

# Chronic obstructive pulmonary disease in over 16s: diagnosis and management

Clinical guideline

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This guideline replaces CG12.

This guideline is the basis of QS10.

## Introduction

This guidance is a partial update of NICE clinical guideline 12 (published February 2004) and replaces it.

An estimated 3 million people have chronic obstructive pulmonary disease (COPD) in the UK. About 900,000 have diagnosed COPD and an estimated 2 million people have COPD which remains undiagnosed<sup>[1]</sup>. Most patients are not diagnosed until they are in their fifties.

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

New recommendations have been added on spirometry, assessment of prognostic factors, and to the section on inhaled therapy (which now incorporates the previously separate sections on inhaled bronchodilators, inhaled corticosteroids and inhaled combination therapy).

Recommendations are marked as [2004], [2007], [2010] or [new 2010].

- [2004] indicates that the evidence has not been updated and reviewed since the original guideline.
- [2004, amended 2010] applies to one specific recommendation where the evidence has not been reviewed since the original guideline but it has been updated because of GDG consensus that it is out of date or no longer reflects clinical practice.
- [2007] applies to two specific recommendations that were developed as part of a technology appraisal in 2007.
- [2010] indicates that the evidence has been reviewed but no change has been made to the recommendation.
- [new 2010] indicates that the evidence has been reviewed and the recommendation has been updated or added.

<sup>[1]</sup>Healthcare Commission (2006) Clearing the air: a national study of chronic obstructive pulmonary disease. London: Healthcare Commission.

## Working definition of COPD

COPD is characterised by airflow obstruction that is not fully reversible. The airflow obstruction does not change markedly over several months and is usually progressive in the long term. COPD is predominantly caused by smoking. Other factors, particularly occupational exposures, may also contribute to the development of COPD. Exacerbations often occur, where there is a rapid and sustained worsening of symptoms beyond normal day-to-day variations.

The following should be used as a definition of COPD:

- Airflow obstruction is defined as a reduced FEV<sub>1</sub>/FVC ratio (where FEV<sub>1</sub> is forced expired volume in 1 second and FVC is forced vital capacity), such that FEV<sub>1</sub>/FVC is less than 0.7.
- If FEV<sub>1</sub> is  $\geq$  80% predicted normal a diagnosis of COPD should only be made in the presence of respiratory symptoms, for example breathlessness or cough.

The airflow obstruction is present because of a combination of airway and parenchymal damage. The damage is the result of chronic inflammation that differs from that seen in asthma and which is usually the result of tobacco smoke. Significant airflow obstruction may be present before the person is aware of it.

COPD produces symptoms, disability and impaired quality of life which may respond to pharmacological and other therapies that have limited or no impact on the airflow obstruction.

COPD is now the preferred term for the conditions in patients with airflow obstruction who were previously diagnosed as having chronic bronchitis or emphysema.

There is no single diagnostic test for COPD. Making a diagnosis relies on clinical judgement based on a combination of history, physical examination and confirmation of the presence of airflow obstruction using spirometry.

## Patient-centred care

This guideline offers best practice advice on the care of people with COPD.

Treatment and care should take into account patients' needs and preferences. People with COPD should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If people do not have the capacity to make decisions, healthcare professionals should follow the [Department of Health's advice on consent](#) and the [code of practice that accompanies the Mental Capacity Act](#). In Wales, healthcare professionals should follow [advice on consent from the Welsh Government](#).

If the patient is under 16, healthcare professionals should follow the guidelines in the Department of Health's '[Seeking consent: working with children](#)'.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the person agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

### Diagnose COPD

- A diagnosis of COPD should be considered in patients over the age of 35 who have a risk factor (generally smoking) and who present with exertional breathlessness, chronic cough, regular sputum production, frequent winter 'bronchitis' or wheeze. [2004]
- The presence of airflow obstruction should be confirmed by performing post-bronchodilator\* spirometry. All health professionals involved in the care of people with COPD should have access to spirometry and be competent in the interpretation of the results. [2004] [\*added 2010]

### Stop smoking

- Encouraging patients with COPD to stop smoking is one of the most important components of their management. All COPD patients still smoking, regardless of age, should be encouraged to stop, and offered help to do so, at every opportunity. [2004]

### Promote effective inhaled therapy

- In people with stable COPD who remain breathless or have exacerbations despite use of short-acting bronchodilators as required, offer the following as maintenance therapy:
  - if  $FEV_1 \geq 50\%$  predicted: either long-acting beta<sub>2</sub> agonist (LABA) or long-acting muscarinic antagonist (LAMA)
  - if  $FEV_1 < 50\%$  predicted: either LABA with an inhaled corticosteroid (ICS) in a combination inhaler, or LAMA. [new 2010]
- Offer LAMA in addition to LABA+ICS to people with COPD who remain breathless or have exacerbations despite taking LABA+ICS, irrespective of their  $FEV_1$ . [new 2010]

### Provide pulmonary rehabilitation for all who need it

- Pulmonary rehabilitation should be made available to all appropriate people with COPD including those who have had a recent hospitalisation for an acute exacerbation. [new 2010]

### Use non-invasive ventilation



- Non-invasive ventilation (NIV) should be used as the treatment of choice for persistent hypercapnic ventilatory failure during exacerbations not responding to medical therapy. It should be delivered by staff trained in its application, experienced in its use and aware of its limitations.
- When patients are started on NIV, there should be a clear plan covering what to do in the event of deterioration and ceilings of therapy should be agreed. [2004]

### Manage exacerbations

- The frequency of exacerbations should be reduced by appropriate use of inhaled corticosteroids and bronchodilators, and vaccinations. [2004]
- The impact of exacerbations should be minimised by:
  - giving self-management advice on responding promptly to the symptoms of an exacerbation
  - starting appropriate treatment with oral steroids and/or antibiotics
  - use of non-invasive ventilation when indicated
  - use of hospital-at-home or assisted-discharge schemes. [2004]

### Ensure multidisciplinary working

- COPD care should be delivered by a multidisciplinary team. [2004]

## 1 Guidance

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

### 1.1 *Diagnosing COPD*

The diagnosis of COPD depends on thinking of it as a cause of breathlessness or cough. The diagnosis is suspected on the basis of symptoms and signs and supported by spirometry.

#### 1.1.1 Symptoms

1.1.1.1 A diagnosis of COPD should be considered in patients over the age of 35 who have a risk factor (generally smoking) and who present with one or more of the following symptoms:

- exertional breathlessness
- chronic cough
- regular sputum production
- frequent winter 'bronchitis'
- wheeze. [2004]

1.1.1.2 Patients in whom a diagnosis of COPD is considered should also be asked about the presence of the following factors:

- weight loss
- effort intolerance
- waking at night
- ankle swelling
- fatigue
- occupational hazards
- chest pain

- haemoptysis.

NB These last two symptoms are uncommon in COPD and raise the possibility of alternative diagnoses. [2004]

- 1.1.1.3 One of the primary symptoms of COPD is breathlessness. The Medical Research Council (MRC) dyspnoea scale (see table 1) should be used to grade the breathlessness according to the level of exertion required to elicit it. [2004]

**Table 1 MRC dyspnoea scale**

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100 metres or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

Adapted from Fletcher CM, Elmes PC, Fairbairn MB et al. (1959) The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population. *British Medical Journal* 2: 257–66.

## 1.1.2 Spirometry

- 1.1.2.1 Spirometry should be performed:

- at the time of diagnosis
- to reconsider the diagnosis, if patients show an exceptionally good response to treatment. [2004]

- 1.1.2.2 Measure post-bronchodilator spirometry to confirm the diagnosis of COPD. [new 2010]

- 1.1.2.3 Consider alternative diagnoses or investigations in:

- older people without typical symptoms of COPD where the FEV<sub>1</sub>/FVC ratio is < 0.7
- younger people with symptoms of COPD where the FEV<sub>1</sub>/FVC ratio is ≥ 0.7. [new 2010]

1.1.2.4 All health professionals involved in the care of people with COPD should have access to spirometry and be competent in the interpretation of the results. [2004]

1.1.2.5 Spirometry can be performed by any healthcare worker who has undergone appropriate training and who keeps his or her skills up to date. [2004]

1.1.2.6 Spirometry services should be supported by quality control processes. [2004]

1.1.2.7 It is recommended that ERS 1993 reference values<sup>[2]</sup> are used but it is recognised that these values may lead to under-diagnosis in older people and are not applicable in black and Asian populations<sup>[3]</sup>. [2004]

### 1.1.3 Further investigations

1.1.3.1 At the time of their initial diagnostic evaluation in addition to spirometry all patients should have:

- a chest radiograph to exclude other pathologies
- a full blood count to identify anaemia or polycythaemia
- body mass index (BMI) calculated. [2004]

