

Chronic obstructive pulmonary disease

Management of chronic obstructive pulmonary disease in adults in primary and secondary care

Clinical Guideline 12

February 2004

Developed by the National Collaborating Centre for
Chronic Conditions

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Issue date: February 2004

This document, which contains the Institute's full guidance on the management of chronic obstructive pulmonary disease in adults, is available from the NICE website (www.nice.org.uk/CG012NICEguideline).

An abridged version of this guidance (a 'quick reference guide') is also available from the NICE website (www.nice.org.uk/CG012quickrefguide). Printed copies of the quick reference guide can be obtained from the NHS Response Line: telephone 0870 1555 455 and quote reference number N0462.

Information for the Public is available from the NICE website or from the NHS Response Line (quote reference number N0463 for a version in English and N0464 for a version in English and Welsh).

The quick reference guide for this guideline has been distributed to the following:

- PCT chief executives
- NHS trust chief executives in England and Wales
- Clinical governance leads in England and Wales
- Audit leads in England and Wales
- Local health board chief executives
- Medical and nursing directors in England and Wales
- NHS trust, PCT and LHB libraries in England and Wales
- Consultants in occupational health medicine in England and Wales
- Consultants in rehabilitation medicine in England and Wales
- Consultants in respiratory medicine in England and Wales
- Consultants in elderly care in England and Wales
- Clinical directors for physiotherapy in England and Wales
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- Commission for Health Improvement
- NHS Clinical Governance Support Team
- Chief Medical, Nursing and Pharmaceutical Officers in England and Wales
- Medical Director & Head of NHS Quality - Welsh Assembly Government
- Representative bodies for health services, professional organisations and statutory bodies and the Royal Colleges

This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Working definition of chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking.

- Airflow obstruction is defined as a reduced FEV₁ (forced expiratory volume in 1 second) and a reduced FEV₁/FVC ratio (where FVC is forced vital capacity), such that FEV₁ is less than 80% predicted and FEV₁/FVC is less than 0.7.
- The airflow obstruction is due to 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 individual 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.
- Other factors, particularly occupational exposures, may also contribute to the development of COPD.

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.

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. The presence of airflow obstruction should be confirmed by performing spirometry.
- All health professionals managing patients with COPD should have access to spirometry and be competent in the interpretation of the results.

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.

Effective inhaled therapy

- Long-acting inhaled bronchodilators (beta₂-agonists and/or anticholinergics) should be used to control symptoms and improve exercise capacity in patients who continue to experience problems despite the use of short-acting drugs.
- Inhaled corticosteroids should be added to long-acting bronchodilators to decrease exacerbation frequency in patients with an FEV₁ less than or equal to 50% predicted who have had two or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12-month period.

Pulmonary rehabilitation for all who need it

- Pulmonary rehabilitation should be made available to all appropriate patients with COPD.

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.

Manage exacerbations

- The frequency of exacerbations should be reduced by appropriate use of inhaled corticosteroids and bronchodilators, and vaccinations.
- 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 corticosteroids and/or antibiotics
 - use of non-invasive ventilation when indicated
 - use of hospital-at-home or assisted-discharge schemes.

Multidisciplinary working

- COPD care should be delivered by a multidisciplinary team.

The following guidance is evidence based. The grading scheme used for the recommendations (A, B, C, D, NICE or HSC) is described in Appendix A; a summary of the evidence on which the guidance is based is provided in the full guideline (see Section 5).

1 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.

D

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.

D

NB These last two symptoms are uncommon in COPD and raise the possibility of an alternative diagnosis.

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.

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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 m 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.

D

1.1.2.2 All health professionals managing patients with COPD should have access to spirometry and be competent in the interpretation of the results.

D

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

D

1.1.2.4 Spirometry services should be supported by quality control processes.

D

1.1.2.5 It is recommended that ERS 1993 reference values* are used but it is recognised that these values may lead to under-diagnosis in the elderly and are not applicable in black and Asian populations.

D

* 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.

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.
- 1.1.3.2 Additional investigations should be performed to aid management in some circumstances (see Table 2).
- 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.

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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 _L 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 ₁ < 50% predicted
Sputum culture	To identify organisms if sputum is persistently present and purulent

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:

D

- repeated FEV₁ 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 FEV₁ 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.

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.

D

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.

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Table 3 Clinical features differentiating COPD and asthma

	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35	Rare	Common
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

1.1.4.4 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 (greater than 400 ml) response to bronchodilators
- a large (greater than 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 FEV₁ and FEV₁/FVC ratio return to normal with drug therapy.

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

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

1.1.5 Assessment of severity

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 Mild airflow obstruction can be associated with significant disability in patients with COPD. A true assessment of severity should include assessment of the degree of airflow obstruction and disability, the frequency of exacerbations and the following known prognostic factors:

- FEV₁
- T_LCO
- breathlessness (MRC scale)
- health status
- exercise capacity
- BMI
- partial pressure of oxygen in arterial blood (PaO₂)
- cor pulmonale.

1.1.5.2 The severity of airflow obstruction should be assessed according to the reduction in FEV₁ as shown in Table 4.

Table 4 Assessment of severity of airflow obstruction according to FEV₁ as a percentage of the predicted value

Severity	FEV ₁
Mild airflow obstruction	50–80% predicted
Moderate airflow obstruction	30–49% predicted
Severe airflow obstruction	< 30% predicted

1.1.6 Identification of early disease

1.1.6.1 Spirometry should be performed in patients who are over 35, current or ex-smokers, and have a chronic cough. **D**

1.1.6.2 Spirometry should be considered in patients with chronic bronchitis. A significant proportion of these will go on to develop airflow limitation. **B**

1.1.7 Referral for specialist advice

1.1.7.1 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). **D**

1.1.7.2 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. **D**

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. **D**

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. **A**

1.2.1.3 Unless contraindicated, bupropion or nicotine replacement therapy combined with an appropriate support programme should be used to optimise smoking quit rates for people with COPD. **B**

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 ₁	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
Aged 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
Frequent infections	Exclude bronchiectasis
Haemoptysis	Exclude carcinoma of the bronchus

