



COPD Assessment Test

User Guide

Expert guidance on frequently asked questions

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[Inside front cover]

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 guide¹⁷.

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 health care 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 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 Mike Polkey
Independent Chair

Professor Claus Vogelmeier
GOLD Science Committee Chair

Professor Mark Dransfield
COPD Foundation Consortium Working Group Chair

On behalf of the CAT Governance Board, May 2022

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 China⁷. 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 100 languages other than English. Only validated translations of the CAT should be used. You can access a subset (60+) of these translations directly on the CAT website, www.CATestonline.org.

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 (appendix 1). 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. 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 or a Consortium Working Group Chair. 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 PROs. GSK continues to own the copyright for the CAT to ensure its integrity. The COPDF maintains the CAT website and is responsible for the administrative support of the CAT Governance Board in addition to making translations of the CAT available for personal use or clinical practice users. The COPDF cannot grant permission to use the CAT otherwise and those requests should be directed to [Mapi Research Trust](#).

Who are members of the CAT Governance Board?

Current Membership of the CAT Governance Board (Jan 2023):

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, Member of the German Center for Lung Research (DZL)
COPD Foundation Working Group Consortium Chair:	Professor Mark Dransfield Division of Pulmonary, Allergy and Critical Care Medicine University of Alabama at Birmingham
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Dr. Rafael Alfonso
Value Evidence Lead , GSK

Foundation Chair: Professor Paul Jones, St George's
University of London, UK

What does the CAT Governance Board do?

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

- Maximising the value of the CAT by promoting uptake and usage as widely as possible and ensuring adoption of new [terms of use](#)
- Maintaining the integrity of CAT by developing and approving translations available via the website and distributed for research use via Mapi Research Trust
- Expanding the use of the CAT and CAAT 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 Chronic Lung Diseases Biomarker and Clinical Outcomes Assessments Qualification Consortium ([CBQC](#))¹⁷.

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 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. Academic and sponsored research uses require that you complete a request for use with Mapi Research Trust. If your proposed use of the CAT is not covered by the terms of use or our distribution agreement with Mapi, then Mapi will 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 for personal use and clinical practice. For other uses contact Mapi Research Trust.

What is the role of the COPD Foundation?

The COPDF provides administrative support to the Governance Board and is the host for the CAT website. In all activities related to the CAT, then COPDF will be guided by the advice and direction given by the CAT Governance Board.

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 condition on their life. It should also help you to identify where COPD has the greatest affect 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 access the CAT questionnaire at www.CATestonline.org. The public site provides easy access to a subset of the over 60 translations. These can be completed by patients online or printed/saved to pdf. Health Care Providers wishing to use the CAT for uses such as integration into EMR systems or for purposes of research should contact [MAPI Research Trust](http://www.MAPIResearchTrust.org) (see 'Permission to Use' section of the website) and request permission to use.

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 the CAT 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 a 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.

What is the CAAT?

The COPD Assessment Test of CAAT is the CAT but with a very small modification to make it usable by patients with obstructive airways other than COPD. The content has not changed. It's purpose is the same as the CAT – to measure the impact of the patients disease on their health status or health-related quality of life. It has recently undergone very comprehensive tests of its validity and these will be published soon. While it does seem that asthma patients and COPD patients respond slightly different to some items, overall it appears that CAAT scores in asthma mean the same thing as in COPD. This is a very important because it means that one simple questionnaire can be used for a range of conditions.

The COPDF will be adopting and supporting the CAAT and produce more guidance about it over the coming year, but basically it will be used in the same way as the CAT.

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?

The CAT is available and free to use globally (no charges will be associated with its use) for personal use, clinical practice, academic and non-profit projects. For sponsored or for-profit research a licensing fee will be assessed.

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 request Permission to Use through MAPI Research Trust. All copyright information must be maintained as they appear on the bottom of the CAT questionnaire.

Is the CAT available in different languages?

