

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

NICE guideline Published: 5 December 2018 Last updated: 26 July 2019

www.nice.org.uk/guidance/ng115

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

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This guideline replaces CG101, ES18, ES17, ESNM72, ESNM57, ESNM8, ESNM9, ESNM21, ESNM33, ESNM47, ESNM49, ESNM52 and ESNM54.

This guideline is the basis of QS10 and QS181.

This guideline should be read in conjunction with NG114.

Overview

This guideline covers diagnosing and managing chronic obstructive pulmonary disease or COPD (which includes emphysema and chronic bronchitis) in people aged 16 and older. It aims to help people with COPD to receive a diagnosis earlier so that they can benefit from treatments to reduce symptoms, improve quality of life and keep them healthy for longer.

NICE has also produced a guideline on antimicrobial prescribing for acute exacerbations of <u>COPD</u>.

NICE has also produced a visual summary covering non-pharmacological management and use of inhaled therapies.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- People with COPD and their families and carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making decisions about your care</u>.

<u>Making decisions using NICE guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Diagnosing COPD

The diagnosis of chronic obstructive pulmonary disease (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 is supported by spirometry.

Symptoms

- 1.1.1 Suspect a diagnosis of COPD in people over 35 who have a risk factor (generally smoking or a history of smoking) and who present with 1 or more of the following symptoms:
 - exertional breathlessness
 - chronic cough
 - regular sputum production
 - frequent winter 'bronchitis'
 - wheeze. [2004]
- 1.1.2 When thinking about a diagnosis of COPD, ask the person if they have:

- weight loss
- reduced exercise tolerance
- waking at night with breathlessness
- ankle swelling
- fatigue
- occupational hazards
- chest pain
- haemoptysis (coughing up blood).

These last 2 symptoms are uncommon in COPD and raise the possibility of alternative diagnoses. **[2004]**

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]**

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

Table 1 MRC dyspnoea scale

Adapted from Fletcher CM, Elmes PC, Fairbairn MB et al. (1959) <u>The significance of</u> respiratory symptoms and the diagnosis of chronic bronchitis in a working population. British Medical Journal 2: 257–66. Chronic obstructive pulmonary disease in over 16s: diagnosis and management (NG115)

Spirometry

- 1.1.4 Perform spirometry:
 - at diagnosis
 - to reconsider the diagnosis, for people who show an exceptionally good response to treatment
 - to monitor disease progression. [2004, amended 2018]
- 1.1.5 Measure post-bronchodilator spirometry to confirm the diagnosis of COPD.[2010]
- 1.1.6 Think about alternative diagnoses or investigations for older people who have an FEV1/FVC ratio below 0.7 but do not have typical symptoms of COPD. **[2010]**
- 1.1.7 Think about a diagnosis of COPD in younger people who have symptoms of COPD, even when their FEV1/FVC ratio is above 0.7. [2010]
- 1.1.8 All healthcare professionals who care for people with COPD should have access to spirometry and be competent in interpreting the results. **[2004]**
- 1.1.9 Spirometry can be performed by any healthcare worker who has had appropriate training and has up-to-date skills. **[2004]**
- 1.1.10 Spirometry services should be supported by quality control processes. [2004]
- 1.1.11 It is recommended that <u>European Respiratory Journal GLI 2012 reference values</u> are used, but it is recognised that these values are not applicable for all ethnic groups. **[2004, amended 2018]**

Incidental findings on chest X-ray or CT scans

1.1.12 Consider primary care respiratory review and spirometry (see the recommendations on <u>symptoms</u> and <u>spirometry</u>) for people with emphysema or signs of chronic airways disease on a chest X-ray or CT scan. **[2018]**

- 1.1.13 If the person is a current smoker, their spirometry results are normal and they have no symptoms or signs of respiratory disease:
 - offer smoking cessation advice and treatment, and referral to specialist stop smoking services (see the <u>NICE guideline on stop smoking interventions and</u> <u>services</u>)
 - warn them that they are at higher risk of lung disease
 - advise them to return if they develop respiratory symptoms
 - be aware that the presence of emphysema on a CT scan is an independent risk factor for lung cancer. [2018]
- 1.1.14 If the person is not a current smoker, their spirometry is normal and they have no symptoms or signs of respiratory disease:
 - ask them if they have a personal or family history of lung or liver disease and consider alternative diagnoses, such as alpha-1 antitrypsin deficiency
 - reassure them that their emphysema or chronic airways disease is unlikely to get worse
 - advise them to return if they develop respiratory symptoms
 - be aware that the presence of emphysema on a CT scan is an independent risk factor for lung cancer. [2018]

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on incidental</u> <u>findings on chest X-ray or CT scans</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> <u>Diagnosing COPD and predicting outcomes</u>.

Further investigations

1.1.15 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]
- 1.1.16 Perform additional investigations when needed, as detailed in table 2. [2004, amended 2018]

Table 2 Additional investigations

Investigation	Role	
Sputum culture	To identify organisms if sputum is persistently present and purulent	
Serial home peak flow measurements	s To exclude asthma if diagnostic doubt remains	
	To assess cardiac status if cardiac disease or pulmonary hypertension are suspected because of:	
	• a history of cardiovascular disease, hypertension or hypoxia or	
ECG and serum natriuretic peptides	 clinical signs such as tachycardia, oedema, cyanosis or features of cor pulmonale 	
	See the <u>NICE guideline on chronic heart failure in adults</u> for recommendations on using serum natriuretic peptides to diagnose heart failure.	
Echocardiogram	To assess cardiac status if cardiac disease or pulmonary hypertension are suspected	
	To investigate symptoms that seem disproportionate to the spirometric impairment	
CT scan of the thorax	To investigate signs that may suggest another lung diagnosis (such as fibrosis or bronchiectasis)	
	To investigate abnormalities seen on a chest X-ray	
	To assess suitability for lung volume reduction procedures	

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Investigation	Role
Serum alpha-1 antitrypsin	To assess for alpha-1 antitrypsin deficiency if early onset, minimal smoking history or family history
Transfer factor for carbon monoxide (TLCO)	To investigate symptoms that seem disproportionate to the spirometric impairment To assess suitability for lung volume reduction procedures

1.1.17 Offer people with alpha 1 antitrypsin deficiency a referral to a specialist centre to discuss how to manage their condition. **[2004]**

Reversibility testing

- 1.1.18 For most people, routine spirometric reversibility testing is not necessary as part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids. It may be unhelpful or misleading because:
 - 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.
 [2004]
- 1.1.19 Untreated COPD and asthma are frequently distinguishable on the basis of history (and examination) in people presenting for the first time. Whenever possible, use features from the history and examination (such as those listed in table 3) to differentiate COPD from asthma. For more information on diagnosing asthma see the <u>NICE guideline on asthma</u>. **[2004, amended 2018]**

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

- 1.1.20 In addition to the features in table 3, use longitudinal observation of people (with spirometry, peak flow or symptoms) to help differentiate COPD from asthma.
 [2004]
- 1.1.21 When diagnostic uncertainty remains, or both COPD and asthma are present, use the following findings to help identify asthma:
 - a large (over 400 ml) response to bronchodilators
 - a large (over 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. **[2004]**

- 1.1.22 If diagnostic uncertainty remains, think about referral for more detailed investigations, including imaging and measurement of transfer factor for carbon monoxide (TLCO). **[2004]**
- 1.1.23 Reconsider the diagnosis of COPD for people who report a marked improvement in symptoms in response to inhaled therapy. **[2004]**

Assessing severity and using prognostic factors

COPD is heterogeneous, so no single measure can adequately assess disease severity in an individual. Severity assessment is, nevertheless, important because it has implications for therapy and relates to prognosis.

- 1.1.24 Do not use a multidimensional index (such as BODE) to assess prognosis in people with stable COPD. **[2018]**
- 1.1.25 From diagnosis onwards, when discussing prognosis and treatment decisions with people with stable COPD, think about the following factors that are individually associated with prognosis:
 - FEV1
 - smoking status
 - breathlessness (MRC scale)
 - chronic hypoxia and/or cor pulmonale
 - low BMI
 - severity and frequency of exacerbations
 - hospital admissions
 - symptom burden (for example, COPD Assessment Test [CAT] score)
 - exercise capacity (for example, 6-minute walk test)
 - TLCO
 - whether the person meets the criteria for long-term oxygen therapy and/or home non-invasive ventilation
 - multimorbidity
 - frailty. [2010, amended 2018]

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the <u>rationale and impact section on assessing</u> <u>severity and using prognostic factors</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> <u>Diagnosing COPD and predicting outcomes</u>.

Assessing and classifying the severity of airflow obstruction

- 1.1.26 Assess the severity of airflow obstruction according to the reduction in FEV1, as shown in table 4. **[2010]**
- 1.1.27 For people with mild airflow obstruction, only diagnose COPD if they have one or more of the symptoms in the <u>recommendation on symptoms</u>. **[2010]**

Table 4 Gradation of severity of airflow obstruction

Post- broncho- dilator FEV1/ FVC	FEV1 %	CG12 (2004) severity of airflow	ATS/ERS 2004 severity of airflow obstruction (post- broncho-dilator)	airflow obstruction (post-	NICE guideline CG101 (2010) severity of airflow obstruction (post- broncho-dilator)
< 0.7	≥ 80%	Not categorised	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 (or FEV1 below 50% with respiratory failure)	Stage 4 – Very severe (or FEV1 below 50% with respiratory failure)

ATS/ERS guidance: Celli BR, MacNee W (2004) Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. European Respiratory Journal 23(6): 932–46.

GOLD guidance: Global Initiative for Chronic Obstructive Lung Disease (GOLD; 2008)

Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease.

