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PRACTICE

GUIDELINES

Chronic obstructive pulmonary disease: diagnosis and management: summary of updated NICE guidance

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What you need to know

- The interventions of highest value for people with chronic obstructive pulmonary disease (COPD) are treatment and support to stop smoking, pulmonary rehabilitation in patients limited by breathlessness, and flu vaccination
- Choice of initial long acting inhaled therapies depends on the presence or absence of asthmatic features/features which suggest steroid responsiveness
- Self management plans improve quality of life and reduce hospital admissions
- Treatment for acute exacerbations of COPD, including rescue packs for patients to use for self management, should be for five days only
- Only prescribe home oxygen for people who are hypoxic and do not smoke currently

There are 1.3 million people in the UK with a diagnosis of chronic obstructive pulmonary disease (COPD) and the condition is responsible for considerable morbidity and mortality.[1] COPD is also a common cause of hospital admission. NHS England has now recognised respiratory disease as a priority area in the Long Term Plan,[2] but Royal College of Physicians COPD Audits[3] identify substantial deficiencies across the healthcare system, including marked under-provision of pulmonary rehabilitation, flu vaccination, and smoking cessation treatment.

This article summarises the most recent recommendations from the National Institute for Health and Care Excellence (NICE).[10] The updated areas are mainly concerned with the management of stable COPD and include self management and education, assessment for lung volume reduction procedures, and home oxygen use. This article focuses on the newly updated sections, with reference to older recommendations where they are particularly important or needed for context.

Effective COPD management pathways require an integrated approach across primary and secondary care and involve a multidisciplinary team of health professionals. The guidance focuses on the need to ensure that good quality care is delivered wherever patients are seen. Specialist care, whether delivered in a hospital or community setting, may be indicated for people with COPD onset at a young age or those with rapidly progressive disease, frequent exacerbations, multimorbidity, hypoxia, or for assessment for a lung volume reduction procedure.

What's new in the guidance?

- A new one page algorithm focuses on the "Five Fundamentals" of COPD care as a "desktop" guide for clinicians, including an explicit reference to the importance of multimorbidity
- Key elements of self management are defined, including what should be covered by written information and the use of action plans for exacerbations of COPD
- Duration of treatment for acute exacerbations of COPD, including an antimicrobial prescribing strategy
- New guidance on indications for the use of long term azithromycin in people with COPD who have frequent exacerbations
- New pathway for inhaled treatment with long acting bronchodilators and inhaled corticosteroids
- New guidance on the use of home oxygen, stating that it should not be used as a treatment for breathlessness in the absence of hypoxia and should not be prescribed for individuals who continue to smoke
- A systematic approach to identifying who should be referred for consideration of a lung volume reduction procedure
- Defines an approach to incidental findings of emphysema on computed tomography scan, which should prompt a primary care respiratory review

What are the key recommendations?

NICE recommendations are based on systematic reviews of best available evidence and explicit consideration of cost

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effectiveness. When minimal evidence is available, recommendations are based on the guideline development group's experience and opinion of what constitutes good practice. Recommendations reproduced exactly are shown by bullet points with information about the source and quality of evidence in italics in square brackets. The older recommendations do not have quality of evidence statements because different criteria were used to judge quality at that time. The rest of the text provides useful additional information or summarises recommendations to save space.

Diagnosis

The guideline still recommends considering a possible diagnosis of COPD in anyone with breathlessness, cough, or chronic sputum production, with risk factors including a history of tobacco smoking or work in an occupation with exposure to dust, fumes, or chemicals. Diagnosis depends on the presence of airflow obstruction which is not reversible, measured using spirometry. A FEV_1/FVC ratio of <0.7 is usually taken to indicate airflow obstruction, though this fixed level may overdiagnose older people and underdiagnose younger people, so correlation with other clinical symptoms and signs is important.

The use of composite scores to guide prognosis in COPD is no longer recommended. Instead, consider individual risk factors that influence long term prognosis (box 1).