1.1.3.2 Additional investigations should be performed to aid management in some circumstances (see table 2). [2004]

Table 2 Additional investigations

Investigation	Role
Serial domiciliary peak flow measurements	To exclude asthma if diagnostic doubt remains
Alpha-1 antitrypsin	If early onset, minimal smoking history or family history

Transfer factor for carbon monoxide (T <sub>L</sub> CO)	To investigate symptoms that seem disproportionate to the spirometric impairment
CT scan of the thorax	To investigate symptoms that seem disproportionate to the spirometric impairment To investigate abnormalities seen on a chest radiograph To assess suitability for surgery
ECG	To assess cardiac status if features of cor pulmonale
Echocardiogram	To assess cardiac status if features of cor pulmonale
Pulse oximetry	To assess need for oxygen therapy If cyanosis or cor pulmonale present, or if FEV <sub>1</sub> < 50% predicted
Sputum culture	To identify organisms if sputum is persistently present and purulent

1.1.3.3 Patients identified as having alpha-1 antitrypsin deficiency should be offered the opportunity to be referred to a specialist centre to discuss the clinical management of this condition. [2004]

## 1.1.4 Reversibility testing

1.1.4.1 In most patients routine spirometric reversibility testing is not necessary as a part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids. It may be unhelpful or misleading because:

- repeated FEV<sub>1</sub> measurements can show small spontaneous fluctuations
- the results of a reversibility test performed on different occasions can be inconsistent and not reproducible
- over-reliance on a single reversibility test may be misleading unless the change in FEV<sub>1</sub> is greater than 400 ml
- the definition of the magnitude of a significant change is purely arbitrary
- response to long-term therapy is not predicted by acute reversibility testing. [2004]

1.1.4.2 COPD and asthma are frequently distinguishable on the basis of history (and examination) in untreated patients presenting for the first time. Features from the history and examination (such as those listed in table 3) should be used to differentiate COPD from asthma whenever possible. [2004]

**Table 3 Clinical features differentiating COPD and asthma**

	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35	Rare	Often
Chronic productive cough	Common	Uncommon
Breathlessness	Persistent and progressive	Variable
Night time waking with breathlessness and/or wheeze	Uncommon	Common
Significant diurnal or day-to-day variability of symptoms	Uncommon	Common

1.1.4.3 Longitudinal observation of patients (whether using spirometry, peak flow or symptoms) should also be used to help differentiate COPD from asthma. [2004]

1.1.4.4 To help resolve cases where diagnostic doubt remains, or both COPD and asthma are present, the following findings should be used to help identify asthma:

- a large (> 400 ml) response to bronchodilators
- a large (> 400 ml) response to 30 mg oral prednisolone daily for 2 weeks
- serial peak flow measurements showing 20% or greater diurnal or day-to-day variability.

Clinically significant COPD is not present if the FEV<sub>1</sub> and FEV<sub>1</sub>/FVC ratio return to normal with drug therapy. [2004]

1.1.4.5 If diagnostic uncertainty remains, referral for more detailed investigations, including imaging and measurement of TLCO, should be considered. [2004]

1.1.4.6 If patients report a marked improvement in symptoms in response to inhaled therapy, the diagnosis of COPD should be reconsidered. [2004]

### 1.1.5 Assessment of severity and prognostic factors

COPD is heterogeneous, so no single measure can give an adequate assessment of the true severity of the disease in an individual patient. Severity assessment is, nevertheless, important because it has implications for therapy and relates to prognosis.

1.1.5.1 Be aware that disability in COPD can be poorly reflected in the FEV<sub>1</sub>. A more comprehensive assessment of severity includes the degree of airflow obstruction and disability, the frequency of exacerbations and the following known prognostic factors:

- FEV<sub>1</sub>
- T<sub>L</sub>CO
- breathlessness (MRC scale)
- health status
- exercise capacity (for example, 6-minute walk test)
- BMI
- partial pressure of oxygen in arterial blood (PaO<sub>2</sub>)
- cor pulmonale.

Calculate the BODE index (BMI, airflow obstruction, dyspnoea and exercise capacity) to assess prognosis where its component information is currently available. [new 2010]

### 1.1.6 Assessment and classification of severity of airflow obstruction

1.1.6.1 The severity of airflow obstruction should be assessed according to the reduction in FEV<sub>1</sub> as shown in table 4. [new 2010]

Table 4 Gradation of severity of airflow obstruction

		NICE clinical guideline 12 (2004)	ATS/ERS <sup>[a]</sup> 2004	GOLD 2008 <sup>[b]</sup>	NICE clinical guideline 101 (2010)
Post-bronchodilator FEV <sub>1</sub> /FVC	FEV <sub>1</sub> % predicted	Severity of airflow obstruction			
			Post-bronchodilator	Post-bronchodilator	Post-bronchodilator
< 0.7	≥ 80%		Mild	Stage 1 – Mild	Stage 1 – Mild*
< 0.7	50–79%	Mild	Moderate	Stage 2 – Moderate	Stage 2 – Moderate
< 0.7	30–49%	Moderate	Severe	Stage 3 – Severe	Stage 3 – Severe
< 0.7	< 30%	Severe	Very severe	Stage 4 – Very severe**	Stage 4 – Very severe**
<p><sup>[a]</sup> Celli BR, MacNee W (2004) Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. <i>European Respiratory Journal</i> 23(6): 932–46.</p> <p><sup>[b]</sup> Global Initiative for Chronic Obstructive Lung Disease (GOLD) (2008) Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease.</p>					

\*Symptoms should be present to diagnose COPD in people with mild airflow obstruction (see recommendation 1.1.1.1).

\*\*Or FEV<sub>1</sub> < 50% with respiratory failure.

## 1.1.7 Identification of early disease

1.1.7.1 Spirometry should be performed in patients who are over 35, current or ex-smokers, and have a chronic cough. [2004]

1.1.7.2 Spirometry should be considered in patients with chronic bronchitis. A significant proportion of these will go on to develop airflow limitation<sup>[4]</sup>. [2004]



## 1.1.8 Referral for specialist advice

- 1.1.8.1 It is recommended that referrals for specialist advice are made when clinically indicated. Referral may be appropriate at all stages of the disease and not solely in the most severely disabled patients (see table 5). [2004]

Table 5 Reasons for referral include

Reason	Purpose
There is diagnostic uncertainty	Confirm diagnosis and optimise therapy
Suspected severe COPD	Confirm diagnosis and optimise therapy
The patient requests a second opinion	Confirm diagnosis and optimise therapy
Onset of cor pulmonale	Confirm diagnosis and optimise therapy
Assessment for oxygen therapy	Optimise therapy and measure blood gases
Assessment for long-term nebuliser therapy	Optimise therapy and exclude inappropriate prescriptions
Assessment for oral corticosteroid therapy	Justify need for long-term treatment or supervise withdrawal
Bullous lung disease	Identify candidates for surgery
A rapid decline in FEV <sub>1</sub>	Encourage early intervention
Assessment for pulmonary rehabilitation	Identify candidates for pulmonary rehabilitation
Assessment for lung volume reduction surgery	Identify candidates for surgery
Assessment for lung transplantation	Identify candidates for surgery
Dysfunctional breathing	Confirm diagnosis, optimise pharmacotherapy and access other therapists
Onset of symptoms under 40 years or a family history of alpha-1 antitrypsin deficiency	Identify alpha-1 antitrypsin deficiency, consider therapy and screen family
Uncertain diagnosis	Make a diagnosis

Symptoms disproportionate to lung function deficit	Look for other explanations including cardiac impairment, pulmonary hypertension, depression and hyperventilation
Frequent infections	Exclude bronchiectasis
Haemoptysis	Exclude carcinoma of the bronchus

1.1.8.2 Patients who are referred do not always have to be seen by a respiratory physician. In some cases they may be seen by members of the COPD team who have appropriate training and expertise. [2004]

## 1.2 *Managing stable COPD*

### 1.2.1 Smoking cessation

1.2.1.1 An up-to-date smoking history, including pack years smoked (number of cigarettes smoked per day, divided by 20, multiplied by the number of years smoked), should be documented for everyone with COPD. [2004]

1.2.1.2 All COPD patients still smoking, regardless of age, should be encouraged to stop, and offered help to do so, at every opportunity. [2004]

1.2.1.3 Unless contraindicated, offer NRT, varenicline or bupropion, as appropriate, to people who are planning to stop smoking combined with an appropriate support programme to optimise smoking quit rates for people with COPD<sup>[5]</sup>. [2010]

The following two recommendations are from '[Varenicline for smoking cessation](#)' (NICE technology appraisal guidance 123).