Identifying early disease

- 1.1.28 Perform spirometry in people who are over 35, current or ex-smokers, and have a chronic cough. **[2004]**
- 1.1.29 Consider spirometry in people with chronic bronchitis. A significant proportion of these people will go on to develop airflow limitation. **[2004]**

Referral for specialist advice

1.1.30 When clinically indicated, refer people for specialist advice. Referral may be appropriate at all stages of the disease and not solely in the most severely disabled people (see table 5). **[2004]**

Reason	Purpose
There is diagnostic uncertainty	Confirm diagnosis and optimise therapy
Suspected severe COPD	Confirm diagnosis and optimise therapy
The person with COPD 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 continued treatment or supervise withdrawal
Bullous lung disease	Identify candidates for lung volume reduction procedures
A rapid decline in FEV1	Encourage early intervention

Table 5 Reasons for referral

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Reason	Purpose
Assessment for pulmonary rehabilitation	Identify candidates for pulmonary rehabilitation
Assessment for a lung volume reduction procedure	Identify candidates for surgical or bronchoscopic lung volume reduction
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
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

1.1.31 People 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

NICE has also produced a visual summary covering non-pharmacological management and use of inhaled therapies.

1.2.1 For guidance on the management of multimorbidity, see the <u>NICE guideline on</u> <u>multimorbidity</u>. [2018]

Smoking cessation

- 1.2.2 Document 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) for everyone with COPD. **[2004]**
- 1.2.3 At every opportunity, advise and encourage every person with COPD who is still smoking (regardless of their age) to stop, and offer them help to do so. **[2004]**
- 1.2.4 Unless contraindicated, offer nicotine replacement therapy, varenicline or bupropion as appropriate to people who want to stop smoking, combined with an appropriate support programme to optimise smoking quit rates for people with COPD. [2010]
- 1.2.5 For more guidance on helping people to quit smoking, see the <u>NICE guideline on</u> <u>stop smoking interventions and services</u>. **[2010]**
- 1.2.6For more guidance on varenicline see the NICE technology appraisal guidance on
varenicline for smoking cessation. [2010]

Inhaled therapy

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

1.2.7 Use short-acting bronchodilators, as necessary, as the initial empirical treatment to relieve breathlessness and exercise limitation. **[2004]**

Inhaled corticosteroids (ICS)

- 1.2.8 Do not use oral corticosteroid reversibility tests to identify which people should be prescribed inhaled corticosteroids, because they do not predict response to inhaled corticosteroid therapy. **[2004]**
- 1.2.9 Be aware of, and be prepared to discuss with the person, the risk of side effects

(including pneumonia) in people who take inhaled corticosteroids for COPD. Follow the MHRA safety advice on the risk of psychological and behavioural side <u>effects</u> associated with inhaled corticosteroids. **[2010, amended 2018]**

Inhaled combination therapy

Inhaled combination therapy refers to combinations of long-acting muscarinic antagonists (LAMA), long-acting beta2 agonists (LABA), and inhaled corticosteroids (ICS).

- 1.2.10 Do not assess the effectiveness of bronchodilator therapy using lung function alone. Include a variety of other measures such as improvement in symptoms, activities of daily living, exercise capacity, and rapidity of symptom relief. **[2004]**
- 1.2.11 Offer LAMA+LABA to people who:
 - have spirometrically confirmed COPD and
 - do not have <u>asthmatic features/features suggesting steroid</u>
 <u>responsiveness</u> and
 - remain breathless or have exacerbations despite:
 - having used or been offered treatment for tobacco dependence if they smoke and
 - optimised non-pharmacological management and relevant vaccinations and
 - using a short-acting bronchodilator. [2018]

Follow the MHRA safety advice on Respimat and Handihaler inhalers.

- 1.2.12 Consider LABA+ICS for people who:
 - have spirometrically confirmed COPD and
 - have asthmatic features/features suggesting steroid responsiveness and
 - remain breathless or have exacerbations despite:

- having used or been offered treatment for tobacco dependence if they smoke and
- optimised non-pharmacological management and relevant vaccinations and
- using a short-acting bronchodilator. [2018]
- 1.2.13 For people who are using long-acting bronchodilators outside of the <u>recommendations on offering LAMA and LABA and considering LABA+ICS</u> and whose symptoms are under control, explain to them that they can continue with their current treatment until both they and their NHS healthcare professional agree it is appropriate to change. **[2018]**
- 1.2.14 Before starting LAMA+LABA+ICS, conduct a clinical review to ensure that:
 - the person's non-pharmacological COPD management is optimised and they have used or been offered treatment for tobacco dependence if they smoke
 - acute episodes of worsening symptoms are caused by COPD exacerbations and not by another physical or mental health condition
 - the person's day-to-day symptoms that are adversely impacting their quality of life are caused by COPD and not by another physical or mental health condition. [2019]
- 1.2.15 For people with COPD who are taking LABA+ICS, offer LAMA+LABA+ICS if:
 - their day-to-day symptoms continue to adversely impact their quality of life or
 - they have a severe exacerbation (requiring hospitalisation) or
 - they have 2 moderate exacerbations within a year. [2019]
- 1.2.16 For people with COPD who are taking LAMA+LABA, consider LAMA+LABA+ICS if:
 - they have a severe exacerbation (requiring hospitalisation) or
 - they have 2 moderate exacerbations within a year. [2019]

- 1.2.17 For people with COPD who are taking LAMA+LABA and whose day-to-day symptoms adversely impact their quality of life:
 - consider a trial of LAMA+LABA+ICS, lasting for 3 months only
 - after 3 months, conduct a clinical review to establish whether or not LAMA+LABA+ICS has improved their symptoms:
 - if symptoms have not improved, stop LAMA+LABA+ICS and switch back to LAMA+LABA
 - if symptoms have improved, continue with LAMA+LABA+ICS. [2019]
- 1.2.18 Document the reason for continuing ICS use in clinical records and review at least annually. **[2019]**
- 1.2.19 Base the choice of drugs and inhalers on:
 - how much they improve symptoms
 - the person's preferences and ability to use the inhalers
 - the drugs' potential to reduce exacerbations
 - their side effects
 - their cost.

Minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible. **[2018]**

1.2.20 When prescribing long-acting drugs, ensure people receive inhalers they have been trained to use (for example, by specifying the brand and inhaler in prescriptions). **[2018]**

For a short explanation of why the committee made the 2018 and 2019 recommendations and how they might affect practice, see the <u>rationale and impact</u> <u>section on inhaled combination therapy.</u>

Full details of the evidence and the committee's discussion are in <u>evidence review F:</u> <u>Inhaled therapies</u> and <u>evidence review I: Inhaled triple therapy</u>.

Delivery systems used to treat stable COPD

Most people with COPD – whatever their age – can develop adequate inhaler technique if they are given training. However, people with significant cognitive impairment may be unable to use any form of inhaler device. In most people with COPD, however, a pragmatic approach guided by individual patient assessment is needed when choosing a device.

Inhalers

- 1.2.21 In most cases bronchodilator therapy is best administered using a hand-held inhaler (including a spacer if appropriate). **[2004]**
- 1.2.22 Provide an alternative inhaler if a person cannot use a particular one correctly or it is not suitable for them. **[2004]**
- 1.2.23 Only prescribe inhalers after people have been trained to use them and can demonstrate satisfactory technique. **[2004]**
- 1.2.24 People with COPD should have their ability to use an inhaler regularly assessed and corrected if necessary by a healthcare professional competent to do so. [2004]

Spacers

- 1.2.25 Provide a spacer that is compatible with the person's metered-dose inhaler. [2004]
- 1.2.26 Advise people to use a spacer with a metered-dose inhaler in the following way:

- administer the drug by single actuations of the metered-dose inhaler into the spacer, inhaling after each actuation
- there should be minimal delay between inhaler actuation and inhalation
- normal tidal breathing can be used as it is as effective as single breaths
- repeat if a second dose is required. [2004]
- 1.2.27 Advise people on spacer cleaning. Tell them:
 - not to clean the spacer more than monthly, because more frequent cleaning affects their performance (because of a build-up of static)
 - to hand wash using warm water and washing-up liquid, and allow the spacer to air dry. [2004, amended 2018]

Nebulisers

- 1.2.28 Think about nebuliser therapy for people with distressing or disabling breathlessness despite maximal therapy using inhalers. **[2004]**
- 1.2.29 Do not prescribe nebulised therapy without an assessment of the person's and/or carer's ability to use it. **[2004]**
- 1.2.30 Do not continue nebulised therapy without assessing and confirming that 1 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]
- 1.2.31 Use a nebuliser system that is known to be efficient. **[2004]**

Follow the MHRA safety advice on non-CE-marked nebulisers for COPD.

- 1.2.32 Offer people 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]**
- 1.2.33 If nebuliser therapy is prescribed, provide the person with equipment, servicing, and ongoing advice and support. **[2004]**

Oral therapy

Oral corticosteroids

- 1.2.34 Long-term use of oral corticosteroid therapy in COPD is not normally recommended. Some people with advanced COPD may need long-term 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]
- 1.2.35 Monitor people who are having long-term oral corticosteroid therapy for osteoporosis, and give them appropriate prophylaxis. Start prophylaxis without monitoring for people over 65. [2004]

Oral theophylline

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

- 1.2.36 Theophylline should only be used after a trial of short-acting bronchodilators and long-acting bronchodilators, or for people who are unable to use inhaled therapy, as plasma levels and interactions need to be monitored. **[2004]**
- 1.2.37 Take particular caution when using theophylline in older people, because of differences in pharmacokinetics, the increased likelihood of comorbidities and the use of other medications. **[2004]**
- 1.2.38 Assess the effectiveness of theophylline by improvements in symptoms, activities

of daily living, exercise capacity and lung function. [2004]

1.2.39 Reduce the dose of theophylline for people who are having an exacerbation if they are prescribed macrolide or fluoroquinolone antibiotics (or other drugs known to interact). **[2004]**

Oral mucolytic therapy

- 1.2.40 Consider mucolytic drug therapy for people with a chronic cough productive of sputum. **[2004]**
- 1.2.41 Only continue mucolytic therapy if there is symptomatic improvement (for example, reduction in frequency of cough and sputum production). **[2004]**
- 1.2.42 Do not routinely use mucolytic drugs to prevent exacerbations in people with stable COPD. **[2010]**

Oral anti-oxidant therapy

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

Oral anti-tussive therapy

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

Oral prophylactic antibiotic therapy

- 1.2.45 Before starting prophylactic antibiotic therapy in a person with COPD, think about whether respiratory specialist input is needed. **[2018]**
- 1.2.46 Consider azithromycin (usually 250 mg 3 times a week) for people with COPD if

they:

- do not smoke and
- have optimised non-pharmacological management and inhaled therapies, relevant vaccinations and (if appropriate) have been referred for pulmonary rehabilitation and
- continue to have 1 or more of the following, particularly if they have significant daily sputum production:
 - frequent (typically 4 or more per year) exacerbations with sputum production
 - prolonged exacerbations with sputum production
 - exacerbations resulting in hospitalisation. [2018]

In July 2019, this was an off-label use of azithromycin. See <u>NICE's</u> information on prescribing medicines.