Box 1: Factors associated with prognosis in COPD

- FEV_1
- 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)
- Carbon monoxide gas transfer (TLco)
- Meeting criteria for long term oxygen therapy and/or home non-invasive ventilation
- Multimorbidity
- Frailty

Incidental findings of lung abnormalities on imaging are an increasingly common way for people with COPD to present. New recommendations suggest that these findings should prompt a primary care respiratory review to identify the presence of symptoms, perform spirometry, and offer treatment and support to stop smoking where appropriate.

Fundamentals of COPD care

As part of the update process a new algorithm was developed that covered non-pharmacological management of COPD and the use of inhaled therapies (fig 1). As part of this process, the most important interventions or treatments were identified and grouped as the "five fundamentals" of COPD care, based on their high value in terms of clinical and cost effectiveness[4] (box 2).

Box 2: The five fundamentals of COPD care

- Offer treatment and support to stop smoking
- Offer pneumococcal and flu vaccinations
- Offer pulmonary rehabilitation if indicated
- Co-develop a personalised self management plan
- Optimise treatment for comorbidities

Consider these items at each review and deliver for all patients if relevant

Patient education and self management

The new guideline stresses the importance of providing information about COPD at multiple points (box 3). Pulmonary rehabilitation programmes, which should be offered to all patients with COPD who are limited by breathlessness, are an important way of delivering help to enable patients to understand how to manage their condition.

Box 3: COPD patient information

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.

Written information should meet the NHS accessible information standard (eg, British Lung Foundation COPD materials https://www.blf.org.uk/support-for-you/copd).

Minimum required information

- 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).

Evidence shows that self management plans, particularly when they include an exacerbation action plan, improve quality of life and reduce hospital admissions. Self management should include an individualised exacerbation action plan for any patient who is at risk of exacerbations with short (five day) courses of oral corticosteroids and oral antibiotics.

- 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. *[Based on very low to high quality evidence from randomised controlled trials and directly applicable health economic evidence]*
- For acute exacerbations of COPD, prescribe a five day course of oral antibiotics (if indicated) and a five day course of 30 mg oral prednisolone. Consult the COPD

antimicrobial prescribing guideline for factors to consider before prescribing antibiotics (box 4).

- 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 three or more courses of oral corticosteroids and/or oral antibiotics in the last year, investigate the possible reasons for this. *[Based on the experience and opinion of the Guideline Committee (GC)]*
- 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. *[Based on low to high quality evidence from randomised controlled trials]*
- If people have excessive sputum, they should be taught:
  - how to use positive expiratory pressure devices
  - active cycle of breathing techniques. *[Carried over unchanged from 2004 guideline]*
- 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). *[Based on the experience and opinion of the GC]*

Box 4: Summary of related guidance on the treatment of acute exacerbations of COPD

Presented in Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing guideline NG114 (https://www.nice.org.uk/guidance/NG114)

Important points:

- Many exacerbations (including some severe exacerbations) are not caused by bacterial infections so will not respond to antibiotics
- Consider prescribing an antibiotic only after taking into account:
  - the severity of symptoms, particularly sputum colour changes and increases in sputum volume or thickness beyond the person's normal day-to-day variation
  - whether the person needs to go into hospital for treatment; previous exacerbation and hospital admission history, and the risk of developing complications
  - previous sputum culture and susceptibility results; and the risk of antimicrobial resistance with repeated courses of antibiotics
- Give oral antibiotics first line if the person can take oral medicines, and the severity of their exacerbation does not require intravenous antibiotics (see table 1 in guideline for choice of antibiotic, dose, and course length)
- Refer people to hospital if they have any signs or symptoms suggesting a more serious illness or condition such as cardiorespiratory failure or sepsis.