1.2.1.4 Varenicline is recommended within its licensed indications as an option for smokers who have expressed a desire to quit smoking. [2007]

1.2.1.5 Varenicline should normally be prescribed only as part of a programme of behavioural support. [2007]

### 1.2.2 Inhaled therapy

**Short-acting beta2 agonists (SABA) and short-acting muscarinic antagonists (SAMA)**

- 1.2.2.1 Short-acting bronchodilators, as necessary, should be the initial empirical treatment for the relief of breathlessness and exercise limitation. [2004]

### Inhaled corticosteroids

- 1.2.2.2 Oral corticosteroid reversibility tests do not predict response to inhaled corticosteroid therapy and should not be used to identify which patients should be prescribed inhaled corticosteroids. [2004]
- 1.2.2.3 Be aware of the potential risk of developing side effects (including non-fatal pneumonia) in people with COPD treated with inhaled corticosteroids and be prepared to discuss with patients. [new 2010]

### Inhaled combination therapy

This section provides recommendations on the sequence of inhaled therapies for people with stable COPD. These recommendations are also given in diagram form in algorithm 2a (see appendix C).

- 1.2.2.4 The effectiveness of bronchodilator therapy should not be assessed by lung function alone but should include a variety of other measures such as improvement in symptoms, activities of daily living, exercise capacity, and rapidity of symptom relief. [2004]
- 1.2.2.5 Offer once-daily long-acting muscarinic antagonist (LAMA) in preference to four-times-daily short-acting muscarinic antagonist (SAMA) to people with stable COPD who remain breathless or have exacerbations despite using short-acting bronchodilators as required, and in whom a decision has been made to commence regular maintenance bronchodilator therapy with a muscarinic antagonist<sup>[6]</sup>. [new 2010]
- 1.2.2.6 In people with stable COPD who remain breathless or have exacerbations despite using short-acting bronchodilators as required, offer the following as maintenance therapy:
- if  $FEV_1 \geq 50\%$  predicted: either long-acting beta<sub>2</sub> agonist (LABA) or LAMA
  - if  $FEV_1 < 50\%$  predicted: either LABA with an inhaled corticosteroid (ICS) in a combination inhaler, or LAMA. [new 2010]

- 1.2.2.7 In people with stable COPD and an FEV<sub>1</sub> ≥ 50% who remain breathless or have exacerbations despite maintenance therapy with a LABA:
- consider LABA+ICS in a combination inhaler
  - consider LAMA in addition to LABA where ICS is declined or not tolerated. [new 2010]
- 1.2.2.8 Offer LAMA in addition to LABA+ICS to people with COPD who remain breathless or have exacerbations despite taking LABA+ICS, irrespective of their FEV<sub>1</sub>. [new 2010]
- 1.2.2.9 Consider LABA+ICS in a combination inhaler in addition to LAMA for people with stable COPD who remain breathless or have exacerbations despite maintenance therapy with LAMA irrespective of their FEV<sub>1</sub>. [new 2010]
- 1.2.2.10 The choice of drug(s) should take into account the person's symptomatic response and preference, and the drug's potential to reduce exacerbations, its side effects and cost. [2010]

### Delivery systems used to treat patients with stable COPD

Most patients – whatever their age – are able to acquire and maintain adequate inhaler technique given adequate instruction. The exception to this is that those with significant cognitive impairment (as a guideline, those with a Hodkinson Abbreviated Mental Test Score of 4 or less) are unable to use any form of inhaler device. In most patients, however, a pragmatic approach guided by individual patient assessment is needed in choosing a device.

### Inhalers

- 1.2.2.11 In most cases bronchodilator therapy is best administered using a hand-held inhaler device (including a spacer device if appropriate). [2004]
- 1.2.2.12 If the patient is unable to use a particular device satisfactorily, it is not suitable for him or her, and an alternative should be found. [2004]
- 1.2.2.13 Inhalers should be prescribed only after patients have received training in the use of the device and have demonstrated satisfactory technique. [2004]

1.2.2.14 Patients should have their ability to use an inhaler device regularly assessed by a competent healthcare professional and, if necessary, should be re-taught the correct technique. [2004]

### Spacers

1.2.2.15 The spacer should be compatible with the patient's metered-dose inhaler. [2004]

1.2.2.16 It is recommended that spacers are used in the following way:

- the drug is administered by repeated single actuations of the metered-dose inhaler into the spacer, with each followed by inhalation
- there should be minimal delay between inhaler actuation and inhalation
- tidal breathing can be used as it is as effective as single breaths. [2004]

1.2.2.17 Spacers should be cleaned no more than monthly as more frequent cleaning affects their performance (because of a build up of static). They should be cleaned with water and washing-up liquid and allowed to air dry. The mouthpiece should be wiped clean of detergent before use. [2004]

### Nebulisers

1.2.2.18 Patients with distressing or disabling breathlessness despite maximal therapy using inhalers should be considered for nebuliser therapy. [2004]

1.2.2.19 Nebulised therapy should not continue to be prescribed without assessing and confirming that one or more of the following occurs:

- a reduction in symptoms
- an increase in the ability to undertake activities of daily living
- an increase in exercise capacity
- an improvement in lung function. [2004]

1.2.2.20 Nebulised therapy should not be prescribed without an assessment of the patient's and/or carer's ability to use it. [2004]

- 1.2.2.21 A nebuliser system that is known to be efficient should be used. Once available, Comité Européen de Normalisation (European Committee for Standardisation, CEN) data should be used to assess efficiency. [2004]
- 1.2.2.22 Patients should be offered a choice between a facemask and a mouthpiece to administer their nebulised therapy, unless the drug specifically requires a mouthpiece (for example, anticholinergic drugs). [2004]
- 1.2.2.23 If nebuliser therapy is prescribed, the patient should be provided with equipment, servicing, advice and support. [2004]

### 1.2.3 Oral therapy

#### Oral corticosteroids

- 1.2.3.1 Maintenance use of oral corticosteroid therapy in COPD is not normally recommended. Some patients with advanced COPD may require maintenance oral corticosteroids when these cannot be withdrawn following an exacerbation. In these cases, the dose of oral corticosteroids should be kept as low as possible. [2004]
- 1.2.3.2 Patients treated with long-term oral corticosteroid therapy should be monitored for the development of osteoporosis and given appropriate prophylaxis. Patients over the age of 65 should be started on prophylactic treatment, without monitoring. [2004]

#### Oral theophylline

In this section of the guideline, the term theophylline is used to mean slow-release formulations of this drug.

- 1.2.3.3 Theophylline should only be used after a trial of short-acting bronchodilators and long-acting bronchodilators, or in patients who are unable to use inhaled therapy, as there is a need to monitor plasma levels and interactions. [2004]
- 1.2.3.4 Particular caution needs to be taken with the use of theophylline in older people because of differences in pharmacokinetics, the increased likelihood of comorbidities and the use of other medications. [2004]

- 1.2.3.5 The effectiveness of the treatment with theophylline should be assessed by improvements in symptoms, activities of daily living, exercise capacity and lung function. [2004]
- 1.2.3.6 The dose of theophylline prescribed should be reduced at the time of an exacerbation if macrolide or fluroquinolone antibiotics (or other drugs known to interact) are prescribed. [2004]

#### **Oral mucolytic therapy**

- 1.2.3.7 Mucolytic drug therapy should be considered in patients with a chronic cough productive of sputum. [2004]
- 1.2.3.8 Mucolytic therapy should be continued if there is symptomatic improvement (for example, reduction in frequency of cough and sputum production). [2004]
- 1.2.3.9 Do not routinely use mucolytic drugs to prevent exacerbations in people with stable COPD. [new 2010]

#### **Oral anti-oxidant therapy**

- 1.2.3.10 Treatment with alpha-tocopherol and beta-carotene supplements, alone or in combination, is not recommended. [2004]

#### **Anti-tussive therapy**

- 1.2.3.11 Anti-tussive therapy should not be used in the management of stable COPD. [2004]

#### **Oral prophylactic antibiotic therapy**

- 1.2.3.12 There is insufficient evidence to recommend prophylactic antibiotic therapy in the management of stable COPD. [2004]

## 1.2.4 Combined oral and inhaled therapy

1.2.4.1 If patients remain symptomatic on monotherapy, their treatment should be intensified by combining therapies from different drug classes. Effective combinations include:

- beta<sub>2</sub> agonist and theophylline
- anticholinergic and theophylline. [2004]

## 1.2.5 Oxygen

### Long-term oxygen therapy (LTOT)

1.2.5.1 Clinicians should be aware that inappropriate oxygen therapy in people with COPD may cause respiratory depression. [2004]

1.2.5.2 LTOT is indicated in patients with COPD who have a PaO<sub>2</sub> less than 7.3 kPa when stable or a PaO<sub>2</sub> greater than 7.3 and less than 8 kPa when stable and one of: secondary polycythaemia, nocturnal hypoxaemia (oxygen saturation of arterial blood [SaO<sub>2</sub>] less than 90% for more than 30% of the time), peripheral oedema or pulmonary hypertension. [2004]

1.2.5.3 To get the benefits of LTOT patients should breathe supplemental oxygen for at least 15 hours per day. Greater benefits are seen in patients receiving oxygen for 20 hours per day. [2004]

1.2.5.4 The need for oxygen therapy should be assessed in:

- all patients with very severe airflow obstruction (FEV<sub>1</sub> < 30% predicted)
- patients with cyanosis
- patients with polycythaemia
- patients with peripheral oedema
- patients with a raised jugular venous pressure
- patients with oxygen saturations ≤ 92% breathing air.



