



COPD Assessment Test

Healthcare Professional User Guide

Expert Guidance on Frequently Asked Questions

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Introducing the COPD Assessment Test™ (CAT)

The COPD Assessment Test (CAT) is a patient-completed instrument that can quantify the impact of COPD on the patient's health. It complements existing approaches to assessing COPD, such as FEV₁ measurement. It was initially designed, using a rigorous scientific development process, to provide a simple and reliable measure of health status in COPD to aid assessment of patients and promote communication between patients and clinicians.

Validation studies conducted during the development of CAT and in the years since it was launched in 2009 have shown that it has properties very similar to much more complex health status questionnaires such as the St George's Respiratory Questionnaire (SGRQ)¹. A recent systematic review² confirmed that the CAT provides reliable measurement of health status and is responsive to change with treatment and exacerbations. Since 2013 it has been incorporated as the preferred measure of symptomatic impact of COPD into clinical assessment schemes and is also included in the COPD Foundation guide.

Although it was developed in English nearly one hundred validated translations have been made and local validation studies have been conducted in countries that include China, Arabic-speaking countries, Brazil, Greece, Japan, South Korea, Turkey and Thailand. All have shown that the CAT is reliable in those setting and that both patients and researchers find it easy to use.

Since the launch of CAT, guidance has been provided for healthcare professionals on how to use and interpret CAT scores in the form of a user manual available through the website (www.catestonline.org). As it is increasingly used in research this update to the user manual has been expanded to include information and advice to both academic and commercial researchers, based upon our current knowledge of the CAT and its measurement properties.

The information in this guide is accompanied by some frequently asked questions in order to make it accessible and applicable to both practice and research.

We look forward to hearing and reading about your experiences using the CAT in the near future!

*Professor Michael Polkey
Independent Chair*

*Professor Claus Vogelmeier
GOLD Science Committee Chair*

*Dr Nadia Hansel
COPD Foundation
Consortium Chair*

On behalf of the CAT Governance Board

The COPD Assessment Test™ (CAT) – the basics

What is the CAT?

The CAT is a validated, short (8-item) and simple patient completed questionnaire, with good discriminant properties, developed for use in routine clinical practice to measure the health status of patients with COPD¹. Despite the small number of component items, it covers a broad range of effects of COPD on patients' health. Studies have shown that it is responsive to change and to treatment.^{2,3,4}

Why has the CAT been developed?

COPD represents a major burden on patients and healthcare systems. Despite the fact that it is projected to become the third leading cause of death by 2030⁵, communicating the impact of COPD can be difficult and this can contribute to under-management of COPD in a significant proportion of people who may suffer increased disability and reduced quality of life as a result.

The care of COPD patients can only be optimised if there is a reliable, standardised measure of the overall effect of disease on each patient's health. Unfortunately, commonly used lung function measurements such as FEV₁ percent predicted do not reflect the full impact of COPD.

CAT was developed to address the need for a simple-to-use tool which can measure the effect of COPD on the patient's health and enhance understanding between patients and physicians of the disease's impact, in order to manage patients optimally and reduce the burden of disease as much as possible.

Development and Governance of the COPD Assessment Test™ (CAT)

How was the CAT developed?

The development of the CAT involved well accepted methodologies used to develop psychometric tools.^{1,6} The initial item generation process involved literature reviews, physician interviews and, most importantly, patient input.⁶ A structured, rigorous scientific approach was then used in the item reduction process to select the best items and generate the final 8-item questionnaire.¹

The CAT was initially validated in prospective studies conducted in the USA and Europe¹ and in China.⁷ In the years since launch further validation studies have been conducted around the world, which show that the CAT is globally applicable. Since 2009 the CAT has been translated and validated for use in more than 90 languages other than English. Only validated translations of the CAT should be used. You can gain access to these translations on the [CAT website](#).

Who developed the CAT?

The CAT was developed by a multidisciplinary group of international experts who have expertise in developing patient reported outcomes tools/questionnaires. The group included pulmonary specialists, primary care physicians, experts in the development of Patient Reported Outcome measures and representatives from patient bodies. Patients with COPD were integral to the development and validation of the tool. The CAT development was commissioned and funded by GlaxoSmithKline (GSK).

How is the CAT governed?