- 1.2.1.4 NICE Technology Appraisal Guidance No 39 (see Section 6) recommends: NICE
- “If a smoker’s attempt to quit is unsuccessful with treatment using either NRT or bupropion, the NHS should normally fund no further attempts within 6 months. However, if external factors interfere with a person’s initial attempt to stop smoking, it may be reasonable to try again sooner.”*

1.2.2 Inhaled bronchodilator therapy

- 1.2.2.1 Short-acting bronchodilators, as necessary, should be the initial empirical treatment for the relief of breathlessness and exercise limitation. B
- 1.2.2.2 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. D
- 1.2.2.3 Patients who remain symptomatic should have their inhaled treatment intensified to include long-acting bronchodilators or combined therapy with a short-acting beta₂-agonist and a short-acting anticholinergic. A
- 1.2.2.4 Long-acting bronchodilators should be used in patients who remain symptomatic despite treatment with short-acting bronchodilators because these drugs appear to have additional benefits over combinations of short-acting drugs. A
- 1.2.2.5 Long-acting bronchodilators should also be used in patients who have two or more exacerbations per year. D
- 1.2.2.6 The choice of drug(s) should take into account the patient’s response to a trial of the drug, the drug’s side effects, patient preference and cost. D

1.2.3 Theophylline

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

- 1.2.3.1 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. D

- | | | |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.3.2 | Particular caution needs to be taken with the use of theophylline in elderly patients because of differences in pharmacokinetics, the increased likelihood of comorbidities and the use of other medications. | D |
| 1.2.3.3 | The effectiveness of the treatment with theophylline should be assessed by improvements in symptoms, activities of daily living, exercise capacity and lung function. | D |
| 1.2.3.4 | 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. | D |

1.2.4 Corticosteroids

Inhaled corticosteroids

None of the inhaled corticosteroids currently available are licensed for use alone in the treatment of COPD. The following recommendations therefore include usage outside licensed indications, and prescribers need to remember that responsibility for such prescribing lies with them.

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|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.4.1 | 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. | A |
| 1.2.4.2 | Inhaled corticosteroids should be prescribed for patients with an FEV ₁ less than or equal to 50% predicted, who are having two or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12-month period. The aim of treatment is to reduce exacerbation rates and slow the decline in health status and not to improve lung function per se. | B |
| 1.2.4.3 | Clinicians should be aware of the potential risk of developing osteoporosis and other side effects in patients treated with high-dose inhaled corticosteroids (especially in the presence of other risk factors), and should discuss the risk with patients. | D |

Oral corticosteroids

- | | | |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.4.4 | 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 | D |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|

these cases, the dose of oral corticosteroids should be kept as low as possible.

- 1.2.4.5 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.

1.2.5 Combination therapy

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

- beta₂-agonist and anticholinergic
- beta₂-agonist and theophylline
- anticholinergic and theophylline
- long-acting beta₂-agonist and inhaled corticosteroid.

- 1.2.5.2 The clinical effectiveness of combined treatments can be assessed by improvements in symptoms, activities of daily living, exercise capacity and lung function. Combination treatment should be discontinued if there is no benefit after 4 weeks.

1.2.6 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

- 1.2.6.1 In most cases bronchodilator therapy is best administered using a hand-held inhaler device (including a spacer device if appropriate).
- 1.2.6.2 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.
- 1.2.6.3 Inhalers should be prescribed only after patients have received training in the use of the device and have demonstrated satisfactory technique.

1.2.6.4 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.

D

1.2.6.5 To ensure optimum efficacy for each patient with COPD, the dose of medication should be titrated according to individual clinical response.

D

Spacers

1.2.6.6 The spacer should be compatible with the patient's metered-dose inhaler.

D

1.2.6.7 It is recommended that spacers are used in the following way.

D

- 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.

1.2.6.8 Spacers should be cleaned no more than monthly as more frequent cleaning affects their performance (due to 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.

D

Nebulisers

1.2.6.9 Patients with distressing or disabling breathlessness despite maximal therapy using inhalers should be considered for nebuliser therapy.

D

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

D

- 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.

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

D

- | | | |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.6.12 | 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. | D |
| 1.2.6.13 | 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). | D |
| 1.2.6.14 | If nebuliser therapy is prescribed, the patient should be provided with equipment, servicing, advice and support. | D |

1.2.7 Oxygen

Long-term oxygen therapy (LTOT)

- | | | |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.7.1 | Clinicians should be aware that inappropriate oxygen therapy in people with COPD may cause respiratory depression. | C |
| 1.2.7.2 | LTOT is indicated in patients with COPD who have a PaO ₂ less than 7.3 kPa when stable or a PaO ₂ greater than 7.3 and less than 8 kPa when stable and one of: secondary polycythaemia, nocturnal hypoxaemia (oxygen saturation of arterial blood [SaO ₂] less than 90% for more than 30% of time), peripheral oedema or pulmonary hypertension. | A |
| 1.2.7.3 | 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. | A |
| 1.2.7.4 | <p>The need for oxygen therapy should be assessed in:</p> <ul style="list-style-type: none"> • all patients with severe airflow obstruction (FEV₁ less than 30% predicted) • patients with cyanosis • patients with polycythaemia • patients with peripheral oedema • patients with a raised jugular venous pressure • patients with oxygen saturations less than or equal to 92% breathing air. <p>Assessment should also be considered in patients with moderate airflow obstruction (FEV₁ 30–49% predicted).</p> | D |

- | | | |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.7.5 | To ensure all patients eligible for long-term oxygen therapy (LTOT) are identified, pulse oximetry should be available in all healthcare settings. | D |
| 1.2.7.6 | The assessment of patients for LTOT should comprise the measurement of arterial blood gasses 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. | D |
| 1.2.7.7 | Patients receiving LTOT should be reviewed at least once per year by practitioners familiar with LTOT and this review should include pulse oximetry. | D |
| 1.2.7.8 | Oxygen concentrators should be used to provide the fixed supply at home for long-term oxygen therapy. | D |
| 1.2.7.9 | Patients should be warned about the risks of fire and explosion if they continue to smoke when prescribed oxygen. | D |

