

# Role of clinical questionnaires in optimizing everyday care of chronic obstructive pulmonary disease

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**Abstract:** Chronic obstructive pulmonary disease (COPD) is a leading cause of disability in all its stages, and death in patients with moderate or severe obstruction. At present, COPD is suboptimally managed; current health is often not measured properly and hardly taken into account in management plans, and the future risk for patients with regard to health status and quality of life is not being evaluated. This review addresses the effect of COPD on the lives of patients and examines ways in which existing assessment tools meet physicians' needs for a standardized, simple method to measure consistently the full impact of COPD on patients in routine clinical practice. Current assessment of COPD severity tends to focus on airflow limitation, but this does not capture the full impact of the disease and is not well correlated with patient perception of symptoms and health-related quality of life. Qualitative studies have demonstrated that patients usually consider COPD impact in terms of frequency and severity of symptoms, and physical and emotional wellbeing. However, patients often have difficulty expressing their disease burden and physicians generally have insufficient time to collect this information. Therefore, it is important that methods are implemented to help generate a more complete understanding of the impact of COPD. This can be achieved most efficiently using a quick, reliable, and standardized measure of disease impact, such as a short questionnaire that can be applied in daily clinical practice. Questionnaires are precision instruments that contribute sensitive and specific information, and can potentially help physicians provide optimal care for patients with COPD. Two short, easy-to-use, specific measures, ie, the COPD Assessment Test and the Clinical COPD Questionnaire, enable physicians to assess patients' health status accurately and improve disease management. Such questionnaires provide important measurements that can assist primary care physicians to capture the impact of COPD on patients' daily lives and wellbeing, and improve long-term COPD management.

**Keywords:** chronic obstructive pulmonary disease, COPD assessment test, disease management, health status, quality of life, questionnaire

## Background

Chronic obstructive pulmonary disease (COPD) is a major public health problem of high and increasing prevalence,<sup>1-5</sup> and is a leading cause of disability in all its stages<sup>6,7</sup> and death in patients with moderate or severe obstruction.<sup>8-10</sup> COPD imposes a profound burden on patients, including medical emergencies, hospitalizations, work absenteeism, and activity limitations. Ultimately, this has a significant physical and emotional impact on patients.<sup>11</sup>

COPD, as defined by airflow limitation, is often underdiagnosed<sup>12-14</sup> and undertreated,<sup>15</sup> leading to poor quality of life for patients.<sup>16</sup> Current assessments of

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COPD severity focus on the amount of air that patients can forcibly exhale from their lungs in the first second of a forced exhalation ( $FEV_1$ ), but this alone does not capture the full impact of the disease.<sup>17</sup> As a consequence, patients with COPD are often suboptimally managed.<sup>18,19</sup> The future risk for patients with COPD with regard to health status and quality of life is not currently being evaluated routinely, but it is likely that this will provide a marker of both current impact and future risk in these patients.<sup>20–24</sup>

Improved COPD management requires a range of patient assessments, including lung function, exacerbation episodes, exercise tolerance, and impact on health status. However, patients often have difficulty expressing the burden of their disease and physicians generally do not have sufficient time to collect this information. Therefore, it is important that methods are implemented to enable clinicians to reach a more complete understanding of the impact of the disease on their patients and identify specific needs. The most efficient way to achieve this is to use a quick, reliable, and standardized measure of disease impact, such as a short questionnaire, that can be applied in daily clinical practice to provide physicians with additional useful information. Validated patient-reported outcomes, eg, measurements of health status (health-related quality of life [HRQoL]), or functional status are now recognized as being key in capturing the patient's experience of important aspects of health in chronic disease.<sup>25</sup> Use of these measures will enable physicians to determine what is really important to the individual patient and highlight differences between patients.

In conjunction with patient-reported measures, health care systems need to be more organized and focused towards meeting the current and future needs of patients with COPD. Patients with chronic disease require both regular clinician assessments and self-management. Application of the chronic care model, which includes fundamental elements (eg, the community, health care system, and patient self-management) needed to support high-quality care for patients with chronic disease, could potentially improve COPD management.<sup>26–28</sup>

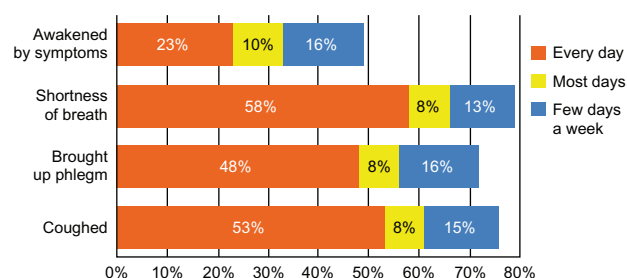
The management of COPD is now directed towards symptomatic benefit, in terms of improved HRQoL and exercise tolerance, and risk reduction (eg, exacerbations, hospital admissions, and death). Assessment of COPD risk can now be done in routine clinical practice using simple multidimensional prognostic scaling systems, such as the DOSE index.<sup>29</sup> The aim of this review, however, is to address the impact of COPD on patients' lives and to discuss ways in which the new assessment tools can meet physicians' needs

for a standardized, simple method to measure consistently the full impact of COPD on patients in routine clinical practice.