Use and further development of the CAT is overseen by a Governance Board established in 2015. The board has an independent, academic chair. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) and The COPD Foundation (COPDF) nominate and confirm representatives on the CAT Governance Board. GOLD is represented by the chair of the Science Committee and COPDF is represented by a member of the Board. Other members of the Governance board represent research in industry and academia. The Board also includes a scientific adviser with expertise in the development and use of PRO. GSK continues to own the copyright for the CAT to ensure its integrity, maintains the CAT websites and is responsible for the administrative support of the CAT Governance Board in addition to making translations of the CAT available to users.

Who are members of the CAT Governance Board?

Current Membership of the CAT Governance Board (2016):

| | |
|-----------------------------------|--|
| Independent Chair: | Professor Michael Polkey, NIHR Respiratory Biomedical Research Unit at the Royal Brompton and Harefield Foundation NHS Trust and Imperial College |
| GOLD Scientific Committee Chair: | Professor Claus Vogelmeier, Professor of Medicine and Chair Department of Medicine, Pulmonary and Critical Care Medicine, University Medical Center Giessen and Marburg, Philipps-University Marburg, Germany, |
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| PRO Scientific Adviser: | Maggie Tabberer, Director, Patient Focussed Outcomes, Value Evidence and Outcomes GSK |
| Foundation Chair: | Professor Paul Jones, Global Medical Expert, GSK |

What does the CAT Governance Board do?

The CAT Governance Board is accountable for the oversight of CAT in terms of materials, platforms and developments. Key activities will include:

- Maximising the value of CAT by promoting uptake and usage as widely as possible and ensuring adoption of terms of use
- Maintaining the integrity of CAT by developing and approving translations available via the website
- Expanding the use of the CAT in clinical practice and in research

The Governance Board will also contribute to the Regulatory qualification efforts of the CAT as a drug development tool by the [COPD Foundation Biomarker Qualification Consortium](#).

How does the Governance Board regulate the use of the CAT?

GSK and the CAT Governance Board have decided that the CAT is free to use in clinical practice and in research within the terms of use there are set out on the CAT website (www.catestonline.org). Please review these terms to ensure that your proposed use of the CAT is covered. If your proposed use of the CAT is not covered by the terms of use, please contact GSK with your proposal and GSK will consider the proposal with the CAT Governance Board on a case-by-case basis having regard to the aims set out above.

Why does GSK hold the copyright for CAT?

GSK continues to hold copyright to ensure that translations of the CAT are conducted appropriately and are collected and made available to clinicians and researchers. Translations of the CAT have been approved by the CAT Governance Board and are available from the website.

GSK also provides administrative support to the Governance Board. In all activities related to the CAT, GSK will be guided by the advice and direction given by the CAT Governance Board. To get valid results from the CAT all eight questions must be used, in the order they are presented on the website.

Using the CAT in everyday clinical practice: why, who and when?

Why should I use the CAT?

The CAT is a short, simple questionnaire which is quick and easy for patients to complete. It provides a framework for discussions with your COPD patients and should enable you and them to gain a common understanding and grading of the impact of the disease on their life. It should also help you to identify where COPD has the greatest effect on the patient's health and daily life. As a result you may be better informed when discussing and making management decisions with your patients and be able to ensure that his or her health status is as good as it can be.

Where and how does the CAT fit into the clinical assessment of COPD?

The CAT provides a reliable measure of the impact of COPD on a patient's health status.^{1,2} It therefore provides supplementary information to that provided by other

aspects of COPD clinical assessment recommended by current management guidelines (i.e. assessment of exacerbation risk and degree of airway obstruction, assessed using spirometry)⁸.

The CAT does not replace COPD treatments but can help you monitor their effects, e.g. rehabilitation programmes or recovery from an exacerbation^{4,10,11}.

For which patients is the CAT suitable?

The CAT is suitable for completion by all patients diagnosed with COPD.

Can the CAT be used in all COPD patients irrespective of disease severity?

Yes. The CAT has been developed and validated in COPD patients of all severities. Stable patients of all severities (defined by FEV₁) and exacerbating patients were included in the development population^{1,3,6}

Does the CAT replace spirometry?

No. The CAT is not a diagnostic tool. Spirometry is essential for the diagnosis of COPD. The CAT and spirometry are complementary measures which can be used together in the clinical assessment of a patient's COPD to ensure that they are being optimally managed.