Ambulatory oxygen therapy

- | | | |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1.2.7.10 | 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. | D |
| 1.2.7.11 | 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. | D |
| 1.2.7.12 | Ambulatory oxygen therapy is not recommended in COPD if PaO ₂ is greater than 7.3 kPa and there is no exercise desaturation. | D |
| 1.2.7.13 | 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, aiming to keep the SaO ₂ above 90%. | D |
| 1.2.7.14 | Small light-weight cylinders, oxygen-conserving devices and portable liquid oxygen systems should be available for the treatment of patients with COPD. | D |

Table 6 Appropriate equipment for ambulatory oxygen therapy

Usage	Equipment
For a duration of use of less than 90 minutes	Small cylinder
For a duration of use less than 4 hours but more than 90 min	Small cylinder with oxygen conserving device
For duration of use more than 4 hours	Liquid oxygen
For flow rates greater than 2 l/min and duration of use more than 30 min	Liquid oxygen

- 1.2.7.15 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 (see Table 6).

D

Short-burst oxygen therapy

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

C

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

D

- 1.2.7.18 When indicated, short-burst oxygen should be provided from cylinders.

D

1.2.8 Non-invasive ventilation

- 1.2.8.1 Adequately treated patients with chronic hypercapnic ventilatory 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.

D

1.2.9 Management of pulmonary hypertension and cor pulmonale

Diagnosis 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.

- 1.2.9.1 A diagnosis of cor pulmonale should be considered if patients have: **D**
- peripheral oedema
 - a raised venous pressure
 - a systolic parasternal heave
 - a loud pulmonary second heart sound.
- 1.2.9.2 It is recommended that the diagnosis of cor pulmonale is made clinically and that this process should involve excluding other causes of peripheral oedema. **D**

Treatment of cor pulmonale

- 1.2.9.3 Patients presenting with cor pulmonale should be assessed for the need for long-term oxygen therapy. **A**
- 1.2.9.4 Oedema associated with cor pulmonale can usually be controlled symptomatically with diuretic therapy. **D**
- 1.2.9.5 The following are not recommended for the treatment of cor pulmonale: **C**
- angiotensin-converting enzyme inhibitors
 - calcium channel blockers
 - alpha-blockers
 - digoxin (unless there is atrial fibrillation).

1.2.10 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 the individual's physical and social performance and autonomy.

- 1.2.10.1 Pulmonary rehabilitation should be made available to all appropriate patients with COPD. **A**
- 1.2.10.2 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. **D**

1.2.10.3 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.

D

1.2.10.4 Pulmonary rehabilitation programmes should include multi-component, 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.

A

1.2.10.5 Patients should be made aware of the benefits of pulmonary rehabilitation and the commitment required to gain these.

D

1.2.11 Vaccination and anti-viral therapy

1.2.11.1 Pneumococcal vaccination and an annual influenza vaccination should be offered to all patients with COPD as recommended by the Chief Medical Officer.

HSC

1.2.11.2 NICE Technology Appraisal Guidance No. 58 (see Section 6) makes the following recommendation.

NICE

“Within their licensed indications, zanamivir and oseltamivir are recommended for the treatment of at-risk adults who present with influenza-like illness and who can start therapy within 48 hours of the onset of symptoms.”

The technology appraisal also notes that zanamivir should be used with caution in people with COPD because of risk of bronchospasm. If people with COPD are prescribed zanamivir they should be made aware of the risks and have a fast-acting bronchodilator available.

1.2.12 Lung surgery

1.2.12.1 Patients who are breathless, and have a single large bulla on a CT scan and an FEV₁ less than 50% predicted should be referred for consideration of bullectomy.

C

1.2.12.2 Patients with severe COPD who remain breathless with marked restrictions of their activities of daily living, despite maximal medical therapy (including rehabilitation), should

A

be referred for consideration of lung volume reduction surgery if they meet all of the following criteria:

- FEV₁ more than 20% predicted
- PaCO₂ less than 7.3 kPa
- upper lobe predominant emphysema
- T_lCO more than 20% predicted.

1.2.12.3 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
- FEV₁
- PaCO₂
- homogeneously distributed emphysema on CT scan
- elevated pulmonary artery pressures with progressive deterioration.

1.2.13 Alpha-1 antitrypsin replacement therapy

1.2.13.1 Alpha-1 antitrypsin replacement therapy is not recommended in the management of patients with alpha-1 antitrypsin deficiency (see also recommendation 1.1.3.3).

1.2.14 Mucolytic therapy

1.2.14.1 Mucolytic drug therapy should be considered in patients with a chronic cough productive of sputum.

1.2.14.2 Mucolytic therapy should be continued if there is symptomatic improvement (for example, reduction in frequency of cough and sputum production).

1.2.15 Anti-oxidant therapy

1.2.15.1 Treatment with alpha-tocopherol and beta-carotene supplements, alone or in combination, is not recommended.

1.2.16 Anti-tussive therapy

1.2.16.1 Anti-tussive therapy should not be used in the management of stable COPD.

1.2.17 Prophylactic antibiotic therapy

- 1.2.17.1 There is insufficient evidence to recommend prophylactic antibiotic therapy in the management of stable COPD.

D

1.2.18 Multidisciplinary management

Multidisciplinary working is breaking down historic demarcation of roles and many of the activities in managing COPD can be undertaken by individuals from different professional backgrounds. 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 it may be necessary for the patient to be referred to a specialist department, such as physiotherapy.

- 1.2.18.1 COPD care should be delivered by a multidisciplinary team.

D

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

D

- 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)
- managing 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.

Respiratory nurse specialists

- 1.2.18.3 It is recommended that respiratory nurse specialists form part of the multidisciplinary COPD team.

D

Physiotherapy

- 1.2.18.4 If patients have excessive sputum, they should be taught:
- the use of positive expiratory pressure masks
 - active cycle of breathing techniques.