Identifying and managing anxiety and depression

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. *[Carried over from 2004 guideline with addition of anxiety to recommendation, based on the experience and opinion of the GC]*

Telehealth monitoring in COPD

- Do not offer routine telehealth monitoring of physiological status as part of management for stable COPD. *[Based on low to high quality evidence from randomised controlled trials and directly applicable health economic evidence]*

  Telehealth monitoring does not improve quality of life or reduce hospitalisations but does lead to higher costs.

Inhaled therapies (see figure – algorithm)

- Only prescribe inhalers after people have been trained to use them and can demonstrate satisfactory technique. *[Carried over unchanged from 2004 guideline]*
- 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. *[Carried over unchanged from 2004 guideline]*
- Use short acting bronchodilators, as necessary, as the initial empirical treatment to relieve breathlessness and exercise limitation. *[Carried over unchanged from 2004 guideline]*

Long acting inhaled therapies are intended to improve day-to-day symptoms and reduce exacerbation risk. Before starting a long acting inhaled therapy, consider whether non-pharmacological COPD management has been optimised and vaccinations offered, if the person has been offered treatment for tobacco dependence if they smoke, and if they remain breathless or have exacerbations despite using a short acting bronchodilator. In addition, examine whether the person's day-to-day symptoms or acute episodes of worsening symptoms are caused by COPD and not by another physical or mental health condition. In particular, cardiac comorbidities, which may also cause breathlessness, are common and often underdiagnosed and undertreated in people with COPD.[5 6]

If the person with COPD remains breathless or has exacerbations despite the above, then offer long acting anti-muscarinic (LAMA)+a long acting β_2 agonist (LABA) if they do not have asthmatic features or features suggesting steroid responsiveness (see below). A combination of LAMA+LABA is the most effective inhaled therapy. LAMA alone is superior to LABA alone, but economic modelling confirms that an initial combination dual bronchodilation strategy is superior to starting one agent and then adding another subsequently. The guideline recommends clinicians should minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible.

People with a diagnosis of asthma and COPD should receive inhaled corticosteroids (ICS) and appropriate additional asthma therapies according to the NICE asthma guideline.[11]

The guidelines acknowledge the difficulty of precisely delineating asthma from COPD in some individuals and the fact that this type of patient has in general been excluded from trials of inhaled therapy in COPD.

The following are defined as "asthmatic features/features suggesting steroid responsiveness":

- any previous, secure diagnosis of asthma or of atopy
- a higher blood eosinophil count
- substantial variation in FEV_1 over time (at least 400 mL) or
- substantial diurnal variation in peak expiratory flow (at least 20%).

"Higher" eosinophil count has been chosen deliberately, rather than specifying a particular value. Firstly, although evidence

suggests a link between eosinophil count and steroid responsiveness, it is not yet clear what the precise threshold should be or on how many occasions or over what time period it should be elevated. Secondly, the term "higher" reflects the fact that the likely threshold is within the normal range of eosinophil counts, but in the upper range.

If asthmatic features or features suggesting steroid responsiveness are present, consider a LABA/ICS inhaler instead of LAMA/LABA as initial long acting inhaled therapy.

Before starting LAMA+LABA+ICS, conduct a clinical review as discussed above.

- For people with COPD who are taking LABA+ICS, offer LAMA+LABA+ICS if
  - their day-to-day symptoms continue to adversely affect their quality of life **or**
  - they have a severe exacerbation (requiring hospitalisation) **or**
  - they have two moderate exacerbations within a year. *[Based on very low to high quality evidence from randomised controlled trials and health economic modelling]*
- For people with COPD who are taking LAMA+LABA, consider LAMA+LABA+ICS if
  - they have a severe exacerbation (requiring hospitalisation) **or**
  - they have two moderate exacerbations within a year. *[Based on low to high quality evidence from randomised controlled trials and health economic modelling]*
- For people with COPD who are taking LAMA+LABA and whose day-to-day symptoms adversely affect their quality of life:
  - consider a trial of LAMA+LABA+ICS, lasting for three months only
  - after three 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. *[Based on low to high quality evidence from randomised controlled trials, health economic modelling and the experience and opinion of the GC]*
    - ♦Document the reason for continuing ICS use in clinical records and review at least annually. *[Based on the experience and opinion of the GC]*
  - 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. *[Carried over from 2010 guideline, but amended with link to MHRA safety alert]*

Prophylactic antibiotics in people with frequent exacerbations

Regular antibiotic therapy can be beneficial in some people with COPD with frequent exacerbations, however it should only be considered in people with a substantial exacerbation burden and after several criteria have been met. Offer the "five fundamentals" of COPD care and treatment with inhaled therapies first.

