

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL
EXCELLENCE**

**QUALITY AND OUTCOMES FRAMEWORK (QOF)
INDICATOR DEVELOPMENT PROGRAMME**

Briefing paper

QOF indicator area: Chronic obstructive pulmonary disease (COPD)

Potential output: Recommendations for indicator development

Date of Primary Care QOF Indicator Advisory Committee meeting:

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This briefing paper was originally presented at the June 2010 QOF Advisory Committee meeting.

This paper has been updated with the following information:

- **Minutes of the June 2010 Advisory Committee discussion on this topic (appendix E)**
- **Indicators that have been generated by the NICE External Contractor following the outcomes of Advisory Committee discussion (appendix F).**

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Introduction

The QOF indicator area is chronic obstructive pulmonary disease (COPD) and this briefing paper presents an assessment of the suitability of NICE clinical guideline recommendations relevant to primary care that have been proposed by stakeholders for QOF indicator development. The recommendations and underlying evidence are taken from the following guideline, with no update searches performed:

- [Management of chronic obstructive pulmonary disease in adults in primary and secondary care](#) (partial update). NICE clinical guideline 101 (2010). This guideline partially updates and replaces NICE clinical guideline 12.

Stakeholder topic suggestion

The stakeholder submissions for this topic identified 5 areas for QOF indicator development in relation to the management of COPD, which have been prioritised by the NICE team for consideration by the Advisory Committee.

The topics and indicators as proposed by stakeholders are outlined below:

- Identification of early disease:
 - The proportion of people aged 40 and above and documented as smokers or ex smokers or used to smoke who have been assessed for the presence of airflow obstruction.
- Oxygen therapy or pulse oximetry:
 - The proportion of people with COPD with a Medical Research Council (MRC) dyspnoea score of 3 or higher who have had pulse oximetry recorded during the previous 15 months.
 - The percentage of all patients with COPD for whom there is a record of oxygen saturation value in the past 15 months.
 - The percentage of patients with COPD whose most recently measured forced expiratory volume in 1 second (FEV₁) is at or below 30% predicted in whom the result of a recording of oxygen saturation measured by pulse oximetry has been recorded within the past 15 months.

- The proportion of people with COPD with a pulse oximetry reading of 92% or less on air who have been referred for clinical assessment for home oxygen
- Pulmonary rehabilitation:
 - The percentage of patients with COPD and Medical Research Council (MRC) Dyspnoea Scale 3 or above for whom a referral to an approved pulmonary rehabilitation programme has been made and documented.
 - The percentage of people with COPD with an MRC dyspnoea score of 3 or higher who have been offered pulmonary rehabilitation.
- Self management:
 - The percentage of people with COPD who have a self-management plan and whose plan has been reviewed within the past 12 months.
 - The proportion of people with FEV₁ of 80% who are recorded in the past 15 months as having been given a self management plan and advice on how to respond promptly when symptoms worsen (for example, treatment with home supply of antibiotics and steroids).
- Frequency of follow up:
 - The proportion of people with very severe COPD (FEV₁ of less than 30%) who have had a clinical review in the past 9 months.

Overview of chronic obstructive pulmonary disease

Epidemiological summary

Definition

Chronic obstructive pulmonary disease (COPD) is characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking. Chronic obstructive pulmonary disease is now the preferred term for the airflow obstruction conditions that were previously diagnosed as chronic bronchitis or emphysema.

Incidence and prevalence and evidence of variation by age, sex and ethnicity

An estimated 3 million people are affected by COPD in the UK. About 900,000 have been diagnosed with COPD and an estimated 2 million people have COPD

that remains undiagnosed. The symptoms of the disease usually develop insidiously, making it difficult to determine the incidence of the disease. Most people are not diagnosed until they are in their fifties. Prevalence increases with age and there are significant geographic variations in the prevalence of COPD. Prevalence rates appear to be increasing steadily in women but have reached a plateau in men. People in urban and deprived areas are more likely to be at risk.