B

D

Identifying and managing anxiety and depression

- 1.2.18.5 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 (SaO₂ less than 92%)
 - who have severe dyspnoea
 - who have been seen at or admitted to a hospital with an exacerbation of COPD.
- 1.2.18.6 The presence of anxiety and depression in patients with COPD can be identified using validated assessment tools.
- 1.2.18.7 Patients found to be depressed or anxious should be treated with conventional pharmacotherapy.
- 1.2.18.8 For antidepressant treatment to be successful, it needs to be supplemented by spending time with the patient explaining why depression needs to be treated alongside the physical disorder.

Nutritional factors

- 1.2.18.9 BMI should be calculated in patients with COPD (see Section 1.1.3).
- The normal range for BMI is 20 to less than 25.
 - 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.

The NICE guideline *Nutritional support in adults: oral supplements, enteral and parenteral feeding*, can be referred to when it is available (scheduled for publication in December 2005).

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

Palliative care

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

1.2.18.12 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.

D

1.2.18.13 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.

D

Assessment for occupational therapy

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

D

1.2.18.15 Clinicians managing patients with COPD should assess their need for occupational therapy using validated tools.

D

Social services

1.2.18.16 Patients disabled by COPD should be considered for referral for assessment by a social services department.

D

Advice on travel

1.2.18.17 All patients on LTOT planning air travel should be assessed in line with the BTS recommendations*.

D

1.2.18.18 All patients with an FEV₁ less than 50% predicted who are planning air travel should be assessed in line with the BTS recommendations.

D

1.2.18.19 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.

D

Advice on diving

1.2.18.20 Scuba diving is not recommended for patients with COPD.

D

Education

1.2.18.21 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.

A

* Managing passengers with respiratory disease planning air travel: British Thoracic Society recommendations (2002) *Thorax* 57(4):289–304.

1.2.18.22 Specific educational packages should be developed for patients with COPD. D

- 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.

1.2.18.23 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). D

Self-management

1.2.18.24 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. A

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

- 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.

1.2.18.26 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). D

1.2.18.27 The appropriate use of these tablets should be monitored. D

1.2.18.28 Patients given self-management plans should be advised to contact a healthcare professional if they do not improve. D

1.2.19 Fitness for general surgery

1.2.19.1 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. D

- 1.2.19.2 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. **D**
- 1.2.19.3 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. **D**

1.2.20 Follow up of patients with COPD

- 1.2.20.1 Follow up of all patients with COPD should include: **D**
- 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).
- 1.2.20.2 Patients with mild or moderate COPD should be reviewed at least once per year, or more frequently if indicated, and the review should cover the issues listed in Table 7. **D**
- 1.2.20.3 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. **D**
- 1.2.20.4 When patients with 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 7. **D**
- 1.2.20.5 Patients with severe disease requiring interventions such as long-term non-invasive ventilation should be reviewed regularly by specialists. **D**

Table 7 Summary of follow up of patients with COPD in primary care

	Mild/Moderate	Severe
Frequency	At least annual	At least twice per year
Clinical assessment	<ul style="list-style-type: none"> • Smoking status and desire to quit • Adequacy of symptom control: <ul style="list-style-type: none"> – breathlessness – exercise tolerance – estimated exacerbation frequency • Presence of complications • Effects of each drug treatment • Inhaler technique • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation 	<ul style="list-style-type: none"> • Smoking status and desire to quit • Adequacy of symptom control: <ul style="list-style-type: none"> – breathlessness – exercise tolerance – estimated exacerbation frequency • Presence of cor pulmonale • Need for long-term oxygen therapy • Patient's nutritional state • Presence of depression • Effects of each drug treatment • Inhaler technique • Need for social services and occupational therapy input • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation
Measurements to make	<ul style="list-style-type: none"> • FEV₁ and FVC • BMI • MRC dyspnoea score 	<ul style="list-style-type: none"> • FEV₁ and FVC • BMI • MRC dyspnoea score • SaO₂

1.3 Management of exacerbations of COPD

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 8.

D

Table 8 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 ₂ < 90%	No	Yes
Changes on the chest radiograph	No	Present
Arterial pH level	≥ 7.35	< 7.35
Arterial PaO ₂	≥ 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 managed in hospital (who will tend to have more severe exacerbations) and those managed in the community.

Primary care

- 1.3.3.1 In patients with an 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.

D

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 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

D

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 managing patients with exacerbations of COPD who would otherwise need to be admitted or stay in hospital.
- 1.3.4.2 The multi-professional team required to operate these schemes should include allied health professionals with experience in managing patients with COPD, and may include nurses, physiotherapists, occupational therapists and generic health workers.
- 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, such as acidosis.
- 1.3.4.4 Patient's preferences about treatment at home or in hospital should be considered.

A

D

D

D

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 and these drugs may be given using different delivery systems.

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. | A |
| 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. | D |
| 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. | D |
| 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. | D |
| 1.3.5.5 | The driving gas for nebulised therapy should always be specified in the prescription. | D |

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. | A |
| 1.3.5.7 | In the absence of significant contraindications, oral corticosteroids should be considered in patients managed in the community who have an exacerbation with a significant increase in breathlessness which interferes with daily activities. | B |
| 1.3.5.8 | Patients requiring corticosteroid therapy should be encouraged to present early to get maximum benefits (see recommendations 1.2.17.24–27). | D |
| 1.3.5.9 | Prednisolone 30 mg orally should be prescribed for 7 to 14 days. | D |

- 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. A
- 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. D
- 1.3.5.12 Osteoporosis prophylaxis should be considered in patients requiring frequent courses of oral corticosteroids. D
- 1.3.5.13 Patients should be made aware of the optimum duration of treatment and the adverse effects of prolonged therapy. D
- 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. D

Antibiotics

- 1.3.5.15 Antibiotics should be used to treat exacerbations of COPD associated with a history of more purulent sputum. A
- 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. B
- 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. D
- 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. D

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. D
- 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. D

- 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.

D

Respiratory stimulants

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

D

1.3.6 Oxygen therapy during exacerbations of COPD

- 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.