Yes. The CAT is available in more than 100 different languages, though only a subset of 60+ are available on the www.CATestonline.org website. 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 MAPI Research Trust or www.CATestonline.org. Requests for

development of new translations should be sent through MAPI. It is not a requirement that new translations be developed via Mapi.

Systematic Use of the CAT

Can I include the CAT routinely in health records in Clinical Practice?

Yes. The CAT was developed to help health care professionals monitor the health status of their patients with COPD so recording CAT scores in the patients medical record assists this process and is encouraged.

Can I include the CAT in my Hospital Electronic Medical Record System?

The systematic inclusion of CAT in an electronic medical record by a hospital or other health organisation is possible. If the CAT is to be completed by the patient then request Permission to Use through MAPI Research Trust. Mapi will review screenshots to ensure they adhere to GSK and Governance Board guidelines. The role of GSK, the CAT steering committee and the CAT Governance Board must be acknowledged. If any change to the CAT layout is made guidance should be sought via [MAPI](#) who will revert to GSK and the CAT Governance Board for guidance.

Using the CAT in Research

During the development of the CAT it became apparent that the measurement properties and responsiveness of the instrument were very similar to those of the more complex and longer SGRQ¹. This relationship has been demonstrated further in a number of studies². A formal mapping exercise was carried out which described the relationship and constructed a 'ladder' of COPD disease impact at different cut-off points of CAT score (Table 1: Jones, Tabberer, Chen 2011).

Furthermore, following extensive translation and linguistic validation the measurement properties and responsiveness of the CAT have been evaluated in many different countries and found to be similar².

The primary focus of the CAT Governance Board is to maximise the use and value of the CAT for patients, health care professionals and researchers. The information in the next sections of this guide will help you to use the CAT productively in research.

How do I get permission to use the CAT?

We have partnered with MAPI Research Trust for the management of requests for use and distribution of the CAT. The Permission to Use tab on the website includes a short summary of information on how to submit a request as well as a link to the MAPI Research Trust [website](#).

How do I obtain translations for my study?

You can obtain multiple translations and supporting certificates from Mapi Research Trust.

What happens if the language I need is not available?

If the language you require is not available you will be able to develop an appropriate translation with guidance from Mapi Research Trust.

How can I get a new translation made?

The CAT is used as a Patient Reported Outcome measure (PRO). It is therefore important that new translations are linguistically validated to the highest standards. Internationally recognised processes for translation¹⁸ are required for all new translations which are commissioned. New translations should be developed under the guidance of [Mapi Research Trust](#).

Why do I have to use approved translations?

To maintain the global use of the CAT in research it is extremely important that only one translation is used for each language in a country. It is for this reason that GSK maintains the copyright of the CAT, provides advice on translations in progress and the Mapi Research Trust manages the distribution of translations.

Can the CAT be used on electronic data collection devices?

The CAT has been tested and used on a number of electronic data collection devices (electronic Clinical Outcomes Assessment or eCOA).

Migration of the CAT to a new eCOA device should be conducted and evaluated using international guidelines^{15, 16}. Further details are provided in the next section of this user guide.

Use of the CAT on electronic data collection platforms

As indicated above, the CAT has been tested and used on a number of electronic data collection devices (eCOA).

Can you tell me more about eCOA's?

There are two main categories of eCOA administration platforms: voice/auditory devices (primarily telephone-based and commonly referred to as interactive voice response (IVR) and screen text devices (such as desktops, laptops and tablets) which provide the respondent with a computerized version of the PRO items and responses in a visual text format. CAT has been migrated to a number of screen text devices.

Does migrating a PRO to an eCOA make a difference?

Generally, existing evidence suggests that as long as only minor modifications were made to a PRO measure during the migration process the psychometric properties of the original measure will still hold for the eCOA version. Measurement equivalence of the two measures will still need to be demonstrated but the level of evidence required may be less than if more substantial changes are required.

What if I want to develop and use a new ePRO adapted from the CAT?