Assessment should also be considered in patients with severe airflow obstruction (FEV<sub>1</sub> 30–49% predicted). [2004]

- 1.2.5.5 To ensure all patients eligible for LTOT are identified, pulse oximetry should be available in all healthcare settings. [2004]
- 1.2.5.6 The assessment of patients for LTOT should comprise the measurement of arterial blood gases on two occasions at least 3 weeks apart in patients who have a confident diagnosis of COPD, who are receiving optimum medical management and whose COPD is stable. [2004]
- 1.2.5.7 Patients receiving LTOT should be reviewed at least once per year by practitioners familiar with LTOT and this review should include pulse oximetry. [2004]
- 1.2.5.8 Oxygen concentrators should be used to provide the fixed supply at home for long-term oxygen therapy. [2004]
- 1.2.5.9 Patients should be warned about the risks of fire and explosion if they continue to smoke when prescribed oxygen. [2004]

#### Ambulatory oxygen therapy

- 1.2.5.10 People who are already on LTOT who wish to continue with oxygen therapy outside the home, and who are prepared to use it, should have ambulatory oxygen prescribed. [2004]
- 1.2.5.11 Ambulatory oxygen therapy should be considered in patients who have exercise desaturation, are shown to have an improvement in exercise capacity and/or dyspnoea with oxygen, and have the motivation to use oxygen. [2004]
- 1.2.5.12 Ambulatory oxygen therapy is not recommended in COPD if PaO<sub>2</sub> is greater than 7.3 kPa and there is no exercise desaturation. [2004]
- 1.2.5.13 Ambulatory oxygen therapy should only be prescribed after an appropriate assessment has been performed by a specialist. The purpose of the assessment is to assess the extent of desaturation, and the improvement in exercise capacity with supplemental oxygen, and the oxygen flow rate required to correct desaturation. [2004]

1.2.5.14 Small light-weight cylinders, oxygen-conserving devices and portable liquid oxygen systems should be available for the treatment of patients with COPD. [2004]

1.2.5.15 A choice about the nature of equipment prescribed should take account of the hours of ambulatory oxygen use required by the patient and the oxygen flow rate required. [2004]

### Short-burst oxygen therapy

1.2.5.16 Short-burst oxygen therapy should only be considered for episodes of severe breathlessness in patients with COPD not relieved by other treatments. [2004]

1.2.5.17 Short-burst oxygen therapy should only continue to be prescribed if an improvement in breathlessness following therapy has been documented. [2004]

1.2.5.18 When indicated, short-burst oxygen should be provided from cylinders. [2004]

## 1.2.6 Non-invasive ventilation

1.2.6.1 Adequately treated patients with chronic hypercapnic respiratory failure who have required assisted ventilation (whether invasive or non-invasive) during an exacerbation or who are hypercapnic or acidotic on LTOT should be referred to a specialist centre for consideration of long-term NIV. [2004]

## 1.2.7 Management of pulmonary hypertension and cor pulmonale

In the context of this guideline, the term 'cor pulmonale' has been adopted to define a clinical condition that is identified and managed on the basis of clinical features. This clinical syndrome of cor pulmonale includes patients who have right heart failure secondary to lung disease and those in whom the primary pathology is retention of salt and water, leading to the development of peripheral oedema.

### Diagnosis of pulmonary hypertension and cor pulmonale

1.2.7.1 A diagnosis of cor pulmonale should be considered if patients have:

- peripheral oedema

- a raised venous pressure
- a systolic parasternal heave
- a loud pulmonary second heart sound. [2004]

1.2.7.2 It is recommended that the diagnosis of cor pulmonale is made clinically and that this process should involve excluding other causes of peripheral oedema. [2004]

### Treatment of cor pulmonale

1.2.7.3 Patients presenting with cor pulmonale should be assessed for the need for long-term oxygen therapy. [2004]

1.2.7.4 Oedema associated with cor pulmonale can usually be controlled symptomatically with diuretic therapy. [2004]

1.2.7.5 The following are not recommended for the treatment of cor pulmonale:

- angiotensin-converting enzyme inhibitors
- calcium channel blockers
- alpha-blockers
- digoxin (unless there is atrial fibrillation). [2004]

## 1.2.8 Pulmonary rehabilitation

Pulmonary rehabilitation is defined as a multidisciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise each patient's physical and social performance and autonomy.

1.2.8.1 Pulmonary rehabilitation should be made available to all appropriate people with COPD (see 1.2.8.2) including those who have had a recent hospitalisation for an acute exacerbation. [new 2010]

1.2.8.2 Pulmonary rehabilitation should be offered to all patients who consider themselves functionally disabled by COPD (usually MRC grade 3 and above).

Pulmonary rehabilitation is not suitable for patients who are unable to walk, have unstable angina or who have had a recent myocardial infarction. [2004]

1.2.8.3 For pulmonary rehabilitation programmes to be effective, and to improve concordance, they should be held at times that suit patients, and in buildings that are easy for patients to get to and have good access for people with disabilities. Places should be available within a reasonable time of referral. [2004]

1.2.8.4 Pulmonary rehabilitation programmes should include multicomponent, multidisciplinary interventions, which are tailored to the individual patient's needs. The rehabilitation process should incorporate a programme of physical training, disease education, nutritional, psychological and behavioural intervention. [2004]

1.2.8.5 Patients should be made aware of the benefits of pulmonary rehabilitation and the commitment required to gain these. [2004]

## 1.2.9 Vaccination and anti-viral therapy

1.2.9.1 Pneumococcal vaccination and an annual influenza vaccination should be offered to all patients with COPD as recommended by the Chief Medical Officer<sup>[7]</sup>. [2004]

## 1.2.10 Lung surgery

1.2.10.1 Patients who are breathless, and have a single large bulla on a CT scan and an FEV<sub>1</sub> less than 50% predicted should be referred for consideration of bullectomy. [2004]

1.2.10.2 Patients with severe COPD who remain breathless with marked restrictions of their activities of daily living, despite maximal medical therapy (including rehabilitation), should be referred for consideration of lung volume reduction surgery if they meet all of the following criteria:

- FEV<sub>1</sub> more than 20% predicted
- PaCO<sub>2</sub> less than 7.3 kPa

- upper lobe predominant emphysema
- T<sub>L</sub>CO more than 20% predicted. [2004]

1.2.10.3 Patients with severe COPD who remain breathless with marked restrictions of their activities of daily living despite maximal medical therapy should be considered for referral for assessment for lung transplantation bearing in mind comorbidities and local surgical protocols. Considerations include:

- age
- FEV<sub>1</sub>
- PaCO<sub>2</sub>
- homogeneously distributed emphysema on CT scan
- elevated pulmonary artery pressures with progressive deterioration. [2004]

### 1.2.11 Alpha-1 antitrypsin replacement therapy

1.2.11.1 Alpha-1 antitrypsin replacement therapy is not recommended for patients with alpha-1 antitrypsin deficiency (see also recommendation 1.1.3.3). [2004]

### 1.2.12 Multidisciplinary management

Many of these activities may be undertaken in the clinic or in the practice as part of routine care by the practitioner seeing the patient but in certain circumstances the patient may need to be referred to a specialist department, for example, physiotherapy. Multidisciplinary working means breaking down historic demarcation of roles because many of the activities in managing COPD can be undertaken by individuals from different professional backgrounds. Competencies are more important than professional boundaries.