## Measuring impact of COPD on patients

The burden of COPD on patients and their families is high.<sup>13,30–32</sup> Furthermore, it is not limited to patients with severe COPD, but is also very prominent in younger patients with only mild or moderate airway obstruction, limiting them in their daily lives.<sup>33</sup> In general, patients have a restricted understanding of both the extent of their loss of pulmonary function and the severity of their COPD. In the Confronting COPD International Survey, patients' perceptions of the severity of their COPD did not consistently correspond with the degree of severity indicated by the Medical Research Council (MRC) dyspnea (breathlessness) scale.<sup>16</sup> In addition, most patients do not appear to place the same level of importance on their exacerbation episodes as health care providers,<sup>34</sup> and a recent study showed that patients generally report smaller changes in HRQoL outcome measures as more clinically meaningful than do physicians.<sup>35</sup> Thus, the provision of measures to document clinical outcomes can help both patients and health care providers improve their knowledge about the impact of COPD on patient health.

Surveys have indicated that patients usually consider the impact of COPD in terms of symptom frequency and severity, and physical and emotional wellbeing.<sup>16</sup> In the Confronting COPD in America survey, 90% of individuals with COPD experienced symptoms either every day or most days during their worst three-month period in the past year (Figure 1).<sup>36</sup>



**Figure 1** Symptom frequency in individuals with COPD (evaluation of worst three-month period in past year). Patients participating in the Confronting COPD in America survey were asked about the frequency of their symptoms during their worst three-month period in the past year (ie, “Has there been any three-month period in the past year when you experienced ... [read item] – every day, most days a week, a few days a week, a few days a month, less than that?”). A high proportion of patients reported that they frequently experienced specific disease-associated outcomes during their worst period in the past year.<sup>36</sup> Reproduced with permission from GlaxoSmithKline.



Also, patients use language such as “good” and “bad” days to define how COPD influences their HRQoL, so patients’ self-reported assessments are important when evaluating the intensity of symptoms, such as dyspnea and fatigue, and their impact on HRQoL.<sup>37</sup>

## Changing health status

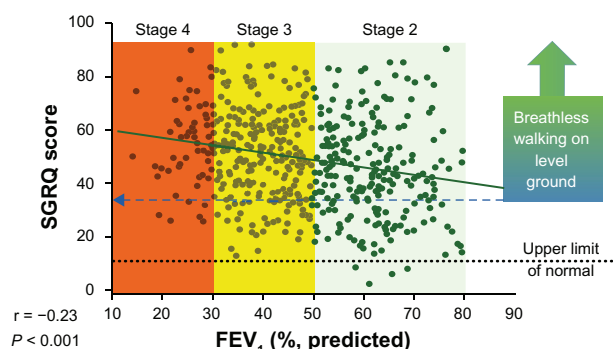
A study in patients with stable COPD showed that changes in health status assessed by patient-reported measures (eg, the St George’s Respiratory Questionnaire [SGRQ], Chronic Respiratory Questionnaire [CRQ], MRC dyspnea scale, and the Hospital Anxiety and Depression Scale [HADS]) worsened significantly over time.<sup>38</sup> However, deteriorations in patient-reported outcomes (eg, symptoms, limitation of daily activities, and wellbeing) showed only a weak correlation with changes in physiological indices such as FEV<sub>1</sub> and maximal oxygen uptake measured at peak exercise.<sup>38</sup> Those authors concluded that to capture the overall deterioration in patients’ health status due to COPD, patient-reported outcomes should be followed independently of physical outcomes.<sup>38</sup>

## Challenges in providing chronic care for patients with COPD

During a consultation, patients tend to understate their disease severity, under-report COPD exacerbations, and do not convey the impact of the disease on their quality of life. In addition, patients often only present to their physicians when their condition has progressed significantly leading to a reduced HRQoL.<sup>14,39</sup> Consequently, there is a need to assess patients’ health status to enable optimal disease management.