- Before starting prophylactic antibiotic therapy in a person with COPD, think about whether respiratory specialist input is needed. *[Based on the experience and opinion of the GC]*
- 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 (eg, antibiotic resistant organisms, atypical mycobacteria, or *Pseudomonas aeruginosa*)
  - training in airway clearance techniques to optimise sputum clearance (see recommendation 1.2.99 on the NICE website)
  - a computed tomography scan of the thorax to rule out bronchiectasis and other lung pathologies. *[Based on the experience and opinion of the GC]*

Subject to the above, consider prophylactic azithromycin (usually 250 mg three times a week) for people with COPD if they do not smoke (as it is ineffective in continuing smokers) and continue to have one or more of the following, particularly if they have substantial daily sputum production:

- frequent (typically four or more per year) exacerbations with sputum production
- prolonged exacerbations with sputum production
- exacerbations resulting in hospitalisation.
- Before starting azithromycin, ensure the person has had
  - an electrocardiogram (ECG) to rule out prolonged QT interval and
  - baseline liver function tests. *[Based on the experience and opinion of the GC]*
- 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. *[Based on the experience and opinion of the GC]*

No long term studies exist on the use of prophylactic antibiotics in people with COPD, therefore there may be some unknown risks or benefits related to their use in this manner for people with COPD. Prescribers and people with COPD should consider the wider antibiotic stewardship agenda and the risk of increasing antimicrobial resistance. Treatment should be reviewed after three months, and then at least every six months and only continued if the benefits outweigh the risks.

- 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 recommendation 1.2.126 on the NICE website). *[Based on the experience and opinion of the GC]*

  Be aware that prophylactic azithromycin can be continued while another antibiotic is added if necessary for the treatment of an acute exacerbation of COPD.

Lung volume reduction

Lung volume reduction (LVR) surgery can improve breathlessness, exercise capacity, and survival in appropriately selected people with COPD with emphysema.[4] Evidence also supports the use of endobronchial valves in people with COPD who have intact interlobar fissures on computed tomography scan[7,8] (box 5). Other new recommendations provide information about when to refer people with COPD for lung transplantation surgery, but it is important that there is an absence of frailty or

major comorbidities that could preclude a good outcome from surgery.

Box 5: When to refer for LVR procedures for COPD (surgery or endobronchial valve placement)

At the end of pulmonary rehabilitation, a person with COPD's condition should have been optimised as far as is going to be possible.

At this point, and at subsequent clinical reviews:

1. Think about whether LVR is a possible intervention if the following criteria are met:
   - FEV_1<50%
   - limited by breathlessness (typically MRC breathlessness score of 4 or 5)
   - person does not smoke
   - able to walk at least 140 m in six minute walk test.
2. If yes, offer a respiratory review to further assess whether
   - lung function shows hyperinflation **and**
   - unenhanced computed tomography scan of the chest shows emphysema **and**
   - treatment of comorbidities has been optimised.
3. If yes, refer to a specialist LVR team to consider technical suitability for LVR.

Oxygen

Long term home oxygen therapy can improve survival in people with COPD who are hypoxic (PaO_2 <7.3 kPa or <8 kPa in the presence of pulmonary hypertension/cor pulmonale or polycythaemia). Offer smokers with hypoxia the highest level of treatment and support to stop smoking as the key evidence based treatment for their underlying COPD. Supplemental oxygen is not an effective treatment for breathlessness in people who are not hypoxic.