- 1.2.47 Before offering prophylactic antibiotics, ensure that the person has had:
 - sputum culture and sensitivity (including tuberculosis culture), to identify other possible causes of persistent or recurrent infection that may need specific treatment (for example, antibiotic-resistant organisms, atypical mycobacteria or *Pseudomonas aeruginosa*)
 - training in airway clearance techniques to optimise sputum clearance (see the <u>recommendation in the section on physiotherapy</u>)
 - a CT scan of the thorax to rule out bronchiectasis and other lung pathologies.
 [2018]
- 1.2.48 Before starting azithromycin, ensure the person has had:
 - an electrocardiogram (ECG) to rule out prolonged QT interval and
 - baseline liver function tests. [2018]
- 1.2.49 When prescribing azithromycin, advise people about the small risk of hearing loss

and tinnitus, and tell them to contact a healthcare professional if this occurs. **[2018]**

- 1.2.50 Review prophylactic azithromycin after the first 3 months, and then at least every 6 months. **[2018]**
- 1.2.51 Only continue treatment if the continued benefits outweigh the risks. Be aware that there are no long-term studies on the use of prophylactic antibiotics in people with COPD. **[2018]**
- 1.2.52 For people who are taking prophylactic azithromycin and are still at risk of exacerbations, provide a non-macrolide antibiotic to keep at home as part of their exacerbation action plan (see the <u>recommendation on offering antibiotics to keep at home in the section on self-management</u>). **[2018]**
- 1.2.53 Be aware that it is not necessary to stop prophylactic azithromycin during an acute exacerbation of COPD. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on oral</u> <u>prophylactic antibiotic therapy</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review E:</u> <u>Predicting and preventing exacerbations</u>.

Oral phosphodiesterase-4 inhibitors

1.2.54 For guidance on treating severe COPD with roflumilast, see <u>NICE's technology</u> appraisal guidance on roflumilast for treating chronic obstructive pulmonary disease. [2018] Chronic obstructive pulmonary disease in over 16s: diagnosis and management (NG115)

Oxygen

Long-term oxygen therapy

- 1.2.55 Be aware that inappropriate oxygen therapy in people with COPD may cause respiratory depression. **[2004]**
- 1.2.56 Assess the need for oxygen therapy in people with:
 - very severe airflow obstruction (FEV1 below 30% predicted)
 - cyanosis (blue tint to skin)
 - polycythaemia
 - peripheral oedema (swelling)
 - a raised jugular venous pressure
 - oxygen saturations of 92% or less breathing air.

Also consider assessment for people with severe airflow obstruction (FEV1 30–49% predicted).

Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. See also the <u>NHS</u> <u>England Patient Safety Alert on the risk of harm from inappropriate</u> <u>placement of pulse oximeter probes.</u>[2004]

- 1.2.57 Assess people for long-term oxygen therapy by measuring arterial blood gases on 2 occasions at least 3 weeks apart in people who have a confident diagnosis of COPD, who are receiving optimum medical management and whose COPD is stable. **[2004]**
- 1.2.58 Consider long-term oxygen therapy for people with COPD who do not smoke and who:
 - have a partial pressure of oxygen in arterial blood (PaO₂) below 7.3 kPa when

stable **or**

- have a PaO₂ above 7.3 and below 8 kPa when stable, if they also have 1 or more of the following:
 - secondary polycythaemia
 - peripheral oedema
 - pulmonary hypertension.

See the MHRA alert on the risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders. [2018]

- 1.2.59 Conduct and document a structured risk assessment for people being assessed for long-term oxygen therapy who meet the criteria in the <u>recommendation on</u> <u>considering long-term oxygen therapy</u>. As part of the risk assessment, cover the risks for both the person with COPD and the people who live with them, including:
 - the risks of falls from tripping over the equipment
 - the risks of burns and fires, and the increased risk of these for people who live in homes where someone smokes (including e-cigarettes).

Base the decision on whether long-term oxygen therapy is suitable on the results of the structured risk assessment. **[2018]**

- 1.2.60 For people who smoke or live with people who smoke, but who meet the other criteria for long-term oxygen therapy, ensure the person who smokes is offered smoking cessation advice and treatment, and referral to specialist stop smoking services (see the <u>NICE guidelines on stop smoking interventions and services</u> and <u>medicines optimisation</u>). **[2018]**
- 1.2.61 Do not offer long-term oxygen therapy to people who continue to smoke despite being offered smoking cessation advice and treatment, and referral to specialist stop smoking services. **[2018]**
- 1.2.62 Advise people who are having long-term oxygen therapy that they should

breathe supplemental oxygen for a minimum of 15 hours per day. [2018]

- 1.2.63 Do not offer long-term oxygen therapy to treat isolated nocturnal hypoxaemia caused by COPD. **[2018]**
- 1.2.64 To ensure everyone eligible for long-term oxygen therapy is identified, pulse oximetry should be available in all healthcare settings. **[2004]**
- 1.2.65 Oxygen concentrators should be used to provide the fixed supply at home for long-term oxygen therapy. **[2004]**
- 1.2.66 People who are having long-term oxygen therapy should be reviewed at least once per year by healthcare professionals familiar with long-term oxygen therapy. This review should include pulse oximetry. [2004]

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on long-term</u> <u>oxygen therapy</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review B:</u> Oxygen therapy in people with stable COPD.

Ambulatory oxygen therapy

- 1.2.67 Do not offer ambulatory oxygen to manage breathlessness in people with COPD who have mild or no hypoxaemia at rest. [2018]
- 1.2.68 Consider ambulatory oxygen in people with COPD who have exercise desaturation and are shown to have an improvement in exercise capacity with oxygen, and have the motivation to use oxygen. **[2004, amended 2018]**
- 1.2.69 Prescribe ambulatory oxygen to people who are already on long-term oxygen therapy, who wish to continue oxygen therapy outside the home, and who are prepared to use it. **[2004]**
- 1.2.70 Only prescribe ambulatory oxygen therapy after an appropriate assessment has

been performed by a specialist. The purpose of the assessment is to assess the extent of desaturation, the improvement in exercise capacity with supplemental oxygen, and the oxygen flow rate needed to correct desaturation. **[2004]**

- 1.2.71 Small light-weight cylinders, oxygen-conserving devices and portable liquid oxygen systems should be available for people with COPD. **[2004]**
- 1.2.72 When choosing which equipment to prescribe, take account of the hours of ambulatory oxygen use and oxygen flow rate needed. **[2004]**

Short-burst oxygen therapy

1.2.73 Do not offer short-burst oxygen therapy to manage breathlessness in people with COPD who have <u>mild or no hypoxaemia</u> at rest. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on ambulatory</u> <u>and oxygen short-burst oxygen therapy</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review B:</u> Oxygen therapy in people with stable COPD.

Non-invasive ventilation

1.2.74 Refer people who are adequately treated but have chronic hypercapnic respiratory failure and have needed assisted ventilation (whether invasive or non-invasive) during an exacerbation, or who are hypercapnic or acidotic on long-term oxygen therapy, to a specialist centre for consideration of long-term non-invasive ventilation. [2004]

Managing pulmonary hypertension and cor pulmonale

In this guideline 'cor pulmonale' is defined as a clinical condition that is identified and managed on the basis of clinical features. It includes people who have right heart failure secondary to lung disease and people whose primary pathology is salt and water retention, leading to the development of peripheral oedema (swelling).

Diagnosing pulmonary hypertension and cor pulmonale

1.2.75 Suspect a diagnosis of cor pulmonale for people with:

- peripheral oedema (swelling)
- a raised venous pressure
- a systolic parasternal heave
- a loud pulmonary second heart sound. [2004]
- 1.2.76 It is recommended that the diagnosis of cor pulmonale is made clinically and that this process should involve excluding other causes of peripheral oedema (swelling). **[2004]**

Treating pulmonary hypertension

- 1.2.77 Do not offer the following treatments solely to manage pulmonary hypertension caused by COPD, except as part of a randomised controlled trial:
 - bosentan
 - losartan
 - nifedipine
 - nitric oxide
 - pentoxifylline
 - phosphodiesterase-5 inhibitors
 - statins. **[2018]**

Treating cor pulmonale

- 1.2.78 Ensure that people with cor pulmonale caused by COPD are offered optimal COPD treatment, including advice and interventions to help them stop smoking. For people who need treatment for hypoxia, see the <u>section on long-term oxygen</u> <u>therapy</u>. [2018]
- 1.2.79 Oedema associated with cor pulmonale can usually be controlled symptomatically with diuretic therapy. **[2004]**
- 1.2.80 Do not use the following to treat cor pulmonale caused by COPD:
 - alpha-blockers
 - angiotensin-converting enzyme inhibitors
 - calcium channel blockers
 - digoxin (unless there is atrial fibrillation). [2018]

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on managing</u> <u>pulmonary hypertension and cor pulmonale</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> <u>Managing pulmonary hypertension and cor pulmonale</u>.