1.2.12.1 COPD care should be delivered by a multidisciplinary team. [2004]

1.2.12.2 The following functions should be considered when defining the activity of the multidisciplinary team:

- assessing patients (including performing spirometry, assessing the need for oxygen, the need for aids for daily living and the appropriateness of delivery systems for inhaled therapy)

- care and treatment of patients (including non-invasive ventilation, pulmonary rehabilitation, hospital-at-home/early discharge schemes, providing palliative care, identifying and managing anxiety and depression, advising patients on relaxation techniques, dietary issues, exercise, social security benefits and travel)
- advising patients on self-management strategies
- identifying and monitoring patients at high risk of exacerbations and undertaking activities which aim to avoid emergency admissions
- advising patients on exercise
- education of patients and other health professionals. [2004]

### Respiratory nurse specialists

1.2.12.3 It is recommended that respiratory nurse specialists form part of the multidisciplinary COPD team. [2004]

### Physiotherapy

1.2.12.4 If patients have excessive sputum, they should be taught:

- the use of positive expiratory pressure masks
- active cycle of breathing techniques. [2004]

### Identifying and managing anxiety and depression

1.2.12.5 Healthcare professionals should be alert to the presence of depression in patients with COPD. The presence of anxiety and depression should be considered in patients:

- who are hypoxic
- who have severe dyspnoea
- who have been seen at or admitted to a hospital with an exacerbation of COPD. [2004]

Refer to '[Depression in adults with a chronic physical health problem](#)' (NICE clinical

guideline 91), which updates the recommendations on the treatment of depression in patients with COPD.

## Nutritional factors

1.2.12.6 BMI should be calculated in patients with COPD:

- the normal range for BMI is 20 to less than 25<sup>[a]</sup>
- if the BMI is abnormal (high or low), or changing over time, the patient should be referred for dietetic advice
- if the BMI is low patients should also be given nutritional supplements to increase their total calorific intake and be encouraged to take exercise to augment the effects of nutritional supplementation.

1.2.12.7 Refer to '[Nutrition support in adults](#)' (NICE clinical guideline 32). [2004]

In older patients attention should also be paid to changes in weight, particularly if the change is more than 3 kg. [2004]

## Palliative care

1.2.12.8 Opioids should be used when appropriate to palliate breathlessness in patients with end-stage COPD which is unresponsive to other medical therapy. [2004]

1.2.12.9 Benzodiazepines, tricyclic antidepressants, major tranquillisers and oxygen should also be used when appropriate for breathlessness in patients with end-stage COPD unresponsive to other medical therapy. [2004]

1.2.12.10 Patients with end-stage COPD and their family and carers should have access to the full range of services offered by multidisciplinary palliative care teams, including admission to hospices. [2004]

## Assessment for occupational therapy

1.2.12.11 Patients should be regularly asked about their ability to undertake activities of daily living and how breathless they become when doing these. [2004]

1.2.12.12 Clinicians involved in the care of people with COPD should assess their need for occupational therapy using validated tools. [2004]

### Social services

1.2.12.13 Patients disabled by COPD should be considered for referral for assessment by a social services department. [2004]

### Advice on travel

1.2.12.14 All patients on LTOT planning air travel should be assessed in line with the BTS recommendations<sup>[9]</sup>. [2004]

1.2.12.15 All patients with an FEV<sub>1</sub> < 50% predicted who are planning air travel should be assessed in line with the BTS recommendations. [2004]

1.2.12.16 All patients known to have bullous disease should be warned that they are at a theoretically increased risk of developing a pneumothorax during air travel. [2004]

### Advice on diving

1.2.12.17 Scuba diving is not generally recommended for patients with COPD. Advise people with queries to seek specialist advice. [2004]

### Education

1.2.12.18 There are significant differences in the response of patients with COPD and asthma to education programmes. Programmes designed for asthma should not be used in COPD. [2004]

1.2.12.19 Specific educational packages should be developed for patients with COPD.

- Suggested topics for inclusion are listed in appendix C of the full guideline (see [section 5](#) for details of the full guideline).
- The packages should take account of the different needs of patients at different stages of their disease. [2004]



1.2.12.20 Patients with moderate and severe COPD should be made aware of the technique of NIV. Its benefits and limitations should be explained so that if it is ever necessary in the future they will be aware of these issues (see section 1.3.7). [2004]

### Self-management

1.2.12.21 Patients at risk of having an exacerbation of COPD should be given self-management advice that encourages them to respond promptly to the symptoms of an exacerbation. [2004]

1.2.12.22 Patients should be encouraged to respond promptly to the symptoms of an exacerbation by:

- starting oral corticosteroid therapy if their increased breathlessness interferes with activities of daily living (unless contraindicated)
- starting antibiotic therapy if their sputum is purulent
- adjusting their bronchodilator therapy to control their symptoms. [2004]

1.2.12.23 Patients at risk of having an exacerbation of COPD should be given a course of antibiotic and corticosteroid tablets to keep at home for use as part of a self-management strategy (see recommendation 1.3.5.9). [2004]

1.2.12.24 The appropriate use of these tablets should be monitored. [2004]

1.2.12.25 Patients given self-management plans should be advised to contact a healthcare professional if they do not improve. [2004]

### 1.2.13 Fitness for general surgery

1.2.13.1 The ultimate clinical decision about whether or not to proceed with surgery should rest with a consultant anaesthetist and consultant surgeon taking account of the presence of comorbidities, the functional status of the patient and the necessity of the surgery. [2004]

1.2.13.2 It is recommended that lung function should not be the only criterion used to assess patients with COPD before surgery. Composite assessment tools such as the ASA scoring system are the best predictors of risk. [2004]

1.2.13.3 If time permits, the medical management of the patient should be optimised prior to surgery and this might include undertaking a course of pulmonary rehabilitation. [2004]

## 1.2.14 Follow-up of patients with COPD

1.2.14.1 Follow-up of all patients with COPD should include:

- highlighting the diagnosis of COPD in the case record and recording this using Read codes on a computer database
- recording the values of spirometric tests performed at diagnosis (both absolute and percent predicted)
- offering smoking cessation advice
- recording the opportunistic measurement of spirometric parameters (a loss of 500 ml or more over 5 years will select out those patients with rapidly progressing disease who may need specialist referral and investigation). [2004]

1.2.14.2 Patients with COPD should be reviewed at least once per year, or more frequently if indicated, and the review should cover the issues listed in table 6. [2004]

1.2.14.3 For most patients with stable severe disease regular hospital review is not necessary, but there should be locally agreed mechanisms to allow rapid access to hospital assessment when necessary. [2004]

1.2.14.4 When patients with very severe COPD are reviewed in primary care, they should be seen at least twice a year, and specific attention should be paid to the issues listed in table 6. [2004]

1.2.14.5 Patients with severe disease requiring interventions such as long-term non-invasive ventilation should be reviewed regularly by specialists. [2004]

### Table 6 Summary of follow-up of patients with COPD in primary care

	Mild/moderate/severe (stages 1 to 3)	Very severe (stage 4)
Frequency	At least annual	At least twice per year
Clinical assessment	<ul style="list-style-type: none"> <li>• Smoking status and desire to quit</li> <li>• Adequacy of symptom control:               <ul style="list-style-type: none"> <li>– breathlessness</li> <li>– exercise tolerance</li> <li>– estimated exacerbation frequency</li> </ul> </li> <li>• Presence of complications</li> <li>• Effects of each drug treatment</li> <li>• Inhaler technique</li> <li>• Need for referral to specialist and therapy services</li> <li>• Need for pulmonary rehabilitation</li> </ul>	<ul style="list-style-type: none"> <li>• Smoking status and desire to quit</li> <li>• Adequacy of symptom control:               <ul style="list-style-type: none"> <li>– breathlessness</li> <li>– exercise tolerance</li> <li>– estimated exacerbation frequency</li> </ul> </li> <li>• Presence of cor pulmonale</li> <li>• Need for long-term oxygen therapy</li> <li>• Patient's nutritional state</li> <li>• Presence of depression</li> <li>• Effects of each drug treatment</li> <li>• Inhaler technique</li> <li>• Need for social services and occupational therapy input</li> <li>• Need for referral to specialist and therapy services</li> <li>• Need for pulmonary rehabilitation</li> </ul>
Measurements to make	<ul style="list-style-type: none"> <li>• FEV<sub>1</sub> and FVC</li> <li>• calculate BMI</li> <li>• MRC dyspnoea score</li> </ul>	<ul style="list-style-type: none"> <li>• FEV<sub>1</sub> and FVC</li> <li>• calculate BMI</li> <li>• MRC dyspnoea score</li> <li>• SaO<sub>2</sub></li> </ul>

### 1.3 Management of exacerbations of COPD

The exacerbation section of this guideline was outside the scope of the 2010 update. However, the GDG was aware that some recommendations in the 'Oxygen therapy during exacerbations of COPD' section (section 1.3.6) of the guideline were out of date, and these have been removed. Readers should refer to local protocols. Deleted recommendations can be found in appendix K of the full guideline.