- 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. *[Based on moderate quality evidence from randomised controlled trials]*

  This is because of the fire hazard and consequent risk to people with COPD themselves and to others.
- Do not offer ambulatory oxygen to manage breathlessness in people with COPD who have mild or no hypoxaemia at rest. *[Based on high quality evidence from randomised controlled trials]*
- 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. *[Recommendation carried over from the 2004 guideline]*

Implementation

The measures set out in this guideline require comprehensive provision of treatment and support to stop smoking by smoking cessation teams and all clinicians caring for people with COPD across primary and secondary care. They also require provision and access to pulmonary rehabilitation in all patients limited by breathlessness, as well as addressing the large numbers of people with COPD (around 300 000 in England and Wales in 2018[9]) who are not receiving flu vaccination.

Accurate diagnosis requires access to quality assured spirometry. Respiratory reviews should be structured to include assessment of relevant comorbidities, as multimorbidity is the norm rather than the exception in COPD.[5] Active review of inhaled therapy is needed and, in particular, the reason why people with COPD are taking inhaled corticosteroids should be accessible.

Access to LVR procedures is limited in the UK, representing a substantial unmet need. Pulmonary rehabilitation pathways will need to incorporate routine assessment for possible onward respiratory review in people who are still limited by breathlessness at the end of the programme to see if they may be eligible.

Guidelines into practice

- How do you ensure that all patients with COPD get systematic access to treatment and support to stop smoking, pulmonary rehabilitation, flu vaccination, self management advice, and psychological support?
- How do you ensure that patients with COPD are on the correct inhaled medication and know how to use it correctly?
- What system do you have in place to review patients who are using rescue packs of antibiotics and corticosteroids for frequent exacerbations?

How patients were involved in the creation of this article

Committee members involved in this guideline update included lay members who contributed to the formulation of the recommendations summarised here.

Future research

The guideline committee prioritised the following research recommendations:

1. In people with COPD, does pulmonary rehabilitation during hospital admission for exacerbation and/or in the early recovery period (within one month of an exacerbation) improve quality of life and reduce hospitalisations and exacerbations compared with a later (defined as after one month) pulmonary rehabilitation programme, and in which groups is it most clinically and cost effective?
2. 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?
3. What is the clinical and cost effectiveness of inhaled therapies (bronchodilators and/or inhaled corticosteroids) in people with both stable COPD and asthma?
4. What features predict inhaled corticosteroid responsiveness most accurately in people with COPD?
5. Which subgroups of people with stable COPD who are at high risk of exacerbations are most likely to benefit from prophylactic antibiotics?

Methods

This guidance was developed by NICE's Guideline Updates Team (GUT) in accordance with NICE guideline development methods (https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf).

A Guideline Committee was established by the GUT, which incorporated healthcare and allied healthcare professionals (one respiratory physiotherapist, one respiratory nurse specialist, two consultant respiratory physicians, two general practitioners, and two senior pharmacists) and three lay members. The co-opted committee members consisted of one clinical psychologist, one consultant respiratory and transplant physician, one clinical scientist, and thoracic surgeon and one consultant radiologist.

The Committee were involved in scoping the 2018 update and agreeing the protocols for the 2018 and 2019 updates. The Committee reviewed the clinical evidence that had been identified and analysed by GUT using standard systematic review methodology. The clinical evidence was assessed for quality using GRADE methodology (www.gradeworkinggroup.org/) or modified GRADE methodology in the case of the diagnostic and prognostic review questions. They also examined the cost effectiveness of interventions where possible, including the use of a novel economic model that was generated for the 2018 inhaled therapy review and modified for the 2019 triple therapy review.

The 2017 scope and 2018/2019 updates went through public consultations where comments from stakeholder organisations were solicited, reviewed by the committee and NICE technical teams (NICE guideline scoping team and GUT) and incorporated into the final scope and guideline versions where appropriate.