Pulmonary rehabilitation

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

1.2.81 Make pulmonary rehabilitation available to all appropriate people with COPD (see the <u>recommendation on offering pulmonary rehabilitation</u>), including people who have had a recent hospitalisation for an acute exacerbation. **[2010]**

- 1.2.82 Offer pulmonary rehabilitation to all people who view themselves as functionally disabled by COPD (usually Medical Research Council [MRC] grade 3 and above). Pulmonary rehabilitation is not suitable for people who are unable to walk, who have unstable angina or who have had a recent myocardial infarction. [2004]
- 1.2.83 For pulmonary rehabilitation programmes to be effective, and to improve adherence, they should be held at times that suit people, in buildings that are easy to get to and that have good access for people with disabilities. Places should be available within a reasonable time of referral. **[2004]**
- 1.2.84 Pulmonary rehabilitation programmes should include multicomponent, multidisciplinary interventions that are tailored to the individual person's needs. The rehabilitation process should incorporate a programme of physical training, disease education, and nutritional, psychological and behavioural intervention.
 [2004]
- 1.2.85 Advise people of the benefits of pulmonary rehabilitation and the commitment needed to gain these. **[2004]**

Vaccination and anti-viral therapy

- 1.2.86 Offer pneumococcal vaccination and an annual flu vaccination to all people with COPD, as recommended by the Chief Medical Officer. **[2004]**
- 1.2.87 For guidance on preventing and treating flu, see the <u>NICE technology appraisals</u> on oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza and <u>amantadine</u>, oseltamivir and zanamivir for the treatment of influenza. **[2004]**

Lung surgery and lung volume reduction procedures

- 1.2.88 Offer a respiratory review to assess whether a lung volume reduction procedure is a possibility for people with COPD when they complete pulmonary rehabilitation and at other subsequent reviews, if all of the following apply:
 - they have severe COPD, with FEV1 less than 50% and breathlessness that

affects their quality of life despite optimal medical treatment (see <u>recommendations 1.2.11 to 1.2.17 in the section on inhaled combination</u> <u>therapy</u>)

- they do not smoke
- they can complete a 6-minute walk distance of at least 140 m (if limited by breathlessness). [2018]
- 1.2.89 At the respiratory review, refer the person with COPD to a lung volume reduction multidisciplinary team to assess whether lung volume reduction surgery or endobronchial valves are suitable if they have:
 - hyperinflation, assessed by lung function testing with body plethysmography and
 - emphysema on unenhanced CT chest scan and
 - optimised treatment for other comorbidities. [2018]
- 1.2.90 Only offer endobronchial coils as part of a clinical trial and after assessment by a lung volume reduction multidisciplinary team. **[2018]**
- 1.2.91 For more guidance on lung volume reduction procedures, see the <u>NICE</u> interventional procedures guidance on lung volume reduction surgery, endobronchial valves and endobronchial coils. [2018]
- 1.2.92 Refer people with COPD for an assessment for bullectomy if they are breathless and a CT scan shows a bulla occupying at least one third of the hemithorax.[2018]
- 1.2.93 Consider referral to a specialist multidisciplinary team to assess for lung transplantation for people who:
 - have severe COPD, with FEV1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment (see <u>recommendations</u> <u>1.2.11 to 1.2.17 in the section on inhaled combination therapy</u>) and
 - do not smoke and

- have completed pulmonary rehabilitation and
- do not have contraindications for transplantation (for example, comorbidities or frailty). [2018]
- 1.2.94 Do not use previous lung volume reduction procedures as a reason not to refer a person for assessment for lung transplantation. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on lung volume</u> reduction procedures, bullectomy and lung transplantation.

Full details of the evidence and the committee's discussion are in <u>evidence review G</u>: <u>Referral criteria for lung volume reduction procedures</u>, <u>bullectomy or lung</u> <u>transplantation</u>.

Alpha-1 antitrypsin replacement therapy

1.2.95 Alpha-1 antitrypsin replacement therapy is not recommended for people with alpha-1 antitrypsin deficiency (see also the <u>recommendation on referral in the</u> <u>section on further investigations</u>). [2004]

Multidisciplinary management

- 1.2.96 COPD care should be delivered by a multidisciplinary team. [2004]
- 1.2.97 When defining the activity of the multidisciplinary team, think about the following functions:
 - assessment (including performing spirometry, assessing which delivery systems to use for inhaled therapy, the need for aids for daily living and assessing the need for oxygen)
 - care and treatment, including:

- pulmonary rehabilitation
- identifying and managing anxiety and depression
- advising people on relaxation techniques
- dietary issues
- exercise
- social security benefits and travel
- hospital-at-home/early discharge schemes
- non-invasive ventilation and palliative care
- advising people on self-management strategies
- identifying and monitoring people at high risk of exacerbations and undertaking activities to avoid emergency admissions
- education for people with COPD, their carers, and for healthcare professionals. [2004]

Respiratory nurse specialists

1.2.98 It is recommended that the multidisciplinary COPD team includes respiratory nurse specialists. **[2004]**

Physiotherapy

- 1.2.99 If people have excessive sputum, they should be taught:
 - how to use positive expiratory pressure devices
 - active cycle of breathing techniques. [2004, amended 2018]

Identifying and managing anxiety and depression

- 1.2.100 Be alert for anxiety and depression in people with COPD. Consider whether people have anxiety or depression, particularly if they:
 - have severe breathlessness
 - are hypoxic
 - have been seen at or admitted to a hospital with an exacerbation of COPD.
 [2004, amended 2018]
- 1.2.101 For guidance on diagnosing and managing depression, see the <u>NICE guideline on</u> depression in adults with a chronic physical health problem. [2004]
- 1.2.102 For guidance on managing anxiety, see the <u>NICE guideline on generalised anxiety</u> disorder and panic disorder in adults. **[2018]**

Nutritional factors

- 1.2.103 Calculate BMI for people with COPD:
 - the normal range for BMI is 20 to less than 25 $\mbox{kg/m}^2$
 - refer people for dietetic advice if they have a BMI that is abnormal (high or low) or changing over time
 - for people with a low BMI, give nutritional supplements to increase their total calorific intake and encourage them to exercise to augment the effects of nutritional supplementation. [2004]

The <u>NICE guideline on obesity</u> states that a healthy BMI range is 18.5 to 24.9 kg/m^2 , but note that this may not be appropriate for people with COPD.

- 1.2.104 For guidance on nutrition support, see the <u>NICE guideline on nutrition support for</u> <u>adults</u>. **[2004]**
- 1.2.105 Pay attention to changes in weight in older people, particularly if the change is more than 3 kg. **[2004]**

Palliative care

- 1.2.106 When appropriate, use opioids to relieve breathlessness in people with end-stage COPD that is unresponsive to other medical therapy. **[2004]**
- 1.2.107 When appropriate, use benzodiazepines, tricyclic antidepressants, major tranquillisers and oxygen for breathlessness in people with end-stage COPD that is unresponsive to other medical therapy. **[2004]**
- 1.2.108 People with end-stage COPD and their family members or carers (as appropriate) should have access to the full range of services offered by multidisciplinary palliative care teams, including admission to hospices. **[2004]**
- 1.2.109 For standards and measures on palliative care, see the <u>NICE quality standard on</u> end of life care for adults. **[2018]**
- 1.2.110 For guidance on care for people in the last days of life, see the <u>NICE guideline on</u> <u>care of dying adults</u>. **[2018]**

Assessment for occupational therapy

- 1.2.111 Regularly ask people with COPD about their ability to undertake activities of daily living and how breathless these activities make them. **[2004]**
- 1.2.112 Clinicians that care for people with COPD should assess their need for occupational therapy using validated tools. **[2004]**

Social services

1.2.113 Consider referring people for assessment by social services if they have disabilities caused by COPD. **[2004]**

Advice on travel

- 1.2.114 Assess people who are using long-term oxygen therapy and who are planning air travel in line with the <u>British Thoracic Society recommendations</u>. **[2004]**
- 1.2.115 Assess people with an FEV1 below 50% predicted who are planning air travel in line with the BTS recommendations. **[2004]**
- 1.2.116 Warn people with bullous disease that they are at a theoretically increased risk of a pneumothorax during air travel. **[2004]**

Advice on diving

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

Education

- 1.2.118 There are significant differences in the response of people with COPD and asthma to education programmes. Programmes designed for asthma should not be used in COPD. **[2004]**
- 1.2.119 At diagnosis and at each review appointment, offer people with COPD and their family members or carers (as appropriate):
 - written information about their condition
 - opportunities for discussion with a healthcare professional who has experience in caring for people with COPD. [2018]
- 1.2.120 Ensure the information provided is:
 - available on an ongoing basis
 - relevant to the stage of the person's condition
 - tailored to the person's needs. [2018]

- 1.2.121 At minimum, the information should cover:
 - an explanation of COPD and its symptoms
 - advice on quitting smoking (if relevant) and how this will help with the person's COPD
 - advice on avoiding passive smoke exposure
 - managing breathlessness
 - physical activity and pulmonary rehabilitation
 - medicines, including inhaler technique and the importance of adherence
 - vaccinations
 - identifying and managing exacerbations
 - details of local and national organisations and online resources that can provide more information and support
 - how COPD will affect other long-term conditions that are common in people with COPD (for example hypertension, heart disease, anxiety, depression and musculoskeletal problems). [2018]
- 1.2.122 Be aware of the obligation to provide accessible information as detailed in the <u>NHS Accessible Information Standard</u>. For more guidance on providing information to people and discussing their preferences with them, see the <u>NICE</u> guideline on patient experience in adult <u>NHS services</u>. [2018]

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on self-</u><u>management, education and telehealth monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review C:</u> <u>Self-management interventions</u>, education and telehealth monitoring.

1.2.123 Advise people with COPD that the following factors increase their risk of exacerbations:

- continued smoking or relapse for ex-smokers
- exposure to passive smoke
- viral or bacterial infection
- indoor and outdoor air pollution
- lack of physical activity
- seasonal variation (winter and spring). [2018]

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the <u>rationale and impact section on risk factors for</u> <u>COPD exacerbations</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review E:</u> <u>Predicting and preventing exacerbations</u>.

