Original Article

The Manchester Cough in Lung Cancer Scale: The Development and Preliminary Validation of a New Assessment Tool

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Abstract

Context. Cough is a common distressing symptom in lung cancer patients. Its assessment is hampered by the lack of a validated scale to measure the complex cough experience in this population.

Objectives. To describe the development and preliminary validation of a scale to measure cough in lung cancer patients.

Methods. In the first phase, collection of qualitative data from patient interviews, a review of literature, and identification of noncancer cough scales resulted in the development of a pool of 30 items. This item pool was tested for appropriateness of content and breadth of coverage with 18 patients with lung cancer and 25 health care professionals. The second phase was the operationalization/phrasing of items. The final phase was the scale’s field testing with 139 patients, 49 of whom repeated the assessment after one week.

Results. The first phase led to the deletion of several items and the addition of four, resulting in a final scale for field testing of 21 items. In the field testing, the scale was decreased to 10 items, eliminating items on psychometric grounds. The final scale’s Cronbach alpha (internal consistency) was 0.86, item to total correlations ranged from 0.40 to 0.76, and test-retest reliability was high (intraclass correlation = 0.83).

Conclusion. We have developed a promising tool to assess cough in lung cancer, but this needs validation, and future studies should determine whether this is a sensitive and responsive tool. A fully validated tool can be used in the clinical
assess the assessment of cough in cancer patients, and as a unidimensional impact scale in the measurement of cough as an outcome in intervention studies. J Pain Symptom Manage 2012; 10:211. © 2012 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words
Cough, lung cancer, measurement, scale, assessment

Introduction
Respiratory symptoms are common in lung cancer and include cough, shortness of breath, and wheezing, which may be compounded in those with a history of smoking or continued smoking. Despite the clinical relevance of cough, a study showed less than a dozen journal articles in which cough was identified as a major outcome in clinical trials. This may be due, in part, to the lack of a valid outcome measure for cough. The studies that have been done show that cough is a symptom found in all stages and types of lung cancer and may respond to chemotherapy, radiation therapy, and palliative care measures.

Cough is one of the most common symptoms in cancer patients, with a prevalence of 47%–86% in lung cancer patients and 23%–37% in general cancer patients; it is also present in 38% of patients with advanced cancer. A longitudinal study of 100 patients with a variety of cancers showed that cough was common in 33.3%–42.9% of the sample over one year from diagnosis, although was reported to be less severe than breathlessness. Our work with lung cancer patients provided initial evidence of the considerable impact of cough on patients’ quality of life, with cough being described as distressing but receiving little attention from health professionals. We also have shown that cough potentially forms a cluster of symptoms together with breathlessness and fatigue, which we describe as a respiratory distress symptom cluster. Furthermore, in a study involving the use of hydrocodone for cough, severe cough interfered with breathing (72%), sleeping patterns (68%), and speech (64%). Other complications may include urinary incontinence, headaches, syncope, back pain, social disruptions, exhaustion, and incidental pain (from musculoskeletal strain or rib fractures).

Although there has been some guidance to aid the clinician in the investigation and management of cough, little attention has been paid to the assessment of cough generally. Subjective measures of cough have included patient diaries; visual analogue scales; a variety of investigator conceived cough-scoring scales (e.g., the Breathlessness, Cough, and Sputum Scale) for specific diseases, such as chronic obstructive pulmonary disease, that are not focused solely on cough; general health-related quality-of-life instruments (e.g., Sickness Impact Profile); and cough-specific health-related quality-of-life instruments (e.g., Cough Quality of Life Questionnaire [CQLQ], the Chronic Cough Impact Questionnaire [CCIQ], and the Leicester Cough Questionnaire [LCQ]). Whereas all of these instruments appear to have been useful in the studies cited, only the Breathlessness, Cough, and Sputum Scale, CQLQ, LCQ, and more recently, the CCIQ, have undergone extensive psychometric testing. None of these scales have been validated or used with lung cancer patients and often include items that are inappropriate for use in lung cancer patients (i.e., items such as “do you worry that your cough may indicate you have lung cancer?”). The assessment of cough has been hampered by the lack of well-validated and standardized tools and by their impracticality for routine clinical use, especially in relation to lung cancer. A review of the literature revealed that to date only one pilot study has attempted to develop a tool to assess the presence and severity of cough in this patient group. This scale has not been fully validated nor used in research or practice since. Furthermore, the limited amount of research investment in cough related to cancer also is highlighted in our recent systematic review.
which showed a limited number of studies in the assessment of cough.

