

Risk Matters



Dear Reader,

Chronic Obstructive Pulmonary Disease (COPD) has become the preferred name (rather than emphysema or chronic bronchitis) for a lung disease that is a significant public health problem. It is estimated that there are over three million people in the UK with significant airway obstruction but only about 900,000 have received the diagnosis and therefore appropriate treatment. The European Respiratory Society (ERS) predicts that by 2020 COPD will account for over six million deaths annually, making it the third leading cause of death worldwide. ERS gives the frequency of clinically relevant disease as between 4% and 10% of the European adult population.

In the UK, the National Institute of Clinical Excellence (NICE) is responsible for providing national guidance on promoting good health and preventing and treating ill health. Their recommendations can also have important implications for the insurance industry as they influence the way doctors diagnose and treat conditions.

The other aspect of the NICE guidelines that is of interest is the bringing together of the studies on mortality and morbidity in a coherent and thorough way. This allows underwriters and actuaries to assess the available evidence more accurately. NICE has recently updated its guidance on COPD, including recommendations on lung function tests (spirometry), assessment of prognostic factors and inhaled therapy. This update draws together many of these strands and presents a challenge to the industry's current thinking on this disease.

For other Gen Re publications please check our website www.genre.com.

Dr. Chris Ball, Consultant Medical Officer
Ross Campbell, Chief Underwriter, Gen Re Life/Health
Research & Development

Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is defined by the Global for Chronic Obstructive Lung Disease (GOLD) as a disease in which the patient experiences a reduction of the airflow in the lungs that is not fully reversible, is usually progressive, and is associated with an abnormal inflammatory response in the lungs to inhaled particles or gases (usually from smoking, but air pollution and more rarely Alpha 1-antitrypsin deficiency also play a part). The authors of the GOLD guidelines say that the disease is both treatable and preventable. The diagnosis should be considered in any patient who has shortness of breath and a chronic cough, and who smokes. Despite this more positive approach to the illness, most patients experience it as progressive and punctuated with exacerbations usually as a result of secondary infection.

COPD is primarily, though not entirely, a smoking-related condition, as smoking induces an inflammatory response leading in turn to tissue destruction in the lungs. It is likely that this process has been going on for a long time before the patient becomes symptomatic. Thereafter, features of chronic bronchitis (inflamed and narrow airways) and emphysema (damaged alveoli and lung structure) combine in COPD to prevent the lungs from emptying fully, making breathing possible only with great effort. Although rates of smoking in the UK have declined, reductions vary among different groups and have been slowest in deprived communities. Most people who develop COPD have therefore been smoking heavily for many years before the onset of

their symptoms. This prompts the National Institute of Clinical Excellence (NICE), in the COPD Update guideline (2010), to ask doctors to seek evidence of COPD in all those who are aged over 35 and who smoke: as well as those who experience the classic symptoms: exertional breathlessness, chronic cough, sputum, frequent winter bronchitis and wheeze.

Diagnosis

Opportunistic screening in the doctor's surgery can be highly effective at picking up early problems and may prompt the smoker to make appropriate lifestyle changes. In order to make the diagnosis the doctor must have ready access to lung function testing and the expertise to do such testing as spirometry, which measures the capacity of the lung to take in and expel air.

A number of measures are generated during testing.

For the purposes of assessing COPD, two measures are particularly important:

Forced Vital Capacity (FVC): the volume of air that can be forcibly expelled from the lung from maximum inspiration to maximum expiration.

Forced Expiratory Volume in one second (FEV₁): the volume of air that can be expelled from maximum inspiration in the first second.

Extensive research has produced normative data by age and gender but definitive reference values for all ethnic populations are still lacking. NICE was only able to identify a single study that measures FEV₁ nationally in the UK and this gives a figure of 10% of men and 11% of women having a lower than predicted reading. It is suggested that the prevalence of the illness has plateaued in men but is continuing to rise in women.

The diagnosis is made upon identification of airway obstruction when a person's FEV₁/FVC ratio is less than 0.7 and their FEV₁ is > 80% of their predicted value in the presence of symptoms. It is important that these measures are taken after a bronchodilator has been administered to help differentiate COPD from asthma which should respond to the drug (see Table 1).

Table 1 – Symptom comparison of COPD and asthma

	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under the age of 35	Rare	Common
Chronic productive cough	Common	Uncommon
Breathlessness	Persistent and progressive	Variable
Symptomatic nighttime waking	Uncommon	Common
Significant variation day by day	Uncommon	Common

Changing diagnostic parameters

In the first NICE COPD guideline (2004), mild disease was defined when the FEV₁/FVC ratio was <0.7 and the FEV₁ was between 50% and 79% of that predicted. The update guideline (2010) aligns their classification with that of the GOLD recommendations (see table 2). Ensuring that all measures are made 'post-bronchodilator' ensures against over-diagnosis of COPD at the expense of asthma but the redefining of the predicted FEV₁ parameters is likely to lead to many more people receiving the diagnosis of mild COPD. It is not entirely clear from the guidelines what these numbers will be but combined with the changes in general practice, it is likely that the numbers with undiagnosed COPD (currently estimated as 2 million) will fall significantly.