D

- 1.3.6.2 If necessary, oxygen should be given to keep the SaO₂ greater than 90%.

C

- 1.3.6.3 Pulse oximeters should be available to all healthcare professionals managing 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 PCO₂ or pH.

D

- 1.3.6.4 In the interim period while the recommendation on the availability of oximeters is implemented, oxygen should be given to all patients with an exacerbation of COPD who are breathless, if the oxygen saturations are not known.

D

- 1.3.6.5 During the transfer to hospital the following points should be considered.

D

- It is not desirable to exceed an oxygen saturation of 93%. Oxygen therapy should be commenced at approximately 40% and titrated upwards if saturation falls below 90% and downwards if the patient becomes drowsy or if the saturation exceeds 93–94%.
- Patients with known type II respiratory failure need special care, especially if they require a long ambulance journey or if they are given oxygen at home for a prolonged period before the ambulance arrives.

- 1.3.6.6 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.

D

- 1.3.6.7 The aim of supplemental oxygen therapy in exacerbations of COPD is to maintain adequate levels of oxygenation (SaO₂ greater than 90%), without precipitating respiratory acidosis or worsening hypercapnia. Patients with pH less than 7.35 should be considered for ventilatory support.

D

1.3.7 Non-invasive ventilation 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.
- 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.
- 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.

A

D

D

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.
- 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 FEV₁, when assessing suitability for intubation and ventilation. Neither age nor FEV₁ should be used in isolation when assessing suitability.
- 1.3.8.3 NIV should be considered for patients who are slow to wean from invasive ventilation.

C

D

A

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.

B

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. D
- 1.3.10.2 Pulse oximetry should be used to monitor the recovery of patients with non-hypercapnic, non-acidotic respiratory failure. D
- 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. D
- 1.3.10.4 Daily monitoring of PEF or FEV₁ 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. D

1.3.11 Discharge planning

- 1.3.11.1 Spirometry should be measured in all patients before discharge. D
- 1.3.11.2 Patients should be re-established on their optimal maintenance bronchodilator therapy before discharge. D
- 1.3.11.3 Patients who have had an episode of respiratory failure should have satisfactory oximetry or arterial blood gas results before discharge. D
- 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. D
- 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. D
- 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. D
- 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. D

2 Notes on the scope of the guidance

All NICE guidelines are developed in accordance with a scope document that defines what the guideline will and will not cover. The scope of this guideline was established at the start of the development of this guideline, following a period of consultation; it is available from www.nice.org.uk/article.asp?a=32649

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 stable patients, 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.

3 Implementation in the NHS

3.1 In general

Local health communities should review their existing practice for the management of COPD against this guideline as they develop their Local Delivery Plans. The review should consider the resources required to implement the recommendations set out in Section 1, the people and processes involved and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways and protocols should be reviewed in the light of this guidance and revised accordingly.

This guideline should be used in conjunction with the NICE technology appraisals listed in Section 6, and with the National Service Framework for Older People, which is available from www.doh.gov.uk/nsf/olderpeople/index.htm

3.2 Audit

Suggested audit criteria are listed in Appendix D. These can be used as the basis for local clinical audit, at the discretion of those in practice.

4 Research recommendations

The following research recommendations have been identified for this NICE guideline. The Guideline Development Group's full set of research recommendations is detailed in the full guideline produced by the National Collaborating Centre for Chronic Conditions (see Section 5).

- **Pharmacological management**
There is a need for long-term studies on the absolute and comparative efficacy of:
 - long-acting bronchodilators
 - theophylline
 - mucolytics (including the development of outcome measures)
 - combination therapies
 - ambulatory oxygen
 - alpha-1 antitrypsin replacement therapy.
- **Adjunctive therapies**
There is a need for further studies on the efficacy of:
 - nebulised therapy
 - non-invasive ventilation
 - oxygen delivery systems
 - physiotherapy
 - pulmonary rehabilitation (in particular its efficacy compared with pharmacological therapies and its efficacy in patients with mild and severe COPD).
- **Patient-focused strategies**
There is a need for further studies on:
 - the content and efficacy of educational packages for patients with COPD
 - the content and efficacy of self-management strategies for exacerbations.

5 Full guideline

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Chronic Conditions. The Centre established a Guideline

Development Group, which reviewed the evidence and developed the recommendations. The full guideline, *Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care*, is published by the National Collaborating Centre for Chronic Conditions; it is available on its website www.rcplondon.ac.uk/college/ceeu/ncccc_index.htm the NICE website (www.nice.org.uk/CG012fullguideline) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

The members of the Guideline Development Group are listed in Appendix B. Information about the independent Guideline Review Panel is given in Appendix C.

The booklet *The Guideline Development Process – Information for the Public and the NHS* has more information about the Institute's guideline development process. It is available from the Institute's website and copies can also be ordered by telephoning 0870 1555 455 (quote reference N0038).

6 Related NICE guidance

National Institute for Clinical Excellence (2002). Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *NICE Technology Appraisal Guidance* No. 39. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk/Docref.asp?d=30617

National Institute for Clinical Excellence (2003). Guidance on the use of zanamivir, oseltamivir and amantadine for the treatment of influenza. *NICE Technology Appraisal Guidance* No. 58. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk/Docref.asp?d=58060

NICE is in the process of developing the following guidance.

- Depression: the management of depression in primary and secondary care. Clinical guideline. (Publication expected June 2004.)
- Anxiety: management of generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults in primary, secondary and community care. Clinical guideline. (Publication expected June 2004.)
- Nutritional support in adults: oral supplements, enteral and parenteral feeding. Clinical guideline. (Publication expected December 2005.)

7 Review date

The process of reviewing the evidence is expected to begin 4 years after the date of issue of this guideline. Reviewing may begin earlier than 4 years if significant evidence that affects the guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

A version of this guideline for patients with COPD and their carers, and for the public, is available from the NICE website (www.nice.org.uk) or from the NHS response line (0870 1555 455: quote reference number N0463 for an English version and N0464 for an English and Welsh version).