### 1.3.1 Definition of an exacerbation

An exacerbation is a sustained worsening of the patient's symptoms from their usual stable state which is beyond normal day-to-day variations, and is acute in onset. Commonly reported symptoms are worsening breathlessness, cough, increased sputum production and change in sputum colour. The change in these symptoms often necessitates a change in medication.

### 1.3.2 Assessment of need for hospital treatment

1.3.2.1 Factors that should be used to assess the need to treat patients in hospital are listed in table 7. [2004]

Table 7 Factors to consider when deciding where to treat the patient

Factor	Treat at home	Treat in hospital
Able to cope at home	Yes	No
Breathlessness	Mild	Severe
General condition	Good	Poor/ deteriorating
Level of activity	Good	Poor/confined to bed
Cyanosis	No	Yes
Worsening peripheral oedema	No	Yes
Level of consciousness	Normal	Impaired
Already receiving LTOT	No	Yes
Social circumstances	Good	Living alone/not coping
Acute confusion	No	Yes
Rapid rate of onset	No	Yes
Significant comorbidity (particularly cardiac disease and insulin-dependent diabetes)	No	Yes

SaO <sub>2</sub> < 90%	No	Yes
Changes on chest radiograph	No	Present
Arterial pH level	≥ 7.35	< 7.35
Arterial PaO <sub>2</sub>	≥ 7 kPa	< 7 kPa

### 1.3.3 Investigation of an exacerbation

The diagnosis of an exacerbation is made clinically and does not depend on the results of investigations; however, in certain situations, investigations may assist in ensuring appropriate treatment is given. Different investigation strategies are required for patients in hospital (who will tend to have more severe exacerbations) and those in the community.

#### Primary care

1.3.3.1 In patients who have their exacerbation managed in primary care:

- sending sputum samples for culture is not recommended in routine practice
- pulse oximetry is of value if there are clinical features of a severe exacerbation. [2004]

#### Patients referred to hospital

1.3.3.2 In all patients with an exacerbation referred to hospital:

- a chest radiograph should be obtained
- arterial blood gas tensions should be measured and the inspired oxygen concentration should be recorded
- an ECG should be recorded (to exclude comorbidities)
- a full blood count should be performed and urea and electrolyte concentrations should be measured
- a theophylline level should be measured in patients on theophylline therapy at admission
- if sputum is purulent, a sample should be sent for microscopy and culture

- blood cultures should be taken if the patient is pyrexial. [2004]

### 1.3.4 Hospital-at-home and assisted-discharge schemes

- 1.3.4.1 Hospital-at-home and assisted-discharge schemes are safe and effective and should be used as an alternative way of caring for patients with exacerbations of COPD who would otherwise need to be admitted or stay in hospital. [2004]
- 1.3.4.2 The multi-professional team required to operate these schemes should include allied health professionals with experience in managing COPD, and may include nurses, physiotherapists, occupational therapists and generic health workers. [2004]
- 1.3.4.3 There are currently insufficient data to make firm recommendations about which patients with an exacerbation are most suitable for hospital-at-home or early discharge. Patient selection should depend on the resources available and absence of factors associated with a worse prognosis, for example, acidosis. [2004]
- 1.3.4.4 Patients' preferences about treatment at home or in hospital should be considered. [2004]

### 1.3.5 Pharmacological management

Increased breathlessness is a common feature of an exacerbation of COPD. This is usually managed by taking increased doses of short-acting bronchodilators.

#### Delivery systems for inhaled therapy during exacerbations

- 1.3.5.1 Both nebulisers and hand-held inhalers can be used to administer inhaled therapy during exacerbations of COPD. [2004]
- 1.3.5.2 The choice of delivery system should reflect the dose of drug required, the ability of the patient to use the device and the resources available to supervise the administration of the therapy. [2004]
- 1.3.5.3 Patients should be changed to hand-held inhalers as soon as their condition has stabilised because this may permit earlier discharge from hospital. [2004]

- 1.3.5.4 If a patient is hypercapnic or acidotic the nebuliser should be driven by compressed air, not oxygen (to avoid worsening hypercapnia). If oxygen therapy is needed it should be administered simultaneously by nasal cannulae. [2004]
- 1.3.5.5 The driving gas for nebulised therapy should always be specified in the prescription. [2004]

### Systemic corticosteroids

- 1.3.5.6 In the absence of significant contraindications oral corticosteroids should be used, in conjunction with other therapies, in all patients admitted to hospital with an exacerbation of COPD. [2004]
- 1.3.5.7 In the absence of significant contraindications, oral corticosteroids should be considered in patients in the community who have an exacerbation with a significant increase in breathlessness which interferes with daily activities. [2004]
- 1.3.5.8 Patients requiring corticosteroid therapy should be encouraged to present early to get maximum benefits (see recommendations 1.2.12.21–25). [2004]
- 1.3.5.9 Prednisolone 30 mg orally should be prescribed for 7 to 14 days. [2004]
- 1.3.5.10 It is recommended that a course of corticosteroid treatment should not be longer than 14 days as there is no advantage in prolonged therapy. [2004]
- 1.3.5.11 For guidance on stopping oral corticosteroid therapy it is recommended that clinicians refer to the 'British national formulary' section 6.3.2. [2004]
- 1.3.5.12 Osteoporosis prophylaxis should be considered in patients requiring frequent courses of oral corticosteroids. [2004]
- 1.3.5.13 Patients should be made aware of the optimum duration of treatment and the adverse effects of prolonged therapy. [2004]
- 1.3.5.14 Patients, particularly those discharged from hospital, should be given clear instructions about why, when and how to stop their corticosteroid treatment. [2004]

## Antibiotics

- 1.3.5.15 Antibiotics should be used to treat exacerbations of COPD associated with a history of more purulent sputum. [2004]
- 1.3.5.16 Patients with exacerbations without more purulent sputum do not need antibiotic therapy unless there is consolidation on a chest radiograph or clinical signs of pneumonia. [2004]
- 1.3.5.17 Initial empirical treatment should be an aminopenicillin, a macrolide, or a tetracycline. When initiating empirical antibiotic treatment prescribers should always take account of any guidance issued by their local microbiologists. [2004]
- 1.3.5.18 When sputum has been sent for culture, the appropriateness of antibiotic treatment should be checked against laboratory culture and sensitivities when they become available. [2004]

## Theophylline and other methylxanthines

- 1.3.5.19 Intravenous theophylline should only be used as an adjunct to the management of exacerbations of COPD if there is an inadequate response to nebulised bronchodilators. [2004]
- 1.3.5.20 Care should be taken when using intravenous theophylline because of interactions with other drugs and potential toxicity if the patient has been on oral theophylline. [2004]
- 1.3.5.21 Theophylline levels should be monitored within 24 hours of starting treatment and subsequently as frequently as indicated by the clinical circumstances. [2004]

## Respiratory stimulants

- 1.3.5.22 It is recommended that doxapram is used only when non-invasive ventilation is either unavailable or considered inappropriate. [2004]



### 1.3.6 Oxygen therapy during exacerbations of COPD

The exacerbation section of this guideline was outside the scope of the 2010 update. However the GDG was aware that some recommendations in this section of the guideline were out of date, and these have been removed. Readers should refer to local protocols. Deleted recommendations can be found in appendix K of the full guideline.