## Clinical assessment questionnaires in COPD

Physicians need to consider several factors when assessing patients with COPD. The impact of COPD depends not only on the degree of airflow limitation but also on the severity of symptoms, systemic effects, and any comorbidities present.<sup>2,31</sup> When a patient experiences an exacerbation they often require several weeks of recovery;<sup>24</sup> sustained worsening of symptoms can also have a significant impact on patients’ HRQoL and mortality.<sup>40–44</sup> Importantly, reductions in objective pulmonary function measurements, such as FEV<sub>1</sub>, are not well correlated with patients’ perception of symptoms and HRQoL (Figure 2).<sup>17,45</sup> When managing patients with COPD it is therefore necessary to measure both pulmonary function and HRQoL.



**Figure 2** Relationship between health status as measured by the SGRQ, and FEV<sub>1</sub> and GOLD stage. Patients’ perception of symptoms and health-related quality of life, as assessed by the SGRQ, were not well correlated with objective pulmonary function measurements, such as FEV<sub>1</sub> and GOLD stage.

Adapted from Jones PW. Health status measurement in chronic obstructive pulmonary disease. *Thorax*. 2001;56:880–887 with permission from the BMJ Publishing Group Limited.<sup>17</sup>

**Abbreviations:** SGRQ, St George’s Respiratory Questionnaire; FEV<sub>1</sub>, forced expiratory volume in one second; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

Physicians require help in realizing the full impact of COPD on their patients. Qualitative studies showed that patients with COPD have difficulty placing themselves along a continuum of disease severity and relating their severity to that of other patients with COPD. During development of the COPD Assessment Test (CAT), patients indicated that they would like to have a method available that would allow them to both assess their own disease severity and communicate this information to their physicians.<sup>46</sup>

Standardized assessments, beyond peak airflow (maximally forced expiration initiated at full inspiration) currently used to assess patients in clinical practice evaluate multidimensional domains (symptoms, physical, psychological, and social) affected by COPD. Examples of disease-specific instruments include the MRC dyspnea scale, the Clinical COPD Questionnaire (CCQ), and the CAT.<sup>46–48</sup> These measures can be assessed in terms of their relative reliability, validity, responsiveness, acceptability, and feasibility in everyday clinical practice.<sup>25</sup> Other questionnaires such as the SGRQ, CRQ, and Short Form 36-item Health Survey (SF-36) comprise many more questions and consequently are not suitable for use in daily clinical practice, so these questionnaires are not discussed further. A comprehensive review of available questionnaires is currently being undertaken by the International Primary Care Respiratory Group ([www.theipcr.org/](http://www.theipcr.org/)).

Questionnaires are precision instruments that can provide sensitive and specific information and, if sufficiently short and simple, can enable physicians in routine clinical practice to assess the health status of their patients accurately, thereby allowing improved COPD management.



# CLINICAL COPD QUESTIONNAIRE



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Patient number: \_\_\_\_\_

Date: \_\_\_\_\_

## CLINICAL COPD QUESTIONNAIRE

Please **circle** the number of the response that best describes how you have been feeling during the **past week**.

(Only **one** response for each question).

On average, <b>during the past week</b> , how often did you feel:	never	hardly ever	a few times	several times	many times	a great many times	almost all the time
1. Short of breath <b>at rest</b> ?	0	1	2	3	4	5	6
2. Short of breath <b>doing physical activities</b> ?	0	1	2	3	4	5	6
3. <b>Concerned</b> about getting a cold or your breathing getting worse?	0	1	2	3	4	5	6
4. <b>Depressed (down)</b> because of your breathing problems?	0	1	2	3	4	5	6
In general, <b>during the past week</b> , how much of the time:							
5. Did you <b>cough</b> ?	0	1	2	3	4	5	6
6. Did you <b>produce phlegm</b> ?	0	1	2	3	4	5	6
On average, <b>during the past week</b> , how limited were you in these activities <b>because of your breathing problems</b> :	not limited at all	very slightly limited	slightly limited	moderately limited	very limited	extremely limited	totally limited/ or unable to do
7. <b>Strenuous physical activities</b> (such as climbing stairs, hurrying, doing sports)?	0	1	2	3	4	5	6
8. <b>Moderate physical activities</b> (such as walking, housework, carrying things)?	0	1	2	3	4	5	6
9. <b>Daily activities at home</b> (such as dressing, washing yourself)?	0	1	2	3	4	5	6
10. <b>Social activities</b> (such as talking, being with children, visiting friends/relatives)?	0	1	2	3	4	5	6

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**Figure 3** The clinical COPD questionnaire.