A quick reference guide for health professionals is also available from the NICE website (www.nice.org/CG012quickrefguide) or from the NHS Response Line (telephone 0870 1555 455; quote reference number N0462)

Appendix A: Grading scheme

The grading scheme and hierarchy of evidence used in this guideline are shown in the table below.

Hierarchy of evidence		Grading of recommendations	
Level	Type of evidence	Grade	Evidence
Ia	Evidence from systematic reviews or meta-analysis of randomised controlled trials	A	Based on hierarchy I evidence
Ib	Evidence from at least one randomised controlled trial		
IIa	Evidence from at least one controlled study without randomisation	B	Based on hierarchy II evidence or extrapolated from hierarchy I evidence
IIb	Evidence from at least one other type of quasi-experimental study		
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies	C	Based on hierarchy III evidence or extrapolated from hierarchy I or II evidence
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities	D	Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II or III evidence
NICE	Evidence from NICE guidelines or Health Technology Appraisal programme	NICE	Evidence from NICE guidelines or Health Technology Appraisal programme
HSC	Evidence from Health Service Circulars	HSC	Evidence from Health Service Circulars

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. *Health Technology Assessment* 5 (16): 1–69.

Appendix B: The Guideline Development Group

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Consultant Geriatrician, University of Manchester

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Senior Lecturer, Kingston University

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Breathe Easy Assistant Manager, British Lung Foundation

Ms Gwen Haylett*
Patient Representative

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* Denotes member of both the Guideline Development Group and the Consensus
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Ms Jane Scullion* (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),
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Ms Elaine Stevenson (attended one meeting as deputy for Julie Booker),

Clinical Practitioner Respiratory Care, Southern Derbyshire Acute
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Professor Jadwiga Wedzicha*

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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
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Ms Alison Bent (attended one meeting as deputy for Mary Hickson)
Dietitian, Hammersmith Hospitals NHS Trust

Professor Peter Calverley

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Dr Sujal Desai (attended one meeting)

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Louise Sewell)

Senior Research Occupational Therapist, Cardiff and Vale NHS Trust

Appendix C: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The Panel includes experts on guideline methodology, health professionals and people with experience of the issues affecting patients and carers. The members of the Guideline Review Panel were as follows.

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 Shovelton

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 D: Technical detail on the criteria for audit

Key priority	Criterion: data item needed	Exceptions: interpreting the evidence
<p>1. 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. The presence of airflow obstruction should be confirmed by performing spirometry. All health professionals managing patients with COPD should have access to spirometry and be competent in the interpretation of the results.</p>	<p>Percentage of smokers over the age of 35 consulting with a chronic cough and/or breathlessness who have had spirometry performed</p> <p>Percentage of patients with a diagnosis of COPD who have had spirometry performed</p>	<p>Patients who are unable to perform spirometry, for example because of facial paralysis.</p>
<p>2. 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.</p>	<p>Percentage of patients with COPD who are current smokers recorded in the general practice records as having been offered smoking cessation advice and or therapy</p>	
<p>3. Effective inhaled therapy Long-acting inhaled bronchodilators should be used to control symptoms and improve exercise capacity in patients who continue to experience problems despite the use of short-acting drugs. Inhaled corticosteroids should be added to long-acting bronchodilators in patients with an FEV₁ ≤ 50% predicted who have had two or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12-month period in order to decrease exacerbation frequency.</p>	<p>Percentage of patients with FEV₁ ≤ 50% predicted who have had two or more exacerbations in a 12-month period who are prescribed inhaled corticosteroid therapy</p>	<p>Patients who decline inhaled steroid therapy</p>
<p>4. Pulmonary rehabilitation for all who need it Pulmonary rehabilitation should be made available to all appropriate patients with COPD.</p>	<p>Percentage of patients with COPD who have undergone pulmonary rehabilitation</p>	<p>Patients who decline rehabilitation</p>

(continued on next page)