Self-management

- 1.2.124 Develop an individualised self-management plan in collaboration with each person with COPD and their family members or carers (as appropriate), and:
 - include education on all relevant points from the <u>recommendation on the</u> information that should be covered in the section on education
 - review the plan at future appointments. [2018]
- 1.2.125 Develop an individualised exacerbation action plan in collaboration with each person with COPD who is at risk of exacerbations. **[2018]**
- 1.2.126 Offer people a short course of oral corticosteroids and a short course of oral antibiotics to keep at home as part of their exacerbation action plan if:
 - they have had an exacerbation within the last year, and remain at risk of exacerbations

- they understand and are confident about when and how to take these medicines, and the associated benefits and harms
- they know to tell their healthcare professional when they have used the medicines, and to ask for replacements. [2018]
- 1.2.127 For guidance on the choice of antibiotics see the <u>NICE guideline on antimicrobial</u> <u>prescribing for acute exacerbations of COPD</u>. [2018]
- 1.2.128 At all review appointments, discuss corticosteroid and antibiotic use with people who keep these medicines at home, to check that they still understand how to use them. For people who have used 3 or more courses of oral corticosteroids and/or oral antibiotics in the last year, investigate the possible reasons for this. [2018]
- 1.2.129 See the <u>recommendations on systemic corticosteroids</u> for more guidance on oral corticosteroids. **[2018]**
- 1.2.130 Encourage people with COPD to respond promptly to exacerbation symptoms by following their action plan, which may include:
 - adjusting their short-acting bronchodilator therapy to treat their symptoms
 - taking a short course of oral corticosteroids if their increased breathlessness interferes with activities of daily living
 - adding oral antibiotics if their sputum changes colour and increases in volume or thickness beyond their normal day-to-day variation
 - telling their healthcare professional. [2018]
- 1.2.131 Ask people with COPD if they experience breathlessness they find frightening. If they do, consider including a cognitive behavioural component in their self-management plan to help them manage anxiety and cope with breathlessness. [2018]
- 1.2.132 For people at risk of hospitalisation, explain to them and their family members or carers (as appropriate) what to expect if this happens (including non-invasive ventilation and discussions on future treatment preferences, ceilings of care and

resuscitation). [2018]

Telehealth monitoring

1.2.133 Do not offer routine telehealth monitoring of physiological status as part of management for stable COPD. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the <u>rationale and impact section on self-</u><u>management, education and telehealth monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review C:</u> <u>Self-management interventions, education and telehealth monitoring</u>.

Fitness for general surgery

- 1.2.134 The ultimate clinical decision about whether or not to proceed with surgery should rest with a consultant anaesthetist and consultant surgeon, taking account of comorbidities, functional status and the need for the surgery. **[2004]**
- 1.2.135 It is recommended that lung function should not be the only criterion used to assess people with COPD before surgery. Composite assessment tools such as the ASA scoring system are the best predictors of risk. **[2004]**
- 1.2.136 If time permits, optimise the medical management of people with COPD before surgery. This might include a course of pulmonary rehabilitation. **[2004]**

Follow-up of people with COPD

- 1.2.137 Follow-up of all people 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 advice and treatment to help them stop smoking, and referral to specialist stop smoking services (see the <u>NICE guideline on stop smoking</u> <u>interventions and services</u>)
- recording the opportunistic measurement of spirometric parameters (a loss of 500 ml or more over 5 years will show which people have rapidly progressing disease and may need specialist referral and investigation).
 [2004, amended 2018]
- 1.2.138 Review people with COPD at least once per year and more frequently if indicated, and cover the issues listed in table 6. **[2004]**
- 1.2.139 For most people with stable severe COPD regular hospital review is not necessary, but there should be locally agreed mechanisms to allow rapid access to hospital assessment when needed. **[2004]**
- 1.2.140 When people with very severe COPD are reviewed in primary care they should be seen at least twice per year, and specific attention should be paid to the issues listed in table 6. [2004]
- 1.2.141 Specialists should regularly review people with severe COPD who need interventions such as long-term non-invasive ventilation. [2004]

Table 6 Summary of follow-up of people 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

	Mild/moderate/severe (stages 1 to 3)	Very severe (stage 4)
Clinical assessment	 Smoking status and motivation to quit Adequacy of symptom control: breathlessness exercise tolerance estimated exacerbation frequency Need for pulmonary rehabilitation Presence of complications Effects of each drug treatment Inhaler technique Need for referral to specialist and therapy services 	 Smoking status and motivation to quit Adequacy of symptom control: breathlessness exercise tolerance estimated exacerbation frequency Presence of cor pulmonale Need for long-term oxygen therapy Person with COPD'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	 FEV1 and FVC calculate BMI MRC dyspnoea score 	 FEV1 and FVC calculate BMI MRC dyspnoea score SaO₂

1.3 Managing exacerbations of COPD

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.

Assessing the need for hospital treatment

1.3.1 Use the factors in table 7 to assess whether people with COPD need hospital treatment.

Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. See also the <u>NHS England Patient</u> <u>Safety Alert on the risk of harm from inappropriate placement of pulse oximeter probes</u>. **[2004]**

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 long-term oxygen therapy	No	Yes

Table 7 Factors to consider when deciding where to treat the person with COPD

Chronic obstructive pulmonary disease in over 16s: diagnosis and management (NG115)

Factor	Treat at home	Treat in hospital
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 chest radiograph	No	Present
Arterial pH level	≥ 7.35	< 7.35
Arterial PaO ₂	≥ 7 kPa	< 7 kPa

Investigating an exacerbation

The diagnosis of an exacerbation is made clinically and does not depend on the results of investigations. However, investigations may sometimes be useful in ensuring appropriate treatment is given. Different investigation strategies are needed for people in hospital (who will tend to have more severe exacerbations) and people in the community.

Primary care

1.3.2 For people 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.

Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. See also the <u>NHS</u> <u>England Patient Safety Alert on the risk of harm from inappropriate</u> <u>placement of pulse oximeter probes</u>. **[2004]**

People referred to hospital

- 1.3.3 In all people presenting to hospital with an acute exacerbation:
 - obtain a chest X-ray
 - measure arterial blood gas tensions and record the inspired oxygen concentration
 - record an ECG (to exclude comorbidities)
 - perform a full blood count and measure urea and electrolyte concentrations
 - measure a theophylline level on admission in people who are taking theophylline therapy
 - send a sputum sample for microscopy and culture if the sputum is purulent
 - take blood cultures if the person has pyrexia. [2004, amended 2018]

Hospital-at-home and assisted-discharge schemes

- 1.3.4 Hospital-at-home and assisted-discharge schemes are safe and effective and should be used as an alternative way of caring for people with exacerbations of COPD who would otherwise need to be admitted or stay in hospital. **[2004]**
- 1.3.5 The multiprofessional team that operates these schemes should include allied health professionals with experience in managing COPD, and may include nurses, physiotherapists, occupational therapists and other health workers. **[2004]**
- 1.3.6 There are currently insufficient data to make firm recommendations about which people with COPD with an exacerbation are most suitable for hospital-at-home or early discharge. Selection should depend on the resources available and absence of factors associated with a worse prognosis (for example, acidosis). **[2004]**
- 1.3.7 Include people's preferences about treatment at home or in hospital in decisionmaking. [2004]

Pharmacological management

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

Delivery systems for inhaled therapy during exacerbations

- 1.3.8 Both nebulisers and hand-held inhalers can be used to administer inhaled therapy during exacerbations of COPD. **[2004]**
- 1.3.9 The choice of delivery system should reflect the dose of drug needed, the person's ability to use the device, and the resources available to supervise therapy administration. **[2004]**
- 1.3.10 Change people to hand-held inhalers as soon as their condition has stabilised, because this may allow them to be discharged from hospital earlier. **[2004]**
- 1.3.11 If a person with COPD is hypercaphic or acidotic the nebuliser should be driven by compressed air rather than oxygen (to avoid worsening hypercaphia). If oxygen therapy is needed, administer it simultaneously by nasal cannulae. [2004]
- 1.3.12 The driving gas for nebulised therapy should always be specified in the prescription. **[2004]**

Systemic corticosteroids

- 1.3.13 In the absence of significant contraindications, use oral corticosteroids, in conjunction with other therapies, in all people admitted to hospital with a COPD exacerbation. [2004]
- 1.3.14 In the absence of significant contraindications, consider oral corticosteroids for people in the community who have an exacerbation with a significant increase in breathlessness that interferes with daily activities. **[2004]**
- 1.3.15 Encourage people who need corticosteroid therapy to present early to get maximum benefits. **[2004]**

1.3.16 Offer 30 mg oral prednisolone daily for 5 days. [2019]

- 1.3.17 For guidance on stopping oral corticosteroid therapy it is recommended that clinicians refer to the BNF. **[2004]**
- 1.3.18 Think about osteoporosis prophylaxis for people who need frequent courses of oral corticosteroids. **[2004]**
- 1.3.19 Make people aware of the optimum duration of treatment and the adverse effects of prolonged therapy. **[2004]**
- 1.3.20 Give people (particularly people discharged from hospital) clear instructions on why, when and how to stop their corticosteroid treatment. **[2004]**

For a short explanation of why the committee made the 2019 recommendation and how it might affect practice, see the <u>rationale and impact section on duration of oral</u> <u>corticosteroid for managing exacerbations</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review J:</u> Length of corticosteroid use during exacerbations.

Antibiotics

1.3.21 For guidance on using antibiotics to treat COPD exacerbations, see the <u>NICE</u> guideline on antimicrobial prescribing for acute exacerbations of COPD. [2018]

Theophylline and other methylxanthines

- 1.3.22 Only use intravenous theophylline as an adjunct to exacerbation management if there is an inadequate response to nebulised bronchodilators. **[2004]**
- 1.3.23 Take care when using intravenous theophylline, because of its interactions with other drugs and potential toxicity if the person has been taking oral theophylline.[2004]

1.3.24 Monitor theophylline levels within 24 hours of starting treatment, and as frequently as indicated by the clinical circumstances after this. **[2004]**

Respiratory stimulants

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

Oxygen therapy during exacerbations of COPD

- 1.3.26 Measure oxygen saturation in people with an exacerbation if there are no facilities to measure arterial blood gases. **[2004]**
- 1.3.27 If necessary, prescribe oxygen to keep the oxygen saturation of arterial blood (SaO₂) within the individualised target range. **[2010]**
- 1.3.28 Pulse oximeters should be available to all healthcare professionals involved in the care of people with exacerbations of COPD, and they should be trained in their use. Clinicians should be aware that pulse oximetry gives no information about the PaCO₂ or pH.

Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. See also the <u>NHS England Patient</u> <u>Safety Alert on the risk of harm from inappropriate placement of pulse oximeter probes</u>. **[2004]**

1.3.29 Measure arterial blood gases and note the inspired oxygen concentration in all people who arrive at hospital with an exacerbation of COPD. Repeat arterial blood gas measurements regularly, according to the response to treatment. **[2004]**

Non-invasive ventilation (NIV) and COPD exacerbations

1.3.30 Use NIV as the treatment of choice for persistent hypercaphic ventilatory failure

during exacerbations despite optimal medical therapy. [2004]

- 1.3.31 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]**
- 1.3.32 When people 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]**

Invasive ventilation and intensive care

- 1.3.33 Treat hospitalised exacerbations of COPD on intensive care units, including invasive ventilation when this is thought to be necessary. **[2004]**
- 1.3.34 When assessing suitability for intubation and ventilation during exacerbations, think about functional status, BMI, need for oxygen when stable, comorbidities and previous admissions to intensive care units, in addition to age and FEV1. Neither age nor FEV1 should be used in isolation when assessing suitability. [2004]
- 1.3.35 Consider NIV for people who are slow to wean from invasive ventilation. [2004]

Respiratory physiotherapy and exacerbations

1.3.36 Consider physiotherapy using positive expiratory pressure devices for selected people with exacerbations of COPD, to help with clearing sputum. [2004, amended 2018]

Monitoring recovery from an exacerbation

- 1.3.37 Monitor people's recovery by regular clinical assessment of their symptoms and observation of their functional capacity. **[2004]**
- 1.3.38 Use pulse oximetry to monitor the recovery of people with non-hypercapnic, non-

acidotic respiratory failure. [2004]

- 1.3.39 Use intermittent arterial blood gas measurements to monitor the recovery of people with respiratory failure who are hypercaphic or acidotic, until they are stable. **[2004]**
- 1.3.40 Do not routinely perform daily monitoring of peak expiratory flow (PEF) or FEV1 to monitor recovery from an exacerbation, because the magnitude of changes is small compared with the variability of the measurement. **[2004]**

Discharge planning

- 1.3.41 Measure spirometry in all people before discharge. [2004]
- 1.3.42 Re-establish people on their optimal maintenance bronchodilator therapy before discharge. [2004]
- 1.3.43 People who have had an episode of respiratory failure should have satisfactory oximetry or arterial blood gas results before discharge. **[2004]**
- 1.3.44 Assess all aspects of the routine care that people receive (including appropriateness and risk of side effects) before discharge. **[2004]**
- 1.3.45 Give people (or home carers) appropriate information to enable them to fully understand the correct use of medications, including oxygen, before discharge.[2004]
- 1.3.46 Make arrangements for follow-up and home care (such as visiting nurse, oxygen delivery or referral for other support) before discharge. **[2004]**
- 1.3.47 The person, their family and their physician should be confident that they can manage successfully before they are discharged. A formal activities of daily living assessment may be helpful when there is still doubt. **[2004]**

Terms used in this guideline

Asthmatic features/features suggesting steroid responsiveness

This includes any previous, secure diagnosis of asthma or of atopy, a higher blood eosinophil count, substantial variation in FEV1 over time (at least 400 ml) or substantial diurnal variation in peak expiratory flow (at least 20%).

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.

A general classification of the severity of an acute exacerbation (from a <u>Cochrane Library</u> <u>systematic review</u>) is:

- mild exacerbation, the person has an increased need for medication, which they can manage in their own normal environment
- moderate exacerbation, the person has a sustained worsening of respiratory status that requires treatment with systemic corticosteroids and/or antibiotics
- severe exacerbation, the person experiences a rapid deterioration in respiratory status that requires hospitalisation.

Mild or no hypoxaemia

People who are not taking long-term oxygen and who have a mean PaO₂ greater than 7.3k Pa.

Recommendations for research

The guideline committee has made the following recommendations for research. As part of the 2018 update, the guideline committee made additional research recommendations on prognostic indices, inhaled therapies, prophylactic antibiotics, pulmonary hypertension and the diagnosis of COPD through incidental CT scans.

Key recommendations for research

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 with a later (defined as after 1 month) pulmonary rehabilitation programme, and in which groups is it most clinically and cost effective?

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 on 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.

2 Multidimensional assessment of outcomes

How can the individual factors associated with COPD prognosis (collected from a range of sources including primary care, imaging and pulmonary rehabilitation results) be combined into a multidimensional analysis that provides accurate and useful information on prognosis?

Why this is important

People with COPD can experience anxiety concerning their disease prognosis. Suitable prognostic tools could help alleviate this stress and allow people to make plans for the future. Existing multidimensional indices are:

- unable to classify people reliably into high- and low-risk groups better than FEV1 alone or
- no better at predicting outcomes than FEV1 alone or
- time-consuming and consisting of components that would not be routinely available in primary care.

However, many individual factors are known to provide information, and the development of an index/indices combining these factors could help with prognosis. These indices should be validated in a general UK COPD population, and in primary care, in a wider range of outcomes than mortality alone.

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on assessing severity and using prognostic factors</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> <u>Diagnosing COPD and predicting outcomes</u>.

3 Inhaled therapies for people with COPD and asthma

What is the clinical and cost effectiveness of inhaled therapies (bronchodilators and/or inhaled corticosteroids) in people with both stable COPD and asthma?

Why this is important

There are a large number of trials that look at the effectiveness of bronchodilators and/or steroids in people with COPD, but the majority of them specifically excluded people with comorbid asthma. As a result, there is a lack of evidence concerning the most clinically and cost-effective treatments for this subgroup of people with COPD. Trials that recruit people with asthma and COPD could provide this evidence and ensure that these people receive the most effective maintenance treatments for their COPD and asthma.

4 Inhaled corticosteroid responsiveness

What features predict inhaled corticosteroid responsiveness most accurately in people with COPD?

Why this is important

Bronchodilators and/or steroids are the main pharmacological treatments used to manage COPD. People with asthma or asthmatic features that may make them steroid responsive may need a different combination of drugs to other groups of people with COPD for the most effective treatment of their symptoms. Identifying these people would help ensure that they receive appropriate treatment.

5 Prophylactic antibiotics for preventing exacerbations

Which subgroups of people with stable COPD who are at high risk of exacerbations are most likely to benefit from prophylactic antibiotics?

Why this is important

People with COPD commonly experience exacerbations, which have a negative impact on their quality of life and are linked to worse disease prognosis. Certain groups of people with COPD are at higher risk of exacerbations, and reducing the number of exacerbations they experience should improve quality of life for them and their families. However, subgroups of these people may benefit particularly from this treatment. Identifying and targeting prophylactic antibiotics for these people should help improve their quality of life. It may also identify people who would not benefit from prophylactic antibiotics, and so reduce the risk of antibiotic resistance by reducing the overall number of people taking prophylactic antibiotics for COPD. Randomised trials that include subgroup analysis of participants based on factors such as biomarkers, clinical features, bacterial patterns and comorbidities could provide useful information on this topic.

Other recommendations for research

6 Diagnosing COPD

What are the characteristics of people diagnosed with COPD as a result of an incidental

finding of emphysema on a CT scan, compared with those diagnosed with symptoms?

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on incidental findings on chest X-ray or CT scans</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> <u>Diagnosing COPD and predicting outcomes</u>.

7 Prophylactic antibiotics for preventing exacerbations

What is the long-term clinical and cost effectiveness of prophylactic antibiotics for people with stable COPD who are at high risk of exacerbations?

What is the comparative effectiveness of different antibiotics, doses and regimens of prophylactic antibiotics for people with stable COPD who are at high risk of exacerbations?

What is the comparative effectiveness of seasonal versus continuous prophylactic antibiotics for people with stable COPD who are at high risk of exacerbations?

8 Pulmonary hypertension

What are the most clinical and cost-effective treatments for pulmonary hypertension in people with COPD?

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on pulmonary hypertension</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> <u>Managing pulmonary hypertension and cor pulmonale</u>.

9 Mucolytic therapy

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

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Incidental findings on chest X-ray or CT scans

Recommendations 1.1.12 to 1.1.14

Why the committee made the recommendations

The evidence showed that CT scans and chest X-rays are accurate tests for identifying people who would test positive for COPD using spirometry, including people without symptoms. However, some of the CT and chest X-ray techniques used in the studies are not routinely used in UK clinical practice. This limited how applicable the evidence was to the NHS, so the committee was unable to make a wider recommendation on using CT scans and chest X-rays for diagnosing COPD. The committee therefore made recommendations on what to do if a CT scan or X-ray that was performed for another reason showed signs of emphysema or chronic airways disease.

There was no evidence on what to do for people who have emphysema or signs of chronic airways disease on a CT scan or chest X-ray, but who have no symptoms. Because of this, the committee made consensus recommendations based on their experience and on current practice in the NHS. The committee also made a <u>recommendation for research on the characteristics of people diagnosed with COPD as a result of incidental findings on chest X-ray or CT scan, to try to determine whether they differ in ways that might mean standard COPD treatment has to be modified for them.</u>

The committee also reviewed evidence on using pulse oximetry or high-sensitivity C-reactive protein (hs-CRP) for diagnosing COPD. They did not recommend these because:

• pulse oximetry is normally used to measure the severity of COPD rather than to diagnose it, and there are other possible causes of low oxygen saturation

- elevated hs-CRP levels are not specifically linked to COPD, and could be caused by other conditions
- the evidence showed that they were not effective diagnostic tests.

The committee amended the 'Additional investigations' table, based on their knowledge and experience, to more accurately reflect good practice.

How the recommendations might affect practice

As the recommendation only covers CT scans or chest X-rays taken for other purposes, there would be no additional costs from these tests. The recommendation to consider spirometry and GP respiratory review and the amendments to the 'Additional investigations' table all reflect current practice. There may be a small number of additional referrals for spirometry, but this is expected to have a minimal resource impact.

Return to recommendations

Assessing severity and using prognostic factors

Recommendations 1.1.24 and 1.1.25

Why the committee made the recommendations

The committee recommended against using multidimensional indices, such as BODE, because they were:

- unable to classify people reliably into high- and low-risk groups better than FEV1 alone or
- no better at predicting outcomes than FEV1 alone or
- time-consuming and consisted of components that would not be routinely available in primary care.

However, the committee recognised the need for an effective prognostic tool that did not have these problems, so they made a <u>recommendation for research on multidimensional</u> <u>assessment of outcomes</u> to address this.