Morbidity and mortality

Chronic obstructive lung disease, mainly COPD, is the third largest cause of respiratory death, accounting for more than one fifth (23%) of all respiratory deaths. Chronic obstructive pulmonary disease accounts for approximately 30,000 deaths each year in the UK, with more than 90% of these occurring in the over 65 age group. Chronic obstructive pulmonary disease coexists with other diseases that share tobacco smoking as a risk factor, of which the most common are coronary heart disease and lung cancer. It is difficult to be certain of the true mortality rate from COPD. Some patients die with the disease rather than because of it. Others will die of causes related to COPD, but their death may be certified as resulting from these complications.

Chronic obstructive pulmonary disease limits a person's ability to breathe and carry out routine daily activities and people can become fearful of undertaking day-to-day activities because of the increasing shortness of breath associated with physical exertion. For people who are severely affected, COPD can result in inability to carry out routine domestic tasks and go out without help (Healthcare Commission 2006). Infective exacerbations of the condition are common, can result in increased GP attendance and hospital admission, and can be distressing and disruptive for patients.

Impact on health services

Primary care

An average general practice in the UK, which cares for about 7000, people will have up to 200 people with COPD on its practice list, and in many of whom the condition will be undiagnosed. This equates to around 1.4 million consultations with GPs each year. People with COPD who are admitted to hospital because of their

condition are frequent users of primary care in the 12 months prior to their admission. The reported 2008/09 QOF COPD prevalence is 1.9% in Scotland, 1.9% in Northern Ireland, 1.5% in England and 2% in Wales.

Secondary care

Chronic obstructive pulmonary disease is the most common reason for emergency admission to hospital with respiratory disease and accounts for the most episodes of care (80% of episodes in people older than 60) and is second only to pneumonia in total bed-days per year.

Current management in primary care

Most people's COPD is managed by GPs and members of the primary healthcare team, with onward referral to secondary care when needed. Making a diagnosis relies on clinical judgement based on a combination of history, physical examination and confirmation of the presence of airflow obstruction using spirometry.

Most people with mild and moderate symptoms, and those who are not experiencing frequent exacerbations, will have their COPD managed predominately in primary care. The treatment and management of COPD is aimed at alleviating symptoms and slowing progression. Follow-up of people with more severe disease will also be predominantly in primary care. People with severe COPD are likely to have frequent exacerbations leading to hospital admissions. They often have complex problems with comorbidities, may be on high levels of treatment, and need monitoring for long-term oxygen therapy (LTOT).

For those with moderate or more advanced COPD, pulmonary rehabilitation is an essential part of the non-pharmacological treatment pathway.

As their COPD progresses people often become hypoxaemic. Many people tolerate mild hypoxaemia well, but once the resting PaO₂ falls below 8 kPa people begin to develop signs of right-sided heart failure (cor pulmonale), principally peripheral oedema. Once this occurs the prognosis is poor and if untreated the 5-year survival is less than 50%. In stable COPD oxygen can be administered for long periods during the day and night. Long term oxygen therapy aims to improve

survival in people with COPD who have severe hypoxaemia ($\text{PaO}_2 < 8\text{kPa}$) as well as reducing the incidence of polycythaemia (raised red cell count), reducing the progression of pulmonary hypertension and improving psychological wellbeing.

The need for oxygen therapy can be assessed on a number of factors including an assessment of oxygen saturation being 92% or less breathing air (NICE COPD clinical guideline) through pulse oximetry.

Pulse oximetry (SpO_2) provides an estimate of arterial oxygen saturation (SaO_2). Oximetry SpO_2 closely tracks arterial SaO_2 under most conditions and is non-invasive. It is easy to measure and the equipment used is inexpensive (it is also very useful to GPs and other healthcare professionals in other clinical contexts).

Pulse oximetry allows a GP to assess the level of oxygen saturation and to determine whether the person should be referred for clinical assessment to determine whether they need LTOT. Pulse oximetry is most valuable as a screening tool to identify people who need referral for assessment for LTOT because oximetry can reliably exclude those who are not hypoxaemic, that is, who have a SaO_2 greater than 92%. What oximetry cannot do is reliably predict which of those with an abnormal reading have hypoxaemia sufficiently severe to need LTOT, which is why such people need further assessment. In diagnostic test terms pulse oximetry has been shown to have a high sensitivity and also a poor specificity for diagnosing those who need LTOT and is thus unsuitable when used alone for assessment (Roberts et al. 1993).