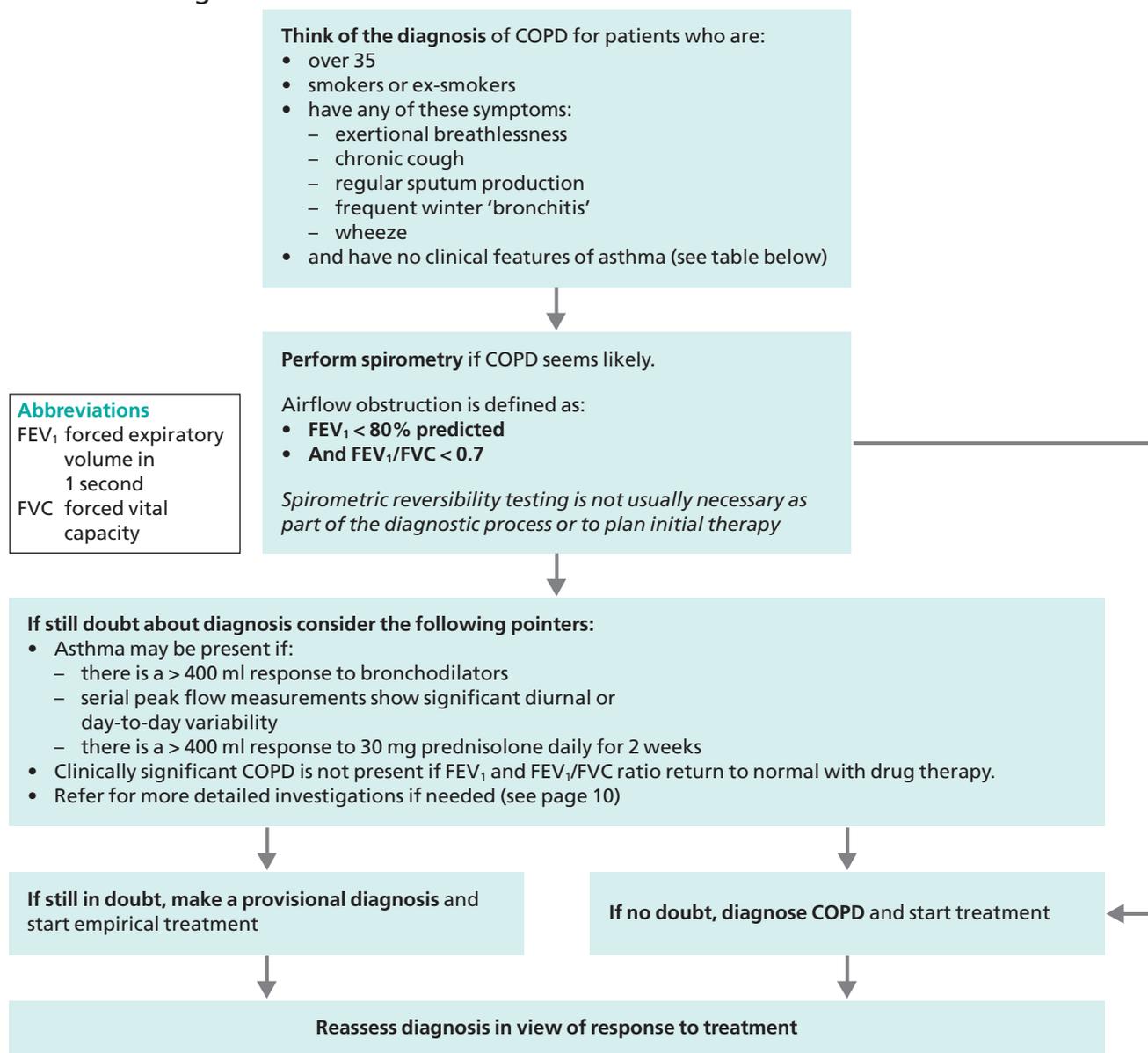
Key priority	Criterion: data item needed	Exceptions: interpreting the evidence
<p>5. Use non-invasive ventilation Non-invasive ventilation (NIV) should be used as the treatment of choice for persistent hypercapnic ventilatory failure during exacerbations not responding to medical therapy. It should be 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 management plan in the event of deterioration and ceilings of therapy should be agreed.</p>	Percentage of patients presenting with acute hypercapnic ventilatory failure who have received NIV	Patients who decline NIV
<p>6. Manage exacerbations The frequency of exacerbations should be reduced by appropriate use of inhaled corticosteroids and bronchodilators, and vaccinations. The impact of exacerbations should be minimised by:</p> <ul style="list-style-type: none"> • giving self-management advice on responding promptly to the symptoms of an exacerbation • starting appropriate treatment with oral corticosteroids and or antibiotics • use of non-invasive ventilation when indicated • use of hospital-at-home or assisted-discharge schemes 	Percentage of patients with exacerbations receiving appropriate corticosteroids and/ or antibiotics	Patient choice

Appendix E: The algorithms

Algorithm 1: Diagnosing COPD

Definition of COPD

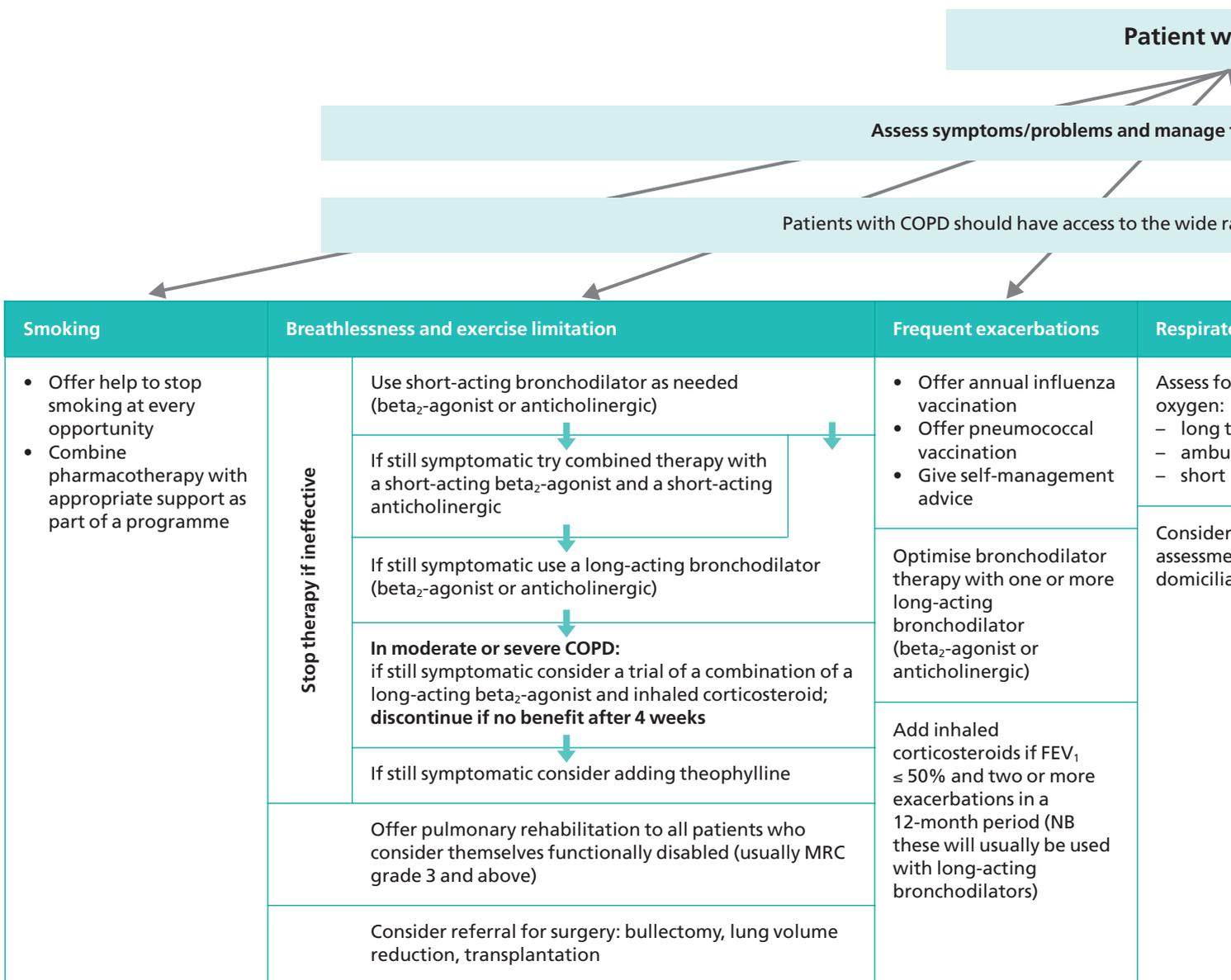
COPD is characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking.