1.3.6.1 The oxygen saturation should be measured in patients with an exacerbation of COPD, if there are no facilities to measure arterial blood gases. [2004]

1.3.6.2 If necessary, oxygen should be given to keep the SaO<sub>2</sub> within the individualised target range<sup>[10]</sup>. [2004, amended 2010]

1.3.6.3 Pulse oximeters should be available to all healthcare professionals involved in the care of patients with exacerbations of COPD and they should be trained in their use. Clinicians should be aware that pulse oximetry gives no information about the PCO<sub>2</sub> or pH. [2004]

1.3.6.4 When the patient arrives at hospital, arterial blood gases should be measured and the inspired oxygen concentration noted in all patients with an exacerbation of COPD. Arterial blood gas measurements should be repeated regularly, according to the response to treatment. [2004]

### 1.3.7 Non-invasive ventilation (NIV) and COPD exacerbations

1.3.7.1 NIV should be used as the treatment of choice for persistent hypercapnic ventilatory failure during exacerbations despite optimal medical therapy. [2004]

1.3.7.2 It is recommended that NIV should be delivered in a dedicated setting with staff who have been trained in its application, who are experienced in its use and who are aware of its limitations. [2004]

1.3.7.3 When patients are started on NIV there should be a clear plan covering what to do in the event of deterioration and ceilings of therapy should be agreed. [2004]

### **1.3.8 Invasive ventilation and intensive care**

- 1.3.8.1 Patients with exacerbations of COPD should receive treatment on intensive care units, including invasive ventilation when this is thought to be necessary. [2004]
- 1.3.8.2 During exacerbations of COPD, functional status, BMI, requirement for oxygen when stable, comorbidities and previous admissions to intensive care units should be considered, in addition to age and FEV<sub>1</sub>, when assessing suitability for intubation and ventilation. Neither age nor FEV<sub>1</sub> should be used in isolation when assessing suitability. [2004]
- 1.3.8.3 NIV should be considered for patients who are slow to wean from invasive ventilation. [2004]

### **1.3.9 Respiratory physiotherapy and exacerbations**

- 1.3.9.1 Physiotherapy using positive expiratory pressure masks should be considered for selected patients with exacerbations of COPD, to help with clearing sputum. [2004]

### **1.3.10 Monitoring recovery from an exacerbation**

- 1.3.10.1 Patients' recovery should be monitored by regular clinical assessment of their symptoms and observation of their functional capacity. [2004]
- 1.3.10.2 Pulse oximetry should be used to monitor the recovery of patients with non-hypercapnic, non-acidotic respiratory failure. [2004]
- 1.3.10.3 Intermittent arterial blood gas measurements should be used to monitor the recovery of patients with respiratory failure who are hypercapnic or acidotic, until they are stable. [2004]
- 1.3.10.4 Daily monitoring of peak expiratory flow (PEF) or FEV<sub>1</sub> should not be performed routinely to monitor recovery from an exacerbation because the magnitude of changes is small compared with the variability of the measurement. [2004]

### 1.3.11 Discharge planning

- 1.3.11.1 Spirometry should be measured in all patients before discharge. [2004]
- 1.3.11.2 Patients should be re-established on their optimal maintenance bronchodilator therapy before discharge. [2004]
- 1.3.11.3 Patients who have had an episode of respiratory failure should have satisfactory oximetry or arterial blood gas results before discharge. [2004]
- 1.3.11.4 All aspects of the routine care that patients receive (including appropriateness and risk of side effects) should be assessed before discharge. [2004]
- 1.3.11.5 Patients (or home carers) should be given appropriate information to enable them to fully understand the correct use of medications, including oxygen, before discharge. [2004]
- 1.3.11.6 Arrangements for follow-up and home care (such as visiting nurse, oxygen delivery, referral for other support) should be made before discharge. [2004]
- 1.3.11.7 Before the patient is discharged, the patient, family and physician should be confident that he or she can manage successfully. When there is remaining doubt a formal activities of daily living assessment may be helpful. [2004]

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<sup>[2]</sup> Quanjer PH, Tammeling GJ, Cotes JE et al. (1993) Lung volumes and forced ventilatory flows. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. *European Respiratory Journal (Suppl)* 16: 5–40.

<sup>[3]</sup> Definitive spirometry reference values are not currently available for all ethnic populations. The GDG was aware of ongoing research in this area.

<sup>[4]</sup> Jonsson JS, Gislason T, Gislason D et al. (1998) Acute bronchitis and clinical outcome three years later: prospective cohort study. *British Medical Journal* 317(7170): 1433.

<sup>[5]</sup> See also '[Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities](#)' (NICE public health guidance 10).

<sup>[6]</sup> The British national formulary states that a SAMA should be discontinued when a LAMA is started.

<sup>[7]</sup> See also '[Oseltamivir, amantadine \(review\) and zanamivir for the prophylaxis of influenza](#)' (NICE technology appraisal guidance 158) and '[Amantadine, oseltamivir and zanamivir for the treatment of influenza](#)' (NICE technology appraisal guidance 168).

<sup>[8]</sup> This recommendation was not reviewed as part of the 2010 guideline update. '[Obesity](#)' (NICE clinical guideline 43), published in 2006, states a healthy range is 18.5 to 24.9 kg/m<sup>2</sup>, but this range may not be appropriate for people with COPD.

<sup>[9]</sup> British Thoracic Society Standards of Care Committee (2002) Managing passengers with respiratory disease planning air travel: British Thoracic Society recommendations. *Thorax* 57(4): 289–304.

<sup>[10]</sup> Readers should refer to local protocols.

## 2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

The guideline offers best practice advice on the care of adults who have a clinical working diagnosis of COPD including chronic bronchitis, emphysema, and chronic airflow limitation/obstruction. The guideline is relevant to primary and secondary healthcare professionals who have direct contact with patients with COPD, and make decisions about their care.

The guideline covers diagnostic criteria and identification of early disease. The guideline also makes recommendations on the management of people with stable COPD, exacerbations and preventing progression of the disease.

The guideline does not cover the management of people with asthma, bronchopulmonary dysplasia and bronchiectasis, nor does it cover children.

### How this guideline was developed

NICE commissioned the National Clinical Guideline Centre for Acute and Chronic Conditions to develop this guideline update. The Centre established a guideline development group (see [appendix A](#)), which reviewed the evidence and developed the recommendations. An independent guideline review panel oversaw the development of the guideline (see [appendix B](#)).

There is more information about [how NICE clinical guidelines are developed](#) on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' is [available](#).

### **3 Implementation**

NICE has developed [tools](#) to help organisations implement this guidance.

## 4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

### 4.1 *Pulmonary rehabilitation during hospital admission*

In people with COPD, does pulmonary rehabilitation during hospital admission for exacerbation and/or in the early recovery period (within 1 month of an exacerbation) improve quality of life and reduce hospitalisations and exacerbations compared to a later (defined as after 1 month) pulmonary rehabilitation programme?

#### **Why this is important**

The greatest reconditioning and potential benefit from rehabilitation may occur in the early post-exacerbation phase. If inpatient pulmonary rehabilitation is demonstrated to be effective this may potentially impact upon service delivery (for example, early discharge schemes). The cost effectiveness of early versus later pulmonary rehabilitation programmes should also be evaluated. Studies should be cluster randomised, be of sufficiently long duration and be adequately powered.

### 4.2 *Multidimensional assessment of outcomes*

Could a simple multidimensional assessment be used to give a better indication of COPD outcomes than either FEV<sub>1</sub> or other components measured alone in a wide range of COPD patients, and applicable in a primary care setting?

#### **Why this is important**

The BODE index assessment is time-consuming and impractical in a primary-care setting. The GDG considered that people entering COPD studies should be characterised by the BODE index to assess whether it has an effect on outcome. Multidimensional assessments should be validated in a general UK COPD population, and in a primary-care setting, in a wider range of outcomes than mortality. Any multidimensional assessment index would need to be subjected to health economic evaluation. All clinical studies of sufficiently long duration should routinely include health economic evaluation.

### 4.3 *Triple therapy*

In people with COPD, does triple therapy improve outcomes when compared with single or double therapy?

#### **Why this is important**

Currently available studies were not designed or powered to assess whether people with mild COPD on single therapy with LABA or LAMA or double therapy with LABA+ICS might benefit from triple therapy. All clinical studies of sufficiently long duration should routinely include health economic evaluation.

### 4.4 *Mucolytic therapy*

In people with COPD, does mucolytic drug therapy prevent exacerbations in comparison with placebo and other therapies?

#### **Why this is important**

People with COPD should have a definitive diagnosis of COPD. Baseline severity and clinical phenotype should be well defined. Concomitant therapies should be stratified in the study design. Comparisons should be made with other effective therapies as well as placebo.



## 5 Other versions of this guideline

### 5.1 *Full guideline*

The full guideline, 'Chronic obstructive pulmonary disease: management of adults with chronic obstructive pulmonary disease in primary and secondary care', contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre for Acute and Chronic Conditions, and is available from our [website](#).

### 5.2 *Information for the public*

NICE has produced [information for the public](#) explaining this guideline.

We encourage NHS and voluntary sector organisations to use text from this information in their own materials about COPD.

## 6 Related NICE guidance

### Published

- Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults: management in primary, secondary and community care. [NICE clinical guideline 113](#) (2011).
- Amantadine, oseltamivir and zanamivir for the treatment of influenza (review of NICE technology appraisal guidance 58). [NICE technology appraisal guidance 168](#) (2009).
- Depression in adults with a chronic physical health problem: treatment and management. [NICE clinical guideline 91](#) (2009).
- Depression: the treatment and management of depression in adults (update). [NICE clinical guideline 90](#) (2009).
- Oseltamivir, amantadine and zanamivir for the prophylaxis of influenza (including a review of NICE technology appraisal guidance 67). [NICE technology appraisal guidance 158](#) (2008).
- Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities. [NICE public health guidance 10](#) (2008).
- Varenicline for smoking cessation. [NICE technology appraisal guidance 123](#) (2007).
- Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. [NICE clinical guideline 43](#) (2006).
- Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition. [NICE clinical guideline 32](#) (2006).