NHS priorities and timeliness for guidance

The NICE QOF Indicator Programme team examined national clinical guidelines, policy documents and national strategies across the UK to assess timeliness of indicators in this topic area. The following were found to be of relevance to COPD:

- NHS 18 Weeks website (ongoing) [18 weeks commissioning pathway for obstructive lung disease \(breathlessness\)](#).
- Royal College of Physicians (ongoing) [The national COPD resources and outcomes project \(NCROP\)](#) Outlines the 3 year study that aims to improve NHS services for people with COPD.

- Department of Health (2010) [Consultation on a strategy for services for COPD in England](#) Launch date: 23 February 2010. Closing date: 6 April 2010.
- Department of Health (2010) [Long-term conditions care planning commitment](#) Letter relating to the commitment made in Darzi's 'High quality care for all' and in 'Our health, our care, our say' that people with long term conditions should have a personalised care plan.
- NHS Quality Improvement Scotland (2010) [Chronic obstructive pulmonary disease services – clinical standards and evaluation](#)
- Department of Health (2009) [Supporting people with long term conditions: commissioning personalised care planning - a guide for commissioners.](#)
- Department of Health (2008) [End of Life Care Strategy – promoting high-quality care for all adults at the end of life](#) See p52 'Understanding chronic obstructive pulmonary disease (COPD) patients' decisions regarding future treatment'.
- Department of Health, Chief Medical Officer (2005) [It takes your breath away: the impact of chronic obstructive pulmonary disease.](#)
- Picker Institute (2008) [Developing the National Service Framework – exploring the experience of seldom heard people affected by chronic obstructive pulmonary disorder.](#)
- Welsh Assembly Government (2008) [Designed to improve health and the management of chronic conditions in Wales: service improvement plan 2008-2011.](#)
- NICE (2007) [Pulmonary rehabilitation service for patients with COPD commissioning guide](#)
- Guidelines and Audit Implementation Network (GAIN) (2007) [Northern Ireland Pulmonary Rehabilitation Audit.](#)
- Welsh Assembly Government (2007) [Designed to improve health and the management of chronic conditions in wales: an integrated model and framework.](#)
- Healthcare Commission (2006) [Clearing the air: A national study of chronic obstructive pulmonary disease.](#)

Review of recommendations

Summary of NICE guideline recommendations

Six recommendations from NICE clinical guideline 101 have been identified as being potentially suitable for QOF indicator development.

Identification of early disease

Recommendation 1.1.7.1

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

Oxygen therapy or pulse oximetry

Recommendation 1.2.5.4

The need for oxygen therapy should be assessed in:

- all patients with very severe airflow obstruction ($FEV_1 < 30\%$ predicted)
- patients with cyanosis
- patients with polycythaemia
- patients with peripheral oedema
- patients with a raised jugular venous pressure
- patients with oxygen saturations $\leq 92\%$ breathing air.

Assessment should also be considered in patients with very severe airflow obstruction ($FEV_1 30\text{--}49\%$ predicted).

Recommendation 1.2.5.5

To ensure all patients eligible for LTOT are identified, pulse oximetry should be available in all healthcare settings.

Pulmonary rehabilitation

Recommendation 1.2.8.1

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

Recommendation 1.2.8.2

Pulmonary rehabilitation should be offered to all patients who consider themselves functionally disabled by COPD (usually MRC grade 3 and above). Pulmonary rehabilitation is not suitable for patients who are unable to walk, have unstable angina or who have had a recent myocardial infarction.

Self management

Recommendation 1.2.12.21

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

Follow up of patients with COPD

Recommendation 1.2.14.4

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

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

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

		<ul style="list-style-type: none"> • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation
Measurements to make	<ul style="list-style-type: none"> • FEV₁ and FVC • calculate BMI • MRC dyspnoea score 	<ul style="list-style-type: none"> • FEV₁ and FVC • calculate BMI • MRC dyspnoea score • SaO₂

Evidence summary

This is a summary of the evidence supporting the proposed evidence-based recommendations presented above. This section relates to the evidence summary table in appendix A of this briefing paper.

Clinical effectiveness

Identification of early disease

Recommendation 1.1.7.1 (identification of early disease) is based on a consensus statement of the Guideline Development Group (GDG) supporting opportunistic case finding based on the presence of risk factors with diagnosis confirmed using spirometry.