The committee used their knowledge and experience to list factors associated with prognosis. In the absence of a single prognostic tool, thinking about these factors can help guide discussions, and help people with COPD to understand how their condition is likely to progress and decide which treatments are right for them.

How the recommendations might affect practice

The BODE index is not used routinely in the NHS and no alternative indices have been recommended, so there should be minimal impact on practice.

Return to recommendations

Inhaled combination therapy

Recommendations 1.2.11 to 1.2.20

Why the committee made the recommendations

Dual therapy

The evidence showed that, compared with other dual therapy combinations and with monotherapy, LAMA+LABA:

- provides the greatest benefit to overall quality of life
- is better than other inhaled treatments for many individual outcomes (such as reducing the risk of moderate to severe exacerbations)
- is the most cost-effective option.

The committee did not recommend a particular LAMA because they were not convinced that the evidence showed any meaningful differences in effectiveness between the drugs in this class. Instead, they updated the existing recommendation on drug and inhaler choice, based on their experience of what factors should be taken into account. In particular, minimising the number and types of inhalers prescribed will make it easier for people to use their inhalers correctly.

Most of the trials specifically excluded people with COPD and asthma, so there was no

direct evidence for this group. The committee recommended LABA+ICS based on their clinical experience and knowledge of the likely benefit of inhaled corticosteroids in certain specific COPD phenotypes.

Although the combination therapies recommended in this guideline are the most effective options, some people are currently using different therapies, such as LAMA or LABA monotherapy, and may have their symptoms under control with these. The committee did not want to make people change treatments unnecessarily, so they made a recommendation highlighting that people did not need to switch treatments until their clinical needs changed.

Triple therapy

Not everyone with COPD will benefit from triple therapy. In addition, for some people the symptoms that give them the most problems are caused by other conditions (such as heart failure or anxiety) rather than their COPD. Because of this, a clinical review is needed first, to ensure that people only receive triple therapy if they will benefit from it. The committee envisaged that this review would take the form of a conversation with the person with COPD about their symptoms, rather than relying on tools such as the CAT score or MRC breathlessness score in isolation.

The committee decided that there should be separate recommendations on triple therapy for people who are currently taking LABA+ICS and for people taking LAMA+LABA. They agreed that there was stronger evidence from a greater number of studies that triple therapy benefits people taking LABA+ICS, compared with people taking LAMA+LABA.

For people currently taking LABA+ICS, the evidence showed that LAMA+LABA+ICS reduced the rate of severe exacerbations, improved FEV1, and did not increase the risk of pneumonia or other serious adverse events.

For people currently taking LAMA+LABA, the evidence showed that LAMA+LABA+ICS reduced the rate of serious exacerbations and provides some quality of life improvement. However, these improvements were smaller than the ones for people who were taking LABA+ICS before they started triple therapy. In addition, people who switched from LAMA+LABA to triple therapy were more likely to get pneumonia.

The criteria for starting triple therapy are based on the inclusion criteria for the studies the committee reviewed and their clinical judgement. For people who are currently taking

LAMA+LABA, the committee made separate recommendations for:

- people who are having severe or frequent exacerbations, for whom the benefit of fewer exacerbations outweighs the increased risk of pneumonia
- people with less severe symptoms, for whom it is less clear if triple therapy provides enough benefits to outweigh the risk of pneumonia.

The 3-month trial is recommended to help identify people in the group with less severe symptoms who will benefit from triple therapy, while ensuring that people who do not benefit can easily switch back to LAMA+LABA. This is to avoid the situation where people continue on triple therapy, with the accompanying risks, without seeing any benefit. As part of the review at the end of the trial, the committee agreed that it was important to explicitly ask the person with COPD if taking the drug had improved their COPD symptoms.

The committee also recommended documenting the reason for continuing ICS, to encourage treatment review so that people are not exposed to the risks of this treatment if they do not benefit from it.

The committee looked at making recommendations for people with asthmatic features. However, the evidence excluded people with asthma and did not provide much information on asthmatic features (such as eosinophil count). Because of this, and because people with asthmatic features are likely to be covered by the recommendation for people taking LABA+ICS, the committee agreed not to make a specific recommendation for this group.

The committee did not make a recommendation in favour of single or multiple inhaler devices as the included evidence did not show a meaningful difference in clinical effectiveness between triple therapy compared to dual therapy based on the number of devices. From the economic evidence, using a single inhaler device was more cost effective, but the committee agreed that there were circumstances where using more than one inhaler to deliver triple therapy may be more appropriate for a particular person with COPD. Finally, the committee had already made a recommendation about the factors to be taken into account when choosing an inhaler device and these included minimising the numbers and types of inhalers where possible and cost so an additional recommendation on this issue was unnecessary.

How the recommendations might affect practice

The recommendation on LAMA+LABA dual therapy is likely to increase the number of people with COPD who are having this treatment. The higher cost of dual therapy compared with monotherapy may result in a significant resource impact, but cost savings are also likely from a reduction in treatments needed for exacerbations (including hospitalisation).

Using LABA+ICS for people with features of <u>asthma/features suggesting steroid</u> responsiveness is in line with current practice.

The recommendations may result in an increase in the number of people who are prescribed triple therapy and an increase in the number of people who need treatment for pneumonia, although this may be mitigated by the relatively widespread current use of triple therapy. However, the criteria for who should be offered triple therapy and the recommendation for a trial period should limit the impact of both of these changes.

Triple therapy regimens have a higher cost than dual long-acting bronchodilator regimens. However, this cost is likely to be at least partially offset by savings from reduced numbers of exacerbations and better management of symptoms for people switching to triple therapy.

It is already routine in practice to have a clinical review before starting triple therapy. The recommendation on clinical review may increase the scope of this review. However, any costs incurred from this should be offset by savings from more optimal management of symptoms in people with COPD, which should be associated with fewer primary care and/ or hospital visits.

The recommendation on how to choose drugs and inhalers covers factors that prescribers routinely consider, so is not a change in practice. However, minimising the number and type of inhaler devices and avoiding unnecessary within-class switching may produce cost savings through lower upfront spending and better symptom control.

Return to recommendations

Oral prophylactic antibiotic therapy

Recommendations 1.2.45 to 1.2.53

Why the committee made the recommendations

The evidence showed that prophylactic antibiotics reduce the risk of people having an exacerbation and the number of exacerbations per year in people with COPD and sputum production. However, prescribing these to large numbers of people with COPD could increase levels of antibiotic resistance. Problems with adherence may make this worse, as people are not taking the antibiotics to help with any current symptoms and (for azithromycin) have to remember to take it 3 times a week. In addition, the longest follow-up in the trials was 12 months, so there is no evidence on the long-term effects of prophylactic antibiotics. With this in mind, the committee made recommendations for the people who would benefit the most from prophylactic antibiotics, and whose exacerbations were not being managed well by other treatments.

The committee recommended azithromycin because this antibiotic had the most evidence of effectiveness (based on the numbers of trials and study participants). The recommended dosage is taken from the trials the committee reviewed.

People taking prophylactic azithromycin may also keep antibiotics at home as part of their exacerbation action plan (see the <u>recommendation on offering antibiotics to keep at home</u> <u>in the section on self-management</u>). This should be a different class of antibiotic to ensure that it is effective when they need it, as the person may develop resistance to azithromycin.

The committee recommended strict criteria for using and reviewing prophylactic antibiotics, to ensure that:

- the risk of antibiotic resistance is minimised, both for the person taking them and for society
- people only take them if it is safe to do so
- people do not continue taking them if there is no benefit.

How the recommendations might affect practice

It is likely that these recommendations will increase the number of people taking prophylactic antibiotics. This is unlikely to have a significant resource impact, given the relatively low cost of antibiotics. By reducing exacerbation frequency it is likely to reduce the amount of oral corticosteroids taken by people with COPD. Return to recommendations

Long-term oxygen therapy

Recommendations 1.2.58 to 1.2.63

Why the committee made the recommendations

There is evidence that continuous long-term oxygen therapy improves survival in people with more severe hypoxaemia, but not for people with mild hypoxaemia. The specific thresholds for long-term oxygen therapy are taken from the trials that provided the evidence.

The recommendation that people should use supplemental oxygen for more than 15 hours a day is based on the available evidence. There is also evidence that long-term oxygen therapy was not effective for isolated nocturnal hypoxaemia caused by COPD.

The evidence showed risks of harm from the use of long-term oxygen therapy, in particular burns and fires as a result of smoking while using oxygen and falls from tripping over equipment. Given these risks to the person with COPD and the people they live with, the committee agreed that it is important to conduct a detailed risk assessment before offering this treatment.

The committee decided that there were 2 levels of risk posed by smoking around oxygen and the recommendations they made reflect these differences:

- People with COPD who do not smoke but who live with people who smoke. Using cigarettes near oxygen could cause fires or burns, but this risk is likely to be lower because the person who smokes can keep away from the oxygen. Oxygen therapy may benefit these people if they meet the eligibility criteria and the risk assessment is favourable.
- People with COPD who smoke. They will be smoking in close proximity to the oxygen, and the risks to them, the people they live with and their neighbours outweigh the potential benefits of long-term oxygen therapy.

How the recommendations might affect practice

These recommendations may result in an increase in demand for stop smoking services, but these are known to provide good value for money. Additional time may be needed to conduct risk assessments. As these should prevent people from being given oxygen therapy if they would not benefit or may be harmed by it, it would be an appropriate use of resources and should not lead to an overall increase in resource use. These recommendations may also reduce the cost of managing harms associated with oxygen use, including falls, burns and the wider costs of fires.

Return to recommendations

Ambulatory and short-burst oxygen therapy

Recommendations 1.2.67 and 1.2.73

Why the committee made the recommendations

The evidence for people with mild or no hypoxaemia showed that neither ambulatory oxygen nor short-burst oxygen provide a clinically meaningful improvement in breathlessness.

How the recommendations might affect practice

Reducing the use of ambulatory and short-burst oxygen therapy in people who would not benefit is likely to be cost saving and will allow resources to be invested in effective treatments for breathlessness instead.