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Your name:

Today's date:



## How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

**Example:** I am very happy    0 ☒ 1 2 3 4 5    I am very sad

		SCORE
I never cough	0 1 2 3 4 5 I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5 My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5 My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5 When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5 I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5 I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5 I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5 I have no energy at all	
		<b>TOTAL SCORE</b> <div style="border: 1px solid black; width: 60px; height: 40px; margin: 0 auto;"></div>

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**Figure 4** The COPD assessment test.  
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## Medical research council dyspnea scale

The MRC dyspnea scale, recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD)<sup>2</sup> and other national guidelines, was developed by Fletcher et al while studying the respiratory problems of Welsh coalminers in the 1940s.<sup>48,49</sup> It is short (comprises five dyspnea items) and has been in use for many years for grading the effect of breathlessness on daily activities. It is simple to administer because it allows patients to indicate the extent to which their breathlessness affects their mobility. However, it only measures one aspect of the patient experience (ie, perceived respiratory disability) and is poorly responsive to change.

## Clinical COPD questionnaire

The CCQ (Figure 3) consists of three domains and 10 items, ie, symptoms (four items), functional state (four items), and mental state (two items). All scores range from 0–6 (0, no impairment).<sup>47</sup> The CCQ was developed in consultation with 32 patients in two countries, and item reduction performed in collaboration with 79 clinicians worldwide. Patients can complete the CCQ quickly (in approximately two minutes) and it is straightforward to score; this allows data to be instantly collected and processed, enabling its use in everyday practice, clinical trials, and quality-of-care monitoring. Three studies in the Netherlands, Italy, and Sweden provided strong supporting evidence for the reliability, validity, and responsiveness of the CCQ.<sup>47,50,51</sup> A change in the total CCQ score of  $\geq 0.4$  from one patient visit to the next is considered to be significant (ie, the minimum clinically important difference).<sup>52</sup> The CCQ is freely available (in 53 languages) for use in clinical practice ([www.ccq.nl](http://www.ccq.nl)).

## COPD assessment test

The CAT (Figure 4) is a short (eight-item) and simple-to-administer patient-completed questionnaire designed for routine use in clinical practice. It covers a wide range of effects of COPD, including cough and sputum, chest symptoms, activity limitation, sleep, fatigue, and confidence leaving home. Patients can complete the CAT quickly (in approximately two minutes) by themselves in the doctor's waiting room. Development of the CAT involved consultation with a large number of patients at each stage of the process. Items covered in the CAT can help physicians measure the overall impact that COPD is having on patient wellbeing and daily life. Thus, the CAT provides a holistic measure of COPD health status;<sup>46</sup> it should facilitate a fact-based, physician-patient dialog and improve communication to present a common understanding and grading of the impact

of COPD. It is supported by strong evidence for reliability and by preliminary data for construct and discriminant validity;<sup>46</sup> additional validity analyses are ongoing. The minimum clinically important difference in CAT score is yet to be established formally,<sup>53</sup> but based upon mapping from the SGRQ at a population level it will be approximately 1.6 units. At the individual patient level, a change in CAT score of  $\geq 2$  units will be clinically significant. The CAT is freely available (although GlaxoSmithKline owns the copyright to protect it from unauthorized changes) for use in daily clinical practice ([www.catestonline.org](http://www.catestonline.org)).

## Summary

An increased understanding of the full impact of COPD on patients and their carers should enable physicians to provide targeted intervention and improve patients' HRQoL.

Care for patients with COPD can be optimized best by use of reliable, standardized measurements of overall disease impact. The measures should be appropriate to the question being addressed, sensitive to changes that are relevant to patients, capable of providing physicians with meaningful scores, and acceptable to both patients and health care providers.<sup>54</sup> The questionnaires reviewed here have those attributes and are quick and easy to use during consultations. Incorporation of questionnaires such as these into the consultation process will enable improved patient-physician partnership decision-making, help prioritize patients for primary care review, and drive effective management of patients with COPD.

## Acknowledgment

Editorial support in the form of development of the manuscript first draft, collating author comments, and referencing was provided by Dr Richard Barry (Quintiles Medical Communications) and was funded by GlaxoSmithKline.

## Disclosure

PWJ has received consultancy and advisory board fees from GlaxoSmithKline, AstraZeneca, Ammirall, Boehringer Ingelheim, Roche, and Spiration; he has also received lecture fees from GlaxoSmithKline. DP has consultant arrangements with Boehringer Ingelheim, GlaxoSmithKline, Merck, Novartis, and Teva. He and/or his research team have received grants and support for research in respiratory disease from the following organizations in the past five years: UK National Health Service, Aerocrine, AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Merck, Novartis, Nycomed, Pfizer, and Teva. He has spoken



for Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Merck, Pfizer, and Teva. TVDM has participated as a speaker at several conferences financed by ALTANA, GlaxoSmithKline, and AstraZeneca. He has served on the advisory boards for Merck, AstraZeneca, and Nycomed. He has received research grants from ALTANA, AstraZeneca, and MSD.

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