Abbreviations
 FEV₁ forced expiratory volume in 1 second
 FVC forced vital capacity

Clinical features differentiating COPD and asthma		
	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35	Rare	Common
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

Algorithm 2: Management of stable COPD



Palliative care

- Opiates can be used for the palliation of breathlessness in patients with end-stage COPD unresponsive to other medical therapy
- Use benzodiazepines, tricyclic antidepressants, major tranquillisers and oxygen when appropriate
- Involve multidisciplinary palliative care teams

Abbreviations

BMI body mass index
 FEV₁ forced expiratory volume in 1 second
 MRC Medical Research Council
 LVRS lung volume reduction surgery

with COPD

those that are present as described below

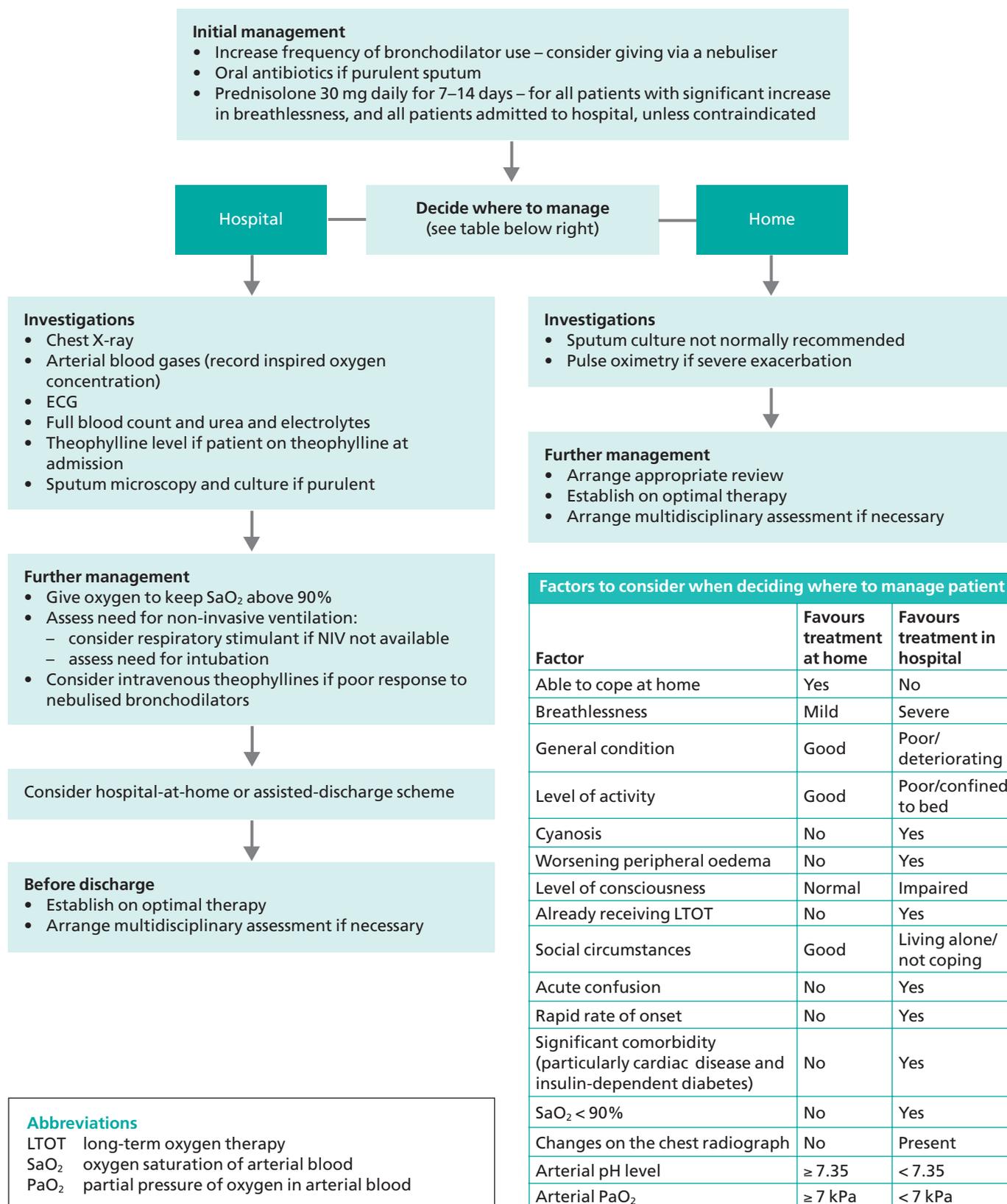
range of skills available from a multidisciplinary team

Respiratory failure	Cor pulmonale	Abnormal BMI	Chronic productive cough	Anxiety and depression
<ul style="list-style-type: none"> • Refer for appropriate respiratory support • Consider referral for long-term NIV 	<ul style="list-style-type: none"> • Assess need for oxygen • Use diuretics 	<ul style="list-style-type: none"> • Refer for dietetic advice • Give nutritional supplements if the BMI is low 	<ul style="list-style-type: none"> • Consider trial of mucolytic therapy • Continue if symptomatic improvement 	<ul style="list-style-type: none"> • Be aware of anxiety and depression and screen for them in those most physically disabled • Treat with conventional pharmacotherapy

Algorithm 3: Managing exacerbations of COPD

Exacerbations of COPD can be associated with increased:

- dyspnoea
- sputum purulence
- sputum volume
- cough





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