Table 2 – Redefining the severity of airflow obstruction

		NICE 2004	GOLD 2008	NICE 2010
Post-bronchodilator FEV ₁ /FVC	FEV ₁ % predicted		Post-bronchodilator	Post-bronchodilator
<0.7	>80%		Stage 1 - Mild	Stage 1 - Mild
<0.7	50-79%	Mild	Stage 2 - Moderate	Stage 2 - Moderate
<0.7	30-49%	Moderate	Stage 3 - Severe	Stage 3 - Severe
<0.7	<30%	Severe	Stage 4 - Very Severe	Stage 4 - Very Severe

Mortality and morbidity

COPD is the third most common cause of respiratory death in the UK. This amounts to 30,000 deaths per year, 90% of which are in the over sixty-fives. The deaths can be attributed to smoking in 85% of cases. Admission to hospital is a significant event as 25% of those who are admitted die within a year. For those with clinically mild disease not requiring constant therapy, the 5 year survival from diagnosis is 78% for men and 72% for women. The mean age of death for those diagnosed with severe COPD is 74.2, 77.2 for those with mild disease, and 78.3 for those without.

COPD has a significant impact on fitness to work. It is estimated that 24 million working days are lost each year as a result of the disease despite only 44% of sufferers being below retirement age. 24% are unable to work in any capacity and a further 9% find their ability to work is compromised.

Co-morbidity is also significant mostly, but not entirely, as a result of smoking. Cardiovascular disease is very common in this group and there is an inverse relationship between the FEV₁ and the risk of developing cancer even after adjusting for smoking. Women appear to have twice the risk of developing lung cancer compared to men.

Prognostic assessment

The FEV₁ has been traditionally used as a prognostic indicator and while it has been very useful to define thresholds for particular interventions and for mortality, it has been less useful when it comes to predicting disability or differentiating COPD from asthma. It is recommended that in addition to the

FEV₁, other clinical indices should be used to give a better prognostic view of the individual person. The guideline asks whether using a multi-dimensional assessment is better at predicting outcomes than FEV₁ alone. The best evidence was available for the BODE Index, which is a composite marker of disease taking into consideration the systemic nature of COPD (Celli et al., 2004). It includes not only the assessment of lung function with FEV₁ (% predicted) but also measures the patient's shortness of breath on the five point (0-4) modified medical research council (MMRC) dyspnoea scale that grades sufferers from breathless only with strenuous exercise (0) through to being too breathless to leave the house (4). The other two components are BMI and exercise tolerance measured as six-minute walking distance (6MWD) in metres.

Table 3 – Components of the BODE Index

Variable	0	1	2	3
B MI	>21	<=21	<=21	<=21
O bsturbation (FEV ₁)	>65	50-64	36-49	<=35
D yspnoea	0-1	2	3	4
E xercise (6MWD)	>=350	250-349	150-249	<=149

After review of the available studies, NICE concluded that the BODE Index better predicts the likelihood of COPD exacerbation at 5.1 years and the time to first exacerbation. It was also a better predictor of hospitalisation over a mean follow-up time of 16.2 years and also of mortality at 16.2, 28 and 36 months. A higher BODE score correlates with an increasing risk of death. With each quartile increase in the BODE score there was a statistically significant increase in the mortality. For the highest quartile (BODE score 7-10) the mortality at 52 months was 80%.

Conclusions

NICE guidelines are a hugely useful tool for clinicians, purchasers of health services and also for insurers. The latest update of the COPD guideline raises a number of important issues. If these guidelines are widely followed then it is likely that many more mild cases of COPD will be identified. If appropriate ratings are to be applied to this group there needs to be an understanding of the prognosis. If the FEV₁ is the only prognostic indicator used, then there will be great variability in the outcomes. Taking note of the recommendation to use a multidimensional assessment incorporating BMI, airflow obstruction, frequency of exacerbations, dyspnoea and exercise capacity as examples, there is a much greater chance that the risk of this group can be more fully assessed.

Further reading

<http://guidance.nice.org.uk/CG101/Guidance/pdf/English>

<http://www.goldcopd.org/Guidelineitem.asp?l1=2&l2=1&intlId=2002>

<http://www.nejm.org/doi/full/10.1056/NEJMoa021322>

Healthcare Commission (2006) *Clearing the air; a national study of COPD*



General Reinsurance London Branch

Corn Exchange
55 Mark Lane
London EC3R 7NE
Tel. +44 20 7426 1800
Fax +44 20 7426 1898
www.genre.com

Editor

Ross Campbell, ross_campbell@genre.com

Photos

© istockphotos/DNY59, Ina Ivanova

©General Reinsurance, London Branch 2010

This information was compiled by Gen Re and is intended to provide background information to our clients as well as to our professional staff. All the information that is contained in this article has been carefully researched and compiled to the best of our knowledge. Nevertheless, no responsibility is accepted for its accuracy, completeness or currency. In particular, this information does not constitute legal advice and cannot serve as a substitute for such advice.