The evidence reviewed in the 2018 and 2019 updates is available as separate review documents, while the evidence for the sections of the guideline that were not updated is contained in the June 2010 full guideline document. The guideline itself contains the recommendations with a new section on the rationale for the 2018 and 2019 recommendations. The documents are all available at https://www.nice.org.uk/guidance/ng115.

Committee and technical team details The members of the guideline committee were Damien Longson (until September 2017), Andrew Molyneux, Katy Beckford, Lauren Hogg, Nicholas Hopkinson (from August 2017), Karen O'Hara, Tony Perkins, Luisa Pettigrew, Louise Restrick, Ravijyot Saggu, Karen Sennett, Chris Warburton (until November 2018), Sarah MacFadyen (until November 2018), Alan Thomas (from November 2018).

The technical members of the Guideline Updates Team were Joshua Pink (until December 2018), Marie C. Harrisingh, Jean Bennie (June 2017 to March 2018), Yolanda Martinez (September 2017 to April 2018), Clare Dadswell (August 2018 to January 2019), Joseph Crutwell (October 2018 to May 2019), Gabriel Rogers, Ben Johnson (until April 2019).

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Competing interests Declaration of interests based on NICE's policy on conflicts of interests (available at https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf): The authors' full statements can be viewed at https://www.nice.org.uk/guidance/ng115/documents/register-of-interests

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Figure

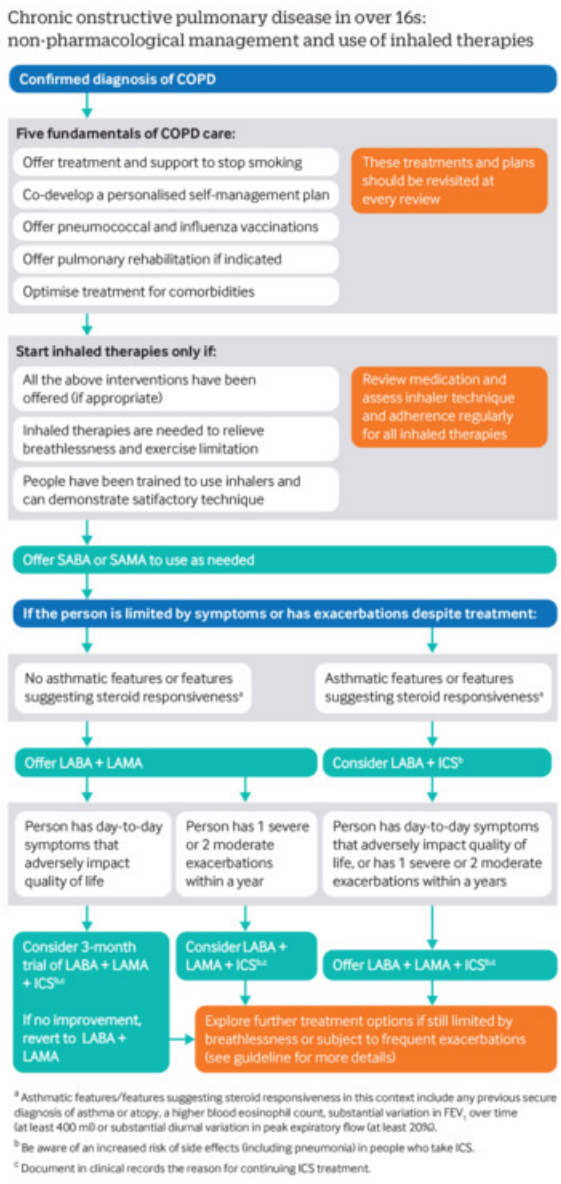

Fig 1 NICE recommended algorithm for non-pharmacological management of COPD and the use of inhaled therapies. SABA: short acting β_2 agonist. SAMA: short acting muscarinic antagonist. LABA: long acting β_2 agonist. LAMA: long acting anti-muscarinic. ICS: inhaled corticosteroids. Reproduced with permission from NICE