Return to recommendations

Managing pulmonary hypertension and cor pulmonale

Recommendations 1.2.77, 1.2.78 and 1.2.80

Why the committee made the recommendations

Pulmonary hypertension

The committee agreed that there was not enough evidence to recommend any of the reviewed treatments for pulmonary hypertension in people with COPD. Although some of the treatments improved blood pressure readings, there was no evidence that they improved quality of life and the clinical trials only involved small numbers of people.

There is a shortage of good evidence in this area, so the committee made an exception for using these treatments in randomised controlled trials, and made a <u>recommendation for</u> <u>research on treatments for pulmonary hypertension</u>.

Cor pulmonale

The evidence on long-term oxygen therapy for people with COPD and cor pulmonale showed no improvement in survival. However, long-term oxygen therapy can also help with hypoxia. The committee saw no evidence that people with cor pulmonale should be treated or assessed for long-term oxygen therapy differently than other people with COPD.

How the recommendations might affect practice

The recommendations will not change practice, as none of the treatments the committee has recommended against for pulmonary hypertension or cor pulmonale are currently in routine use specifically for these conditions in people with COPD.

Return to recommendations

Lung volume reduction procedures, bullectomy and lung transplantation

Recommendations 1.2.88 to 1.2.94

Why the committee made the recommendations

The evidence showed that people with severe COPD show improvements in lung function,

exercise capacity, quality of life and long-term mortality as a result of lung volume reduction surgery. The criteria for who should be referred for this procedure are based on the criteria used in the trials reviewed by the committee and the committee's clinical expertise, taking into account current practice in the NHS.

It was not clear from the evidence whether endobronchial coils work better than standard lung volume reduction surgery. In addition, the procedure is relatively new. For these reasons, the committee recommended that it is only offered as part of a clinical trial.

The recommendations on referral for bullectomy and lung transplantation are based on the committee's knowledge and experience. The lung transplantation referral criteria were adapted from the criteria used for the respiratory review for lung volume reduction surgery. The committee noted that some people are refused lung transplantation because they have had previous lung volume reduction procedures. These people could still benefit from transplantation, so the committee made a recommendation to reflect this.

How the recommendations might affect practice

It is current clinical practice to assess for future treatment plans after pulmonary rehabilitation. However, the criteria for referring people to a multidisciplinary team to assess for lung volume reduction assessment have been broadened, as recommended treatment options now include endobronchial valves. The broadening of criteria will lead to more referrals and improved access to these treatments. This will have an impact on resource use, in particular, as a new group of people for whom lung volume reduction surgery was unsuitable may now be treated with endobronchial valves.

Return to recommendations

Risk factors for COPD exacerbations

Recommendation 1.2.123

Why the committee made the recommendation

The factors associated with exacerbations are taken from the evidence available and the committee's experience. The evidence on physical activity was not reviewed, but as promoting exercise and physical activity is an important part of management for stable

COPD the committee agreed to include it. The list only covers the factors that people can avoid or reduce their exposure to. Other factors are also associated with exacerbations (for example, disease-related factors, biomarkers and other medicines), but people cannot avoid these on their own and these factors are addressed in other areas of the guideline.

How the recommendation might affect practice

These recommendations are unlikely to have a significant impact on resources, as the marginal cost of providing advice on exacerbations to people with COPD is very low. An increased emphasis on physical activity may lead to an increase in referrals to pulmonary rehabilitation, which is known to be a highly cost-effective intervention for people with COPD. The recommendations may produce some cost savings by reducing the number of exacerbations people have.

Return to recommendations

Self-management, education and telehealth monitoring

Recommendations 1.2.119 to 1.2.121 and 1.2.124 to 1.2.133

Why the committee made the recommendations

Evidence showed that self-management plans improve quality of life and reduce hospital admissions. The committee recommended that self-management plans include:

- patient education, because this was a common component of the self-management plans they examined and because education alone was shown to improve knowledge about COPD
- cognitive behavioural components for people with frightening breathlessness, because there is some evidence that these reduce distress (although they do not help with the symptoms of breathlessness).

The list of topics to be covered in information about COPD is taken from the selfmanagement plans the committee examined and their own clinical and personal experience. Exacerbation action plans were shown to improve quality of life and reduce hospital admissions for people at risk of exacerbations. Most of the exacerbation action plans that the committee examined provided people with short courses of antibiotics and corticosteroids to use at home to respond to symptoms, and monitoring to make sure they were using those medicines appropriately. Therefore these components were included in the recommendations. The committee also discussed the potential for antibiotic overuse, and stressed the importance of continued monitoring to ensure people are using these medicines appropriately.

Telehealth monitoring does not improve quality of life or reduce hospitalisations for people with COPD, and it leads to higher costs. However, the committee did not want to prevent telehealth monitoring being used for specific reasons that were not covered in the evidence they reviewed, such as short-term monitoring following hospital discharge, so they only recommended against routine telehealth monitoring.

How the recommendations might affect practice

Self-management plans are already in place for some people with COPD. The recommendations may change the content of these plans, and may increase the number of people using a self-management plan. However, self-management plans are highly cost effective and the increased cost of providing them should be offset by cost savings from a reduction in hospitalisations.

The number of people with stable COPD who are having telehealth monitoring should decrease, which is likely to reduce costs.

Return to recommendations

Duration of oral corticosteroids for managing exacerbations

Recommendation 1.3.16

Why the committee made the recommendations

There are risks associated with long-term corticosteroid use, so it is important to use the shortest effective treatment duration. Treatment is recommended for 5 days because the

evidence showed no benefit from taking corticosteroids for more than 7 days and shorter courses of 5 days are routinely used in clinical practice already. The 2019 review did not look at corticosteroid doses, so the dose from the original 2004 recommendation was retained.

How the recommendations might affect practice

The recommendation may reduce the amount of corticosteroids used in clinical practice, which may result in a cost saving. However, the overall impact is likely to be small because oral corticosteroids are cheap, and because prescribing corticosteroids for 5 days is current practice for many clinicians.

Return to recommendations

Context

<u>British Lung Foundation statistics</u> show that there are approximately 1.2 million people with a diagnosis of chronic obstructive pulmonary disease (COPD) in the UK. Although there are 115,000 new diagnoses per year, most people with COPD are not diagnosed until they are in their fifties or older and many more people may remain undiagnosed. The UK has the 12th highest recorded deaths from COPD in the world, with an age-standardised mortality rate of 210.7 deaths per million people between 2001 and 2010.

Recently, new evidence has emerged and practice has changed in relation to the use of inhaled triple therapy and oral corticosteroids. This evidence and the changes in how care is delivered may have a significant impact on people with COPD who are still experiencing symptoms despite being prescribed triple therapy.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> topic page on chronic obstructive pulmonary disease.

For full details of the evidence and the guideline committee's discussions, see the <u>evidence reviews</u> and full guideline. You can also find information about <u>how the guideline</u> <u>was developed</u>, including details of the committee.

NICE has produced <u>tools and resources to help you put this guideline into practice</u>. For general help and advice on putting our guidelines into practice, see <u>resources to help you</u> <u>put NICE guidance into practice</u>.

Update information

July 2019: We have reviewed evidence on inhaled triple therapy for managing stable COPD, and oral corticosteroids for managing exacerbations.

Recommendations are marked [2019] if the evidence has been reviewed.

In recommendations ending [2004], [2004, amended 2018], [2010], [2010, amended 2018] or [2018], we have not reviewed the evidence.

December 2018: This guideline is an update of NICE guideline CG101 (published June 2010) and replaces it.

We have reviewed evidence on diagnosis and prognosis, inhaled combination therapies, prophylactic antibiotics, oxygen therapy, managing pulmonary hypertension and cor pulmonale, lung surgery and lung volume reduction procedures, education, self-management and telehealth monitoring for people with chronic obstructive pulmonary disease (COPD). These recommendations are marked **[2018]**.

We have also made some changes without an evidence review:

- The 'working definition of COPD' has been deleted, because it was not based on an evidence review and it was unclear whether the thresholds it used were correct and up to date.
- Recommendation 1.1.4 had an extra bullet point on disease progression added in, based on the information in table 5.
- Recommendation 1.1.11 has been amended to signpost to the more recent <u>European</u> <u>Respiratory Journal GLI 2012 reference values</u> for spirometry.
- In recommendation 1.1.25:
 - the order of investigations was changed, based on the committee's experience, to put the most important factors nearer the top
 - health status was removed from the list and replaced by a number of separate factors (frailty, severity and frequency of exacerbations, hospital admissions,

multimorbidity and symptom burden)

- the cor pulmonale entry was expanded to include chronic hypoxia, which replaced partial pressure of oxygen in arterial blood (PaO₂)
- long-term oxygen therapy and/or home non-invasive ventilation (NIV) was added to the list
- smoking status was added to the list.
- The first note under table 3 was made into a recommendation, to make it more prominent.
- A footnote was added to recommendation 1.2.9 to refer to relevant safety information from the Medicines and Healthcare products Regulatory Agency (MHRA) about inhaled corticosteroids that was posted after the 2010 COPD guideline update.
- Recommendations on inhaled therapy that don't fit in the new treatment pathway have been deleted.
- A footnote was added to recommendation 1.2.11 to refer to relevant safety information from the MHRA about tiotropium inhalers that was posted after the 2010 COPD guideline update.
- Recommendation 1.2.27 has been amended so that it no longer refers to wiping the mouthpiece, because this is not needed if it has been washed and allowed to dry.
- Recommendation 1.2.99 has been amended to refer to 'positive expiratory pressure devices' instead of positive expiratory pressure masks.
- Recommendation 1.2.100 was amended to refer to anxiety in the first sentence, to make it internally consistent.
- The opening sentence of recommendation 1.3.3 was amended to make it clearer who this referred to.
- Recommendation 1.3.36 has been amended to refer to 'positive expiratory pressure devices' instead of positive expiratory pressure masks.

These recommendations are marked [2004, amended 2018] or [2010, amended 2018].

Recommendations marked **[2004]** or **[2010]** last had an evidence review in 2004 or 2010. In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

Minor changes since publication

October 2022: We added text to indicate that pulse oximetry may be less reliable in people with dark skin. We also added a link to the NHS patient safety alerton the risk of harm from inappropriate placement of pulse oximeter probes. See recommendations 1.2.56, 1.3.1, 1.3.2 and 1.3.28.

ISBN: 978-1-4731-3468-3