Oxygen therapy or pulse oximetry

The evidence for recommendations relating to oxygen therapy in the NICE clinical guideline, which includes recommendation 1.2.5.4, are drawn from evidence statements from the RCP Report (RCP 1999). These in turn are based on 2 major randomised controlled trials: the UK MRC trial of LTOT and the Nocturnal Oxygen Therapy Trial Group (NOTT).

The evidence reviewed in the NICE guidelines on pulse oximetry was based on existing guidelines and the GDG deemed there was sufficient consensus to recommend the use of pulse oximetry in primary care, as recommended in recommendation 1.2.5.5.¹

¹ The evidence review panel of the 2010 Department of Health COPD strategy also supported the use of pulse oximetry in primary care.

Pulmonary rehabilitation²

There is evidence from meta-analyses and randomised controlled trials across relevant health outcomes (including improved quality of life, increased exercise capacity) to support the use of pulmonary rehabilitation in people with COPD, including those who have had a recent hospitalisation for an acute exacerbation, as recommended in recommendation 1.2.8.2.

The GDG noted that there are limited research data on which to justify referral criteria, although there was a consensus, based on the GDG expertise and existing position statements, that introducing rehabilitation is appropriate when patients become aware of their disability and that the threshold for referral would usually be breathlessness equivalent to MRC dyspnoea grade 3.

Self management

The evidence for self management advice (recommendation 1.2.12.21) came from one systematic review and one randomised controlled trial, assessing a range of outcomes associated with self management education. The GDG considered that if used correctly, self management plans should lead to patients starting courses of antibiotics or oral steroids that they have been given to keep at home and may lead to reduced hospital admissions. The GDG noted that self-management plans in COPD are designed to enable patients to respond appropriately to the first signs of an exacerbation and are not concerned with minor day-to-day variations in symptoms, unlike their use in management of asthma. Whilst the evidence supported the use of self-management plans, further research was needed to refine the content of effective self-management plans.

Frequency of follow up for people with very severe COPD

The GDG noted that good quality data on frequency of follow up are lacking. There was GDG consensus to support the recommendation of at least twice-yearly review when reviewing people with very severe COPD in primary care (recommendation 1.2.14.4).

² Pulmonary rehabilitation can be defined as a multidisciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise each patient's physical and social performance and autonomy. It is widely used for patients with COPD.

A table of the gradation of severity of airflow obstruction (2010 update table) is provided in appendix C.

Cost effectiveness

There is evidence that opportunistic case finding in primary care and pulmonary rehabilitation is cost effective in the out-patient setting..

Assessment of recommendations against current practice

Current practice

Identification of early disease

QOF indicator COPD 1 incentivises practices to produce a register as a prerequisite for monitoring patients with COPD. The supporting national QOF guidance for COPD 1 states that a 'diagnosis of COPD should be considered in any patient who has symptoms of persistent cough, sputum production, or dyspnoea and/or a history of exposure to risk factors for the disease'.

Oxygen therapy or pulse oximetry

In the Royal College of Physicians 2008 COPD Audit of GP practice in relation to the management of COPD, 67% replied that they had pulse oximetry in their practice (RCP 2008).

Information on the provision of oxygen therapy for people with COPD was not provided by the stakeholder and no published data were identified by the NICE QOF team to assess the provision of oxygen therapy in the UK.

Pulmonary rehabilitation

The 2007 NICE commissioning guide 'Services for people with chronic obstructive pulmonary disease' estimated that for an average practice with a list size of 10,000, the number of people expected to receive pulmonary rehabilitation is likely to be 23. The NICE commissioning guide estimated that 25% of people with diagnosed COPD at MRC dyspnoea scale grade 3 are eligible for pulmonary rehabilitation, and that 67% of these take up the offer of a rehabilitation

programme. The Royal College of Physicians 2008 COPD Audit (RCP 2008) reported that coverage is variable across England and programme content varies:

- 58% of providers reported they had a formal programme for all eligible patients, 32% had a formal programme for some but not all patients, and 10% had no access at all
- 70% of primary care organisations replied that a pulmonary rehabilitation programme was available in their area
- 15% of patients discharged from hospital following an exacerbation had taken part in a pulmonary rehabilitation programme.

There is growing interest in running rehabilitation in community settings, which may make it easier for patients to attend.