## 7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

## **Appendix A: The Guideline Development Group**

### *2010 guideline update development group members*

**Dr Michael Rudolf (Chair)**

Respiratory Physician, Ealing Hospital NHS Trust

**Dr John O'Reilly (Clinical Advisor)**

Consultant in General and Respiratory Medicine, University Hospital Aintree NHS Trust

**Ms Jill Parnham**

Operations Director, NCGC

**Ms Nicola Sloan**

Research Fellow, NCGC until March 2009

**Dr Emily Crowe**

Senior Research Fellow, NCGC

**Dr Rachel O'Mahony**

Senior Research Fellow, NCGC from March 2009

**Ms Katrina Sparrow**

Senior Research Fellow, NCGC from January 2010

**Ms Kate Lovibond**

Health Economist, NCGC

**Ms Lina Gulhane**

Senior Information Scientist, NCGC

**Dr Celia Pincus**

Project Manager, NCGC from January 2010

**Mrs Margaret Barnard**

Patient/carer member, Secretary of Breathe Easy Neathe Valley

**Ms Katherine Leach**

Patient/carer member, Project Manager at British Lung Foundation

**Dr Kevin Gruffydd-Jones**

General Practitioner (specialist in COPD), Principal in General Practice, Wiltshire

**Dr Melvyn Jones**

General Practitioner (non COPD specialist), GP Warden Lodge Surgery and Hon Consultant East and North Hertfordshire PCT, Senior Lecturer UCL

**Dr Phyo Myint**

Geriatrician, Consultant Physician, Department for Elderly, Norfolk and Norwich University Hospital

**Professor Sally Singh**

Head of Cardiac and Pulmonary Rehabilitation, University Hospitals of Leicester NHS Trust

**Professor Wisia Wedzicha**

Consultant Respiratory Physician, Royal Free Hospital, London NHS Trust

**Professor Peter Calverley**

Consultant Respiratory Physician, University Hospital Aintree NHS Trust

**Ms Karen Heslop**

Respiratory Nurse Consultant, Chest Clinic, Royal Victoria Infirmary, Newcastle (secondary care nurse representative)

**Ms Christine Loveridge**

COPD and Spirometry Clinical Lead, Education for Health (primary care nurse)

***Invited expert***

**Dr David Halpin**

Consultant Respiratory Physician, Royal Devon and Exeter NHS Trust

## *Deputies*

### **Dr Graham Burns**

Respiratory Physician (acted as a deputy for Peter Calverley for one GDG meeting)

### **Ms Erica Haines**

Primary Care Nurse (acted as a deputy for Christine Loveridge for one GDG meeting)

### **Ms Barbara Foggo**

Respiratory Nurse (acted as a deputy for Karen Heslop), Freeman Hospital, Newcastle

## *2004 clinical guideline 12 development group members*

### **Dr David MG Halpin<sup>[11]</sup> (Lead and Clinical Advisor)**

Consultant Physician and Senior Lecturer, Royal Devon & Exeter Hospital

### **Ms Jill Parnham<sup>[11]</sup>**

Senior Health Services Research Fellow in Guideline Development, National Collaborating Centre for Chronic Conditions

### **Dr David Bellamy<sup>[11]</sup>**

General Practitioner, Bournemouth

### **Ms Julie Booker<sup>[11]</sup>**

Respiratory Nurse Specialist, Rotherham General Hospital

### **Professor Peter Calverley<sup>[11]</sup> (seconded from the Consensus Reference Group for three meetings)**

Professor of Respiratory Medicine, University of Liverpool and Aintree Hospital NHS Trust

### **Dr Martin Connolly<sup>[11]</sup>**

Consultant Geriatrician, University of Manchester

### **Dr Rachel Garrod<sup>[11]</sup>**

Senior Lecturer, Kingston University

### **Mr Ashley Green (deputy for Esther Threlfall)**

Breathe Easy Assistant Manager, British Lung Foundation

**Ms Gwen Haylett<sup>[11]</sup>**

Patient member

**Dr Michael ML Morgan<sup>[11]</sup> (seconded from the Consensus Reference Group for one meeting)**

Consultant Physician, University Hospitals of Leicester NHS Trust

**Ms Karen Reid<sup>[11]</sup>**

Information Scientist, National Collaborating Centre for Chronic Conditions

**Dr Michael Rudolf<sup>[11]</sup>**

Consultant Physician, Ealing Hospital NHS Trust

**Ms Katherine Stevens<sup>[11]</sup>**

Research Associate in Health Economics, School of Health and Related Research, University of Sheffield

**Esther Threlfall<sup>[11]</sup>**

UK Breathe Easy Manager, British Lung Foundation

**Ms Jane Scullion<sup>[11]</sup> (attended two meetings as deputy for Julie Booker)**

Respiratory Consultant Nurse, University Hospital of Leicester

**Ms Teresa Smith (attended five meetings as deputy for Julie Booker)**

Senior Respiratory Nurse/Chest Clinic Manager, Heatherwood and Wexham Park NHS Trust

**Ms Elaine Stevenson (attended one meeting as deputy for Julie Booker)**

Clinical Practitioner Respiratory Care, Southern Derbyshire Acute Hospitals Trust

**Professor Jadwiga Wedzicha<sup>[11]</sup>**

Professor of Respiratory Medicine, St Bartholomew's and the Royal London School of Medicine

### *Consensus Reference Group*

To support the development of this guideline, a Consensus Reference Group was formed. This group used formal consensus techniques in its consideration of clinically important areas where there was insufficient evidence or disagreement over the interpretation of the evidence.

**Professor Duncan Geddes (Chair)**

Professor of Respiratory Medicine, Royal Brompton Hospital NHS Trust

**Ms Alison Bent (attended one meeting as deputy for Mary Hickson)**

Dietitian, Hammersmith Hospitals NHS Trust

**Professor Peter Calverley**

Professor of Respiratory Medicine, University of Liverpool and Aintree Hospital NHS Trust

**Dr Stephen Connellan**

Consultant Physician, The Royal Wolverhampton Hospitals NHS Trust

**Dr Sujal Desai (attended one meeting)**

Radiologist, King's College Hospital

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<sup>[11]</sup> Member of both the Guideline Development Group and the Consensus Reference Group



## **Appendix B: The Guideline Review Panel**

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

### *2010 guideline update Guideline Review Panel*

**Dr John Hyslop (Chair)**

Consultant Radiologist, Royal Cornwall Hospital NHS Trust

**Dr Ash Paul**

Medical Director, Bedfordshire Primary Care Trust

**Mr Jon Hopper**

Medical Director (Northern Europe), ConvaTec Ltd

**Professor Liam Smeeth**

Professor of Clinical Epidemiology, London School of Hygiene and Tropical Medicine

**Mr Peter Gosling**

Lay member

### *2004 clinical guideline 12 Guideline Review Panel*

**Dr Bernard Higgins (Chair)**

Consultant Chest Physician, Freeman Hospital, Newcastle upon Tyne

**Dr Robert Higgins**

Consultant in Renal and General Medicine, University Hospitals Coventry and Warwickshire

**Dr Marcia Kelson**

Director, Patient Involvement Unit for NICE, London

**Dr Peter Rutherford**

Senior Lecturer in Nephrology, Medical Director, University College of Wales College of Medicine

**Dame Helena Shovelto**

Chief Executive, British Lung Foundation

**Fiona Wise**

Acting Director of Modernisation, Bedfordshire and Hertfordshire Strategic Health Authority

**Dr John Young**

Medical Director, Merck Sharp and Dohme

## Appendix C: The algorithms

These algorithms have been updated and replace the algorithms in NICE clinical guideline 12 (published February 2004). The algorithms are in the [full guideline](#).

## About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the National Collaborating Centre for Acute and Chronic Conditions. The Collaborating Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

This guidance is a partial update of NICE clinical guideline 12 (published February 2004) and replaces it.

The recommendations from this guideline have been incorporated into a [NICE Pathway](#). We have produced [information for the public](#) explaining this guideline. Tools to help you put the guideline into practice and information about the evidence it is based on are also [available](#).

### Changes since publication

January 2012: minor maintenance.

March 2013: minor maintenance.

April 2015: minor maintenance

### Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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## Accreditation