Can I use the CAT to diagnose COPD?

No, the CAT cannot be used alone as a diagnostic tool. Although the CAT is a scientifically developed tool for measurement of health status it is not a diagnostic instrument, unlike measures of lung function such as FEV₁, which confirm the diagnosis of COPD and assess the degree of airway obstruction.

Will the CAT help me make management decisions regarding any co-morbidities which my COPD patients may also have?

No. The CAT is a disease-specific tool to measure the impact of COPD on patients. It will not provide an assessment of co-morbid conditions or provide information to help guide any management decisions for co-morbid conditions.

How does the CAT compare with other health status measures used in COPD?

The CAT has very similar discriminative properties to the much more complex SGRQ which is often used in clinical trials showing that it will be able to measure the impact of COPD on individual patient's health¹. However, the CAT is much simpler and quicker to complete. This similarity enables us to describe what a patient's CAT score may mean and, more importantly, to interpret changes in CAT score.

Practical use of the CAT

When do I give the CAT to my patients to complete?

It is recommended that you ask a COPD patient to complete a CAT questionnaire when they arrive for a check-up appointment for their COPD or immediately before attending. The CAT test can also be completed online via the CAT website and printed out or emailed directly to you and takes only a couple of minutes. Patients could complete it whilst waiting to see you or at home prior to consultation. The completed CAT questionnaire can then provide a framework for your consultation.

Where can I access the CAT questionnaire?

You can download the CAT questionnaire from www.CATestonline.org

Will patients require much instruction to complete the CAT?

The content of the CAT questionnaire has been driven by COPD patients. It comprises 8 simple questions that most patients should be able to understand and answer easily. You should not need to assist patients to complete it. In fact it is much better if they complete this independently.

What is the scoring range of the CAT?

The CAT has a scoring range of 0-40.

What do CAT scores mean?

The implication of the CAT scores needs to be considered in relation to an individual's disease severity. Several studies have indicated that the relationship between lung function (FEV1) and health status scores is generally weak^{9,12}. As recognised by the GOLD strategic document the lung function, exacerbation frequency and health status are complementary⁸ and all together help to define the severity of the disease in a particular patient.

How frequently should the CAT be used in patients?

The CAT Governance Board and the GOLD strategic document recommend that patients routinely complete the CAT questionnaire every 2 to 3 months to detect changes and trends in CAT score⁸.

What change in CAT score is meaningful?

A difference or change of 2 or more units over 2 to 3 months in a patient suggests a clinically significant difference or change in health status. Research has been published to define ranges of CAT score severity and to understand the minimal clinically relevant change (often referred to as the Minimum Clinically Important Difference or MCID) in a CAT score from one visit to the next^{3,4,11}.

Can CAT be used to set a target score?

Since COPD is a progressive disease, a fixed target score for all patients cannot be set. In Practice, a target for improvement in individual patient CAT scores may be set, based on an holistic assessment of the patient. A change of 2 units suggests a meaningful difference.

What if my patient's CAT score gets worse?

Based on the correlation with SGRQ the CAT score would not be expected to decrease by more than 1 unit per year¹⁰. Worsening scores may indicate that patients are experiencing exacerbations that they have not reported to you. CAT scores may also worsen where a patient has stopped or is not taking their treatment effectively. Check inhaler technique as well as adherence to treatment. Where rapid disease progression is suspected, referral for specialist opinion may be required.

In addition, for each scenario, the CAT Development Steering Group proposed some potential management considerations¹³