Migration of the CAT to a new eCOA platform or device needs to be supported by evidence to demonstrate the comparability, or measurement equivalence, of the ePRO to the paper-based CAT. Important considerations with regard to the level of evidence needed include a) the extent of modification required to administer the PRO on the eCOA device and b) how best to effectively test the measurement equivalence of the two modes of administration. Published reports and guidance are available which provide support and general frameworks for this development¹⁵.

Are there specific requirements for migrating CAT to a new eCOA platform?

When migrating CAT to a new screen based platform the horizontal format of the questions must be maintained, i.e.; the anchor statements should be located at each end of the response scale (not above or below the scale). Additional line breaks may be incorporated into each anchor statement. On e-diary devices it is acceptable to show one question per screen with the instructions on one or more introductory screens. For devices with larger screens multiple questions may be shown, In the ideal case the whole questionnaire should be presented to the patient however international requirements on text size and usability may prevent this.

Any incorporation of CAT into a 'bring your own device' data collection method should take into account the screen sizes likely to be used in any study¹⁶.

Further information on the requirements for eCOA migration and formatting can be obtained from [Mapi Reseach Trust](#).

Modes of administration

What mode of administration was the CAT developed for?

The CAT was developed for patient self-complete mode of administration.

Can the CAT be administered via clinician/investigator interview?

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. As such we cannot confirm that the CAT will behave the same way as it would in self-complete mode of administration. If it is absolutely necessary to undertake interview administration (e.g., due to profound vision impairment), then the interviewer must endeavour to read the instructions, items, and responses in a neutral tone, adding emphasis only where indicated via the text. The patient's selected response should be repeated to him/her to confirm.

Can the CAT be administered via caregiver interview?

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. We do not permit caregiver interview using the CAT.

Other materials for Researchers

Other materials are available on the website to assist your research

Within the website we have provided links to the publications describing the development of the CAT. You may wish to refer to these key references in your protocol, analysis plan and subsequent publication.

When using the CAT in a Regulatory submission in the US, please refer to A Drug Master File containing compiled data on CAT has been submitted by the COPD Foundation to the FDA and can be referenced by interested companies by contacting CATmailbox@copdfoundation.org

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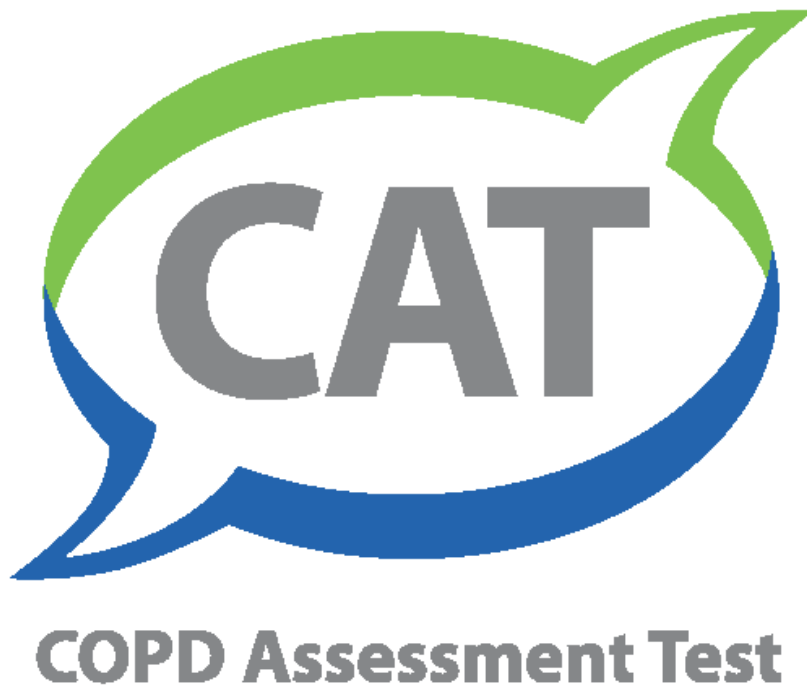
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19. [Back cover]



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