**Aims and Objectives**

The overall aim of the study was to develop a valid and reliable measure to assess the frequency, severity, and quality-of-life aspects of coughing specifically in lung cancer patients. This instrument could be used to evaluate cough in lung cancer patients and aid in the early assessment and initiation of interventions for cough. In addition, this instrument could be used to detect changes resulting from symptom management approaches.

**Methodological Process**

A three-stage methodological process was adopted for the development of the cough assessment scale. This process, outlined below, is based on the guidance from Sprangers et al.\(^{20}\) on the development of quality-of-life scales and Rasch modeling to optimize the overall reliability and measurement precision of the instrument.\(^{21}\) Ethical approval for all phases of the process was obtained from a multisite Research Ethics Committee, the Ethics and Research Committee of the University of Manchester, and all the hospitals involved in recruitment.

**Phase 1: Generation of Issues/Items and Questionnaire Development**

The first stage of the methodological process was to develop a provisional pool of items for the scale from three data sources.

**Patient Interviews.** These data derived from the interviews with lung cancer patients recruited to two earlier qualitative studies, one specifically assessing the experience of cough in lung cancer patients,\(^{7}\) and the other focusing on the experience of a respiratory distress symptom cluster\(^{9}\) and the distress from symptoms in lung cancer.\(^{22}\)

**Existing Scales and Relevant Literature.** These data were obtained from existing scales that were identified from literature searches and the relevant literature on assessing cough. The scales that were reviewed included the preliminary Lung Cancer Cough Questionnaire,\(^{3}\) and noncancer scales, such as the CQLQ,\(^{16}\) the CCIQ,\(^{17}\) and the LCQ.\(^{18}\)

A preliminary pool of 51 items was generated (41 related to cough and 10 related to wheezing). Working with a team of academics and clinicians collaborating on the project, duplicate items or items with similar meaning were deleted, and a comprehensive list of 30 items was finally generated.

**Appropriateness of Content and Breadth of Coverage of Items/Domains.** In the next step, the list of items was presented to a sample of lung cancer patients (\(n = 18\)) and health care professionals (\(n = 25\)) to determine the relevance of each item in terms of their experience. Strict eligibility criteria were adopted to ensure that subjects adequately represented the target population for which the scale was being devised; as a result, a relatively small number of patients were used in this phase of the scale development. Sprangers et al.\(^{20}\) recommend 5–10 patients to be included for each different treatment group or disease stage.

Inclusion criteria for this sample were (1) adult patients with primary lung cancer who had experienced cough for at least two weeks, (2) patients who had completed chemotherapy and/or radiotherapy (half the sample) or patients undergoing chemotherapy and/or radiotherapy (half the sample), and (3) patients at Stages III and IV of their disease.

Assessment of relevance was achieved by using a 0–10 scale (0 = least relevant and 10 = most relevant). Item reduction took place through this assessment using hierarchical methods,\(^{23}\) removing discriminative descriptors. A score of four or more per item was taken as indicative of a criterion level for inclusion in the scale. We also asked patients and staff to choose the 10 most important items for them in the list (“priority” items), and our cut-off point for this was items that were recorded by at least 25% of the sample. Items were excluded at this stage if they were below the cut-off point for both the relevance and priority assessment. Patients also were asked if all the items were easily understood, if there were any confusing items, and if there were any upsetting items. Both patients and staff further were asked to propose any items/issues that were important in their experience but not included in the scale.

Content validity was the key construct that was assessed through the comprehensive
literature review. The presentation and evaluation of the scale by patients and health care professionals was obtained for feedback on the appropriateness of content and breadth of coverage of the scale.