| CAT score | Impact level | Broad clinical picture of the impact of COPD by CAT score | Possible management considerations |
|-----------|--------------|--|---|
| >30 | Very high | Their condition stops them doing everything they want to do and they never have any good days. If they can manage to take a bath or shower, it takes them a long time. They cannot go out of the house for shopping or recreation, or do their housework. Often, they cannot go far from their bed or chair. They feel as if they have become an invalid. | Patient has significant room for improvement In addition to the guidance for patients with low and medium impact CAT scores consider: <ul style="list-style-type: none"> Referral to specialist care (if you are a primary care physician) Also consider: <ul style="list-style-type: none"> Additional pharmacological treatments Referral for pulmonary rehabilitation Ensuring best approaches to minimising and managing exacerbations |
| >20 | High | COPD stops them doing most things that they want to do. They are breathless walking around the home and when getting washed or dressed. They may be breathless when they talk. Their cough makes them tired and their chest symptoms disturb their sleep on most nights. They feel that exercise is not safe for them and everything they do seems too much effort. They are afraid and panic and do not feel in control of their chest problem. | |
| 10-20 | Medium | COPD is one of the most important problems that they have. They have a few good days a week, but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests. | Patient has room for improvement – optimise management In addition to the guidance provided for patients with low impact CAT scores consider: <ul style="list-style-type: none"> Reviewing maintenance therapy – is it optimal? Referral for pulmonary rehabilitation Ensuring best approaches to minimising and managing exacerbations Reviewing aggravating factors – is the patient still smoking? |
| <10 | Low | Most days are good, but COPD causes a few problems and stops people doing one or two things that they would like to do. They usually cough several days a week and get breathless when playing sports and games and when carrying heavy loads. They have to slow down or stop when walking up hills or if they hurry when walking on level ground. They get exhausted easily. | <ul style="list-style-type: none"> Smoking cessation Annual influenza vaccination Reduce exposure to exacerbation risk factors Therapy as warranted by further clinical assessment. |
| 5 | | Upper limit of normal in healthy non-smokers | |

What effect does an exacerbation have on CAT scores?

We know from the first CAT validation study that CAT scores in patients with moderate-severe exacerbations are approximately 5 units higher than in those who have stable COPD.^{1,3} This finding is supported by subsequent research¹⁴. Patients responding to treatment for their exacerbation have been shown to reduce their CAT score by 2 units in 14 days, whilst patients who did not respond had no change in score³. A systematic review of research studies have also shown that it may take many weeks for patients to recover fully from a single moderate-severe exacerbation and some patients may never recover fully². Therefore another potential application of the CAT may be to assess the degree of recovery following an acute exacerbation by re-assessing the CAT score 2-3 months after the event.

Will I be able assess response to therapy with the CAT?

We know that the CAT has good repeatability^{1,2}, which is similar to that for the FEV₁ and, based upon our current knowledge, we believe that the relative size of its response to therapy will also be similar to that of the FEV₁. In a study of patients undergoing rehabilitation, CAT scores decreased by 3 units over 42 days in patients reporting an improvement in their COPD. In patients who reported worsening of COPD over the same period CAT scores increased by 2 units³. In assessing whether an *individual patient* has had a worthwhile response to a specific therapy, a thorough individual assessment taking a number of factors into account – including change in CAT score - will be required. However, the CAT *will* provide a measure of the individual patient's health that will be very useful in initial assessment and for following medium to long-term trends. It should also provide a prognostic measure of future health resource use in *individual patients*. The design of the CAT may also allow clinicians to readily identify areas of a patient's health that are more severely impaired than others, such as mood, daytime physical function or sleep.

Can I just use a few of the questions included in the CAT?

No. The CAT should be used in its entirety. The CAT was validated as an 8-item questionnaire and the questions should not be split up or used independently of each other which will reduce the integrity and measurement properties of the questionnaire. However, responses to the individual items can be used to provide you with an indication of the areas of the patient's health that are more affected than others. For example, one patient may have higher scores for cough and sputum, whereas another may have highest scores for the items about activity or sleep.

Is the CAT free to use?

Yes. The CAT is available and free to use globally (no charges will be associated with its use) in the situations described in the terms of use on the CAT website.

Do I need permission to use the CAT?

The CAT can be used in clinical practice without permission, as long as you respect the integrity of the test. To use the CAT in research you will need to agree to the terms and conditions of use which appear on the [CAT website](#). All copyright information must be maintained as they appear on the bottom of the CAT questionnaire. Details of how to access the CAT for use in research are given in the next sections of this User Guide.

Is the CAT available in different languages?

Yes. The CAT is available in more than 90 different languages. Only approved translations of the CAT questionnaire should be used to ensure the validity and measurement properties of the questionnaire are maintained. For further details on validated translations please visit www.CATestonline.org.

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www.CATestonline.org

The COPD Assessment Test was developed by a multi-disciplinary group of international experts in COPD supported by GSK. GSK activities with respect to the COPD Assessment Test are overseen by a governance board that includes independent external experts, one of whom chairs the board.

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