations.

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## ABBREVIATIONS

**α:** Cronbach's Alpha; **AQ:** Awareness Questionnaire; **BCKQ:** Bristol COPD Knowledge Questionnaire; **CI:** Confidence Interval; **COPD:** Chronic Obstructive Pulmonary Disease; **COPD-AQ:** Chronic Obstructive Pulmonary Disease Awareness Questionnaire; **CVI:** Content Validity Index; **DACQ:** Disease

Awareness and Concerns Questionnaire; **GMCH**: Government Medical College and Hospital; **ICC**: Intra-Class Correlation; **I-CVI**: Item-Level Content Validity Index; **IEC**: Institutional Ethics Committee; **IRB**: Institutional Review Board; **κ**: Cohen's Kappa; **Q**: Question; **r**: Pearson's Correlation Coefficient; **S-CVI**: Scale-Level Content Validity Index; **S-CVI/Ave**: Scale-Level Content Validity Index Average; **SD**: Standard Deviation; **SPSS**: Statistical Package for the Social Sciences; **WHO**: World Health Organization; **yrs**: Years.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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