Self management

The uptake of self management plans for COPD in UK primary care is difficult to establish. The proportion of patients with COPD who receive some level of self-care support, including advice, is not consistently reported. The provision of self management for people presenting with exacerbations can be estimated from the Royal College of Physicians COPD Audit (RCP 2008), which reported that only 34% of COPD patients admitted to hospital had been given antibiotic rescue packs. The take-up of care plans in England for COPD is expected to improve as a result of the COPD strategy.

Follow up of patients with severe COPD

Annual review of **all** patients with COPD is incentivised as a QOF indicator under COPD 13.

Health inequalities

COPD is also a condition that particularly affects older people, and those in communities with higher levels of deprivation who are more likely to be smokers and less likely to gain access to healthcare services as people in more affluent areas.

[Relevance to health inequalities: medium/high.]

Will implementation of these recommendations lead to cost-effective improvements in the delivery of primary care?

The recommendations relating to use of oxygen therapy, pulmonary rehabilitation and self management plans are in general supported by good quality trial evidence. There is also consensus across the area to support early identification of early disease and regularity of follow up for people with COPD. The stakeholder submissions received by NICE have stated that there is evidence of variation in rates of case finding, quality of diagnosis and in the use of pulmonary rehabilitation.

Identification of early disease

It is uncertain to what extent recommendation 1.1.7.1 would represent a shift in practice. Practices are required to produce a QOF register for COPD1 on the following basis: a 'diagnosis of COPD should be considered in any patient who has symptoms of persistent cough, sputum production, or dyspnoea and/or a history of exposure to risk factors for the disease'.

Oxygen therapy or pulse oximetry

The RCP COPD Audit survey of GPs reported that around two thirds of GPs have pulse oximetry.

Pulmonary rehabilitation

There is good evidence about the benefits that pulmonary rehabilitation can produce and there is good evidence that pulmonary rehabilitation is cost effective in the outpatient setting compared with usual care. Availability of pulmonary rehabilitation in the UK is reported to be variable; implementation of this recommendation is expected to lead to a moderate to major shift in clinical practice.

Self management

The guideline does not review the extent to which self management plans are used in the UK; the Department for Health has recommended that people with long term conditions have a self management plan.

Frequency of follow up

Practices are required to follow up annually all patients with COPD as part of QOF indicator COPD 13.

Initial feasibility assessment

Identification of early disease

Recommendation 1.1.7.1 (identification of early disease) is considered feasible because diagnosis is confirmed by spirometry but there are issues about defining chronic cough. There is also overlap with the smoking domain.

Oxygen therapy or pulse oximetry

Stakeholders suggest indicators to help identify patients who may benefit from long-term oxygen therapy (recommendations 1.2.5.4, 1.2.5.5).

Indicators relating to oxygen saturation measurement have previously been considered for QOF. There are 2 separate indicators that could be considered:

- Measuring the percentage of patients with COPD in whom there is a record of oxygen saturation.
- Measuring the percentage of patients with COPD in whom there is a record of oxygen saturation value of 92% or less who have been referred for further assessment.

An alternative to the proposed outcome indicator above (indicator 2) would be referral for further assessment of all patients with very severe airflow obstruction ($FEV_1 < 30\%$ predicted). This is considered to be more technically challenging but could be explored further as part of indicator development.

Pulmonary rehabilitation

Recommendations 1.2.8.1 and 1.2.8.2 build on COPD 13 and are considered feasible. The stakeholder submissions suggest including 'referral to an approved pulmonary rehabilitation programme made and documented' for patients with COPD and MRC Dyspnoea Scale 3 or above. Many who are MRC Dyspnoea Scale 5 will be unsuitable and others may be unwilling to be referred.

Self management

Recommendation 1.2.12.21 (self management plans) would present considerable challenges. There are definitional issues with the term 'exacerbation' and the underpinning register would be complex.

Frequency of follow up

There is overlap between recommendation 1.2.14.4 (frequency of review for severe COPD) and existing QOF indicator COPD 13. Initial feasibility assessment suggests there would need to be a second register of people whose FEV₁ is less than 30%. It is noted that many of these people with very severe COPD may be primarily under the care of secondary care.

Key considerations

The following key considerations summarise the main points made in the briefing paper. The Committee is asked to consider these in