**Phase 2: Operationalization**

This step included the construction of the exact wording of the remaining items on the scale. Other relevant scales may be used for their wording, with any necessary adaptation. The resulting list of items from Phase 1 and the wording of each item were reviewed for clarity and overlap by persons not involved in Phase 1 (four academic colleagues and three clinicians). On the basis of these final comments, the list of items required further adaptation before they were administered to patients in the field-testing phase.

**Phase 3: Field Testing**

The field testing involved administering the final questionnaire to lung cancer patients (broadly half while they were undergoing treatments and half after the end of treatments), with early or advanced stage, either gender, and irrespective of whether they currently had cough or not. The time-reference frame of the scale was “in the past week” and item response was agreed to be on a six-point scale, with 1 = “never” experiencing the given descriptor and 6 = “all the time” experiencing the descriptor. The number of patients to be recruited was based on psychometric theory, suggesting 5–10 patients per item in a scale; hence, we needed a minimum of 100 participants in the study.24 Also, Altman25 suggests a minimum of 50 participants for test-retest reliability. Patients completed this scale while they were waiting for their outpatient appointment as a self-report, with no assistance from the researchers. They also could complete this scale when they were back at home and return it to the researchers using prepaid envelopes.

**Analysis**

The first step of this methodological process pertained to final item reduction using the following: (1) missing data for individual items—set at greater than 25%, (2) data skewness and kurtosis—set at greater than two (raw score), (3) floor and ceiling levels—set at greater than 50%, and (4) fit to the Rasch unidimensional model. In the absence of generally accepted ranges, Criteria 1–3 were decided upon based on an extensive review of scores used in other published scales and understanding of item response theory.

Elimination of items may be warranted on psychometric grounds. If an item in the scale lowered the overall alpha of the scale, the item would be eliminated. Furthermore, items with limited variability or non-normal distribution (high skewness and kurtosis) also would be eliminated. In skewness, a value of zero indicates that the values in the scale are relatively evenly distributed (symmetric distribution). Kurtosis is a measure of “peakedness” of the probability distribution, and higher kurtosis means that the variance in the result is because of infrequent extreme deviations. For both skewness and kurtosis, a score of ±1 is very good and ±2 is usually acceptable.

Rasch analysis is a mathematical technique that allows the goodness of fit of each item to the overall model (i.e., overall score) to be tested statistically. A key function of Rasch analysis is to test how well items in an instrument conform to a unidimensional model. In other words, it checks if all the items in the questionnaire work together to measure a single underlying construct, enabling a valid total score to be summated.26 The following iterative analyses were applied using Rasch modeling using the RUMM2020 (RUMM Laboratory Pty., Ltd., Perth, Australia) program:27

1. Testing each item’s responses for consistent ordering of cough impact using item-threshold maps. Inconsistent ordering can be improved by collapsing adjacent categories.
2. Testing each item for goodness of fit to a unidimensional model—item fit Chi-square P values and item residuals.
3. Testing each item for consistent measurement properties between different cough severity groups—visually assessing item characteristic curves.
4. Testing the overall model for internal consistency using the Person-Separation Index (PSI) (which is analogous with the Cronbach alpha), and the item-trait interaction Chi-square (a non-significant P value indicates fit to the Rasch model).
5. Examining the targeting of the items to the severity of cough of the patient population.
The reliability testing of the resultant cough scale was another aspect of the scale’s development and involved the assessment of internal consistency and repeatability. Internal consistency is typically a measure based on the correlations between different items on the same test, and it measures whether several items that propose to measure the same general construct produce similar scores. Repeatability is a precision measure that represents the value below which the absolute difference between two repeated test results may be expected to lie with a probability of 95%. We used the test-retest reliability method for this, with a repeat completion of the scale one week apart.

The following analyses were done to test the hypothesized scale’s structure and to establish the scale’s reliability:

1. Item-to-total correlations. This is the Pearson correlation of the item with the total of scores on all other items. A low item-total correlation means the item has little correlation with the overall scale (≤0.30 for large samples or not significant for small samples) and the researcher should consider omitting the item.
2. Cronbach’s alpha reliability (internal consistency). This should be of a magnitude of greater than 0.70.
3. Test-retest reliability (or stability) was tested using the intraclass correlation coefficient (ICC) between the two assessments in a subsample of individuals from the original sample who were asked to complete the same scale one week later.
4. Exploratory principal components (factor) analysis using varimax rotation and eigenvalues greater than 1.

**Face Validity.** This was explored using an analysis of qualitative comments made by the patients, who were asked to comment if they found any questions confusing, upsetting, or difficult to answer, and whether they would like to make any general comments about the structure and content of the scale.

**Results**

**Appropriateness of Scale Content**

Eighteen lung cancer patients and 25 health care professionals working with lung cancer patients participated in this evaluation. Patients were recruited from three centers in the U.K. Health professionals were recruited from four different centers, and comprised 16 specialist nurses in lung cancer, community palliative care, and Macmillan nurses; one nurse consultant in palliative care; four palliative medicine doctors; three oncologists; and one occupational therapist.

The sixteen items retained after this assessment are shown in Table 1. Items 7 and 8 were referring to the same concept, and as one was retained and the other was not, it was agreed that these two items should form a single item, considering the information we had about this from our qualitative study. Items 22 and 23 were about specific types of pain, and as one was retained and the other not, we agreed to combine these two items under a general “any pain” item. Considering the qualitative data we had from the cough experience in this group, it was thought appropriate to retain items 26 and 27 but to form a single combined item. New items were added, based on comments from the patients and the health care professionals, including if patients experienced a sore throat after coughing, if they coughed up blood, being around people, and severity of cough. During the operationalization process, the phrasing of each item also was made consistent across all items to fit with the response format. This resulted in a scale of 21 items that was then used for the field testing.

**Field Testing**

A sample of 139 patients was used for this part of the scale’s assessment. There were 89 men (64%) and 50 women (36%). The mean (SD) age of the group was 69.2 (9) years (range 37–88 years). The majority had a diagnosis of non–small-cell lung cancer (n = 110, 85.9%), with smaller numbers of patients with small-cell lung cancer (9.4%) and mesothelioma (4.7%). Stage IV was the most common cancer stage (35.3%), followed by stage III (24.5%), stage II (12.9%), and stage I (9.4%), with no staging information available for 15 patients (10.8%). The group with small-cell lung cancer had limited disease (4.3%) or extensive disease (2.9%). More than half (54.5%) of the patients received a combination of chemotherapy and radiotherapy, 18.2% of patients received chemotherapy, 26.4% of patients received radiotherapy, and
there was one patient (0.8%) who had received only surgery. Recruitment took place at five clinical sites, contributing each with 51, 45, 27, 11, and 5 patients, respectively.

**Missing Values.** No items had missing data greater than 4%; hence, no items were removed at this stage.

**Skewness and Kurtosis.** Five items were eliminated because the values of skewness and kurtosis were greater than two and with limited variability. These included the following items: (1) Does coughing cause you any pains? Kurtosis = 2.8; (2) Do you get a sore throat because of your cough? Kurtosis = 3.27; (3) Do you cough up blood? Skewness = 3.73;...
Kurtosis $= 14.3$; (4) Does producing sputum distress you? Kurtosis $= 2.84$; and (5) Do you avoid going to public places because of your cough or sputum? Skewness $= 2.42$, Kurtosis $= 5.25$.

Floor and Ceiling Effects. No items demonstrated a ceiling effect. However, five more items were removed because of floor effects, that is, a greater than 50% of positive response to “Never”. These included, (1) Does cough make you anxious? (2) Does coughing interfere with your enjoyment of life? (3) Does cough make it difficult to be around other people? (4) Do you worry that other people think something is wrong with you because of your cough? and (5) Does coughing get in the way of normal activities?

Rasch Analysis. The remaining 11 items were entered into RUMM2020. Initial fit to the Rasch model was poor (total-item Chi-square $= 41.04$; $P = 0.0036$). One item (Do you produce sputum when you cough?) demonstrated a poor fit to the model (item residual $= 3.5$; $P = 0.05$) (see Fig. 1a and b for an example of a poor and good fitting item). Assessment of the transition between item response categories was performed using item threshold maps (Figs. 2 and 3). A disordered threshold (Fig. 3) is a situation in which respondents demonstrate an inconsistent transition between response options. Correct ordering can be achieved by combining adjacent response categories and rescoring the item. Items 1, 9, and 10 had marginally ordered thresholds (Fig. 2) and the remaining seven items were disordered (Fig. 3). The 10 items were collapsed from six to five categories to improve overall fit to the model and consistency in response options between items. This process resulted in adequate fit of the 10-item set to the Rasch unidimensional model.

Model Fit and Repeatability of the Final Item-Set. The final 10-item set had very good internal reliability ($\text{PSI} = 0.86$). The total-item Chi-square probability was 0.09, supporting the conclusion that the items formed a unidimensional measure of overall cough impact. The targeting of the 10-item set to the patient population was good (Fig. 4) although on average the items are targeted to patients who would have slightly more severe cough. The Cronbach alpha reliability for the sample for the 10-item scale also was 0.86, whereas the Cronbach alpha for the repeat completion of the scale was 0.83.

Item to Total Correlations. The 10 remaining items had high item to total correlations, ranging from 0.40 to 0.76 ($P < 0.001$).

Test-Retest Reliability (Stability). The initial 30-item scale was completed again approximately after a week by 49 patients of the original group (76.2% of men; 95.2% of non-small-cell lung cancer patients; 61% Stages III
and IV cancer patients). Spearman’s rho correlation between the first completion and the repeat completion was 0.76 (P < 0.001), indicating a high level of stability. The ICC of average measure was 0.83 (95% confidence interval 0.74–0.90).

Principal Components Analysis. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.91, indicating a large enough sample for this analysis. No specific factors were identified, as all items clustered around a single factor, suggesting a unidimensional scale.

Descriptive Data of the New Scale. Total scores could range from 1 to 40 (reversing item 8), with higher scores indicating higher impact of cough in the patient’s daily life (Table 2). Just under half the sample (48.2%) experienced cough frequently. The mean scores for severity (item 10) and distress (item 5) suggested that cough was of moderate level and moderately distressing. The total mean (SD) score was 18.3 (8) (range 1–39), again indicating low to moderate impact of cough on patients’ lives.

Patient Comments. Patients were asked to comment on the aspects of the scale they completed, and most did so. Most patients found the scale easy to complete, simple, useful, comprehensive, and clear. Only one patient wanted clarification as to what was meant by “normal activities” (item in original scale), and one patient questioned the time frame of one week that was used, as his experience would have been different if this time frame was longer, that is, one month. This assessment supports the scale’s face validity.

Discussion

We have developed and conducted the initial psychometric testing of a scale to measure the cough experience in lung cancer patients, using a patient-centered approach. Several iterations have resulted in a 10-item scale (Appendix) that has high acceptability (minimal missing data, acceptable skewness/kurtosis, and floor/ceiling effects), good reliability, and good test-retest stability, measuring the overall impact of cough on patients’ lives. Fit to the Rasch unidimensional model has been demonstrated, providing a simple summative total score for cough impact to be calculated. This is the only validated scale specific for lung cancer patients.

The ICC of 0.83, although acceptable according to published criteria, is moderate and lower than that usually seen with such tools. This is likely because the initial 30-item (and not the final 10-item) set was repeated by participants. It is likely that the inclusion of items that were later found to be not
reliable measures of cough impact may have influenced the ICC, and it should only be considered a preliminary value. A subsequent validity study using the final 10-item set would be required to confirm the tool’s true ICC. Furthermore, it is not surprising that the factor analysis did not identify important domains of the construct in this short scale because the 10-item set demonstrated fit to the Rasch unidimensional model.

Our earlier Cochrane review identified the assessment of cough in past trials as problematic, as many trials included potentially biased physician-estimated cough assessments, and used nonvalidated, self-developed, and single-item scales.19 The lack of sensitive and reliable results in such trials and the limited quantity of trials (with significant methodological shortcomings) bring into question many of the results published so far in the literature. It is surprising that such a commonly occurring and distressing respiratory symptom7 has not received adequate research attention, with evidence mostly deriving from the 1970s.10 There are also indications that health professionals do not address this symptom equally to other patient symptoms, even when patients try to communicate its presence and distressing nature.7 The availability of a short and valid cough scale may stimulate more research in this field and also assist health care professionals to assess cough and its impact on patients’ lives more elaborately. It also could be used in trials as an outcome measure for evaluating the effectiveness of cough interventions.

It is interesting that a number of items that were identified as distressing experiences by patients in our earlier qualitative interviews were not picked up as highly relevant items in the quantitative iterations of the scale’s development. This highlights some disparity between qualitative and quantitative data, and supports our process to use the qualitative interviews as hypothesis-generating information that was filtered through the quantitative iterations to a more concrete construct. Also, patients may tolerate increasing symptoms and under-report them in questionnaires. A final limitation of the current study also may be the absence of comparison between the self-reported tool and more objective cough counting methods; this comparison will greatly enhance the scale’s reliability estimates.

This short 10-item scale is generic enough to assess the patients with cough at large, although this will necessitate more studies on patients with non-lung cancer diagnoses. Existing health status measures, such as the LCQ and CQLQ, also could be used in the studies on lung cancer patients, although modifications may be needed in items such as “I am concerned I have cancer” or “I am concerned I have AIDS or TB.” Also, these scales are relatively long (19 and 28 items, respectively), which may increase the patient burden in studies, particularly if they are used alongside other study scales. The advantage of the new tool is that it has been developed in a group of lung cancer patients.

Advanced methodology was used in developing this tool to ensure reliable measurement...
properties. The application of Rasch modeling facilitated the development of a questionnaire using the minimum number of items required to represent the underlying construct being measured (i.e., the impact of cough on quality of life) in addition to ensuring that the response options present patients with a logical progression from less severe impact to more severe impact. Reducing the item response options from six to five decreased the scaling range from 50 to 40; however, this was a reasonable compromise because that process provided fit of the 10-item set to the Rasch model. These are important considerations when developing patient-reported outcome measures for use in populations where there is a high risk of response burden, such as the lung cancer patients.

Although initial testing of this new cough scale has provided preliminary evidence of adequate psychometric properties, further assessment is necessary to establish its construct validity, sensitivity, cross-cultural reliability, and responsiveness to treatments. Translations of the scale to other languages should follow careful translation-back translation processes to establish linguistic equivalence with the English scale. Being a short scale, it can be used in the future both clinically and in intervention research.

Disclosures and Acknowledgments

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References


**Appendix**

**Manchester Cough in Lung Cancer Scale**

This questionnaire asks you to describe your experience of cough in the past week.

Please answer question one and then read the instructions before completing the rest of the questionnaire.

1. In the past week how often have you coughed?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

If you answered “Never” to question 1, please stop completing the questionnaire and return it to us.

If you indicated that you have experienced cough in the past week, then please complete the rest of the questionnaire.

For each question, please circle one option that best describes your experience over the past week.

2. Do you have difficulty breathing when you cough?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

3. Do you have difficulty bringing up sputum (phlegm) when you cough?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

4. Does your cough disturb your sleep?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

5. Does your cough distress you?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

6. Does coughing make you frustrated?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

7. Do you worry that your cough means that your condition is getting worse?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

8. Do you feel in control of your cough?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

9. Does coughing interrupt your conversations or telephone calls?  
   - Never  
   - Some of the time  
   - Often  
   - Most of the time  
   - All of the time

In question 10, you should indicate how severe your cough has been in the past week.

10. Please rate how severe you think your cough is  
    - Very mild  
    - Mild  
    - Moderate  
    - Severe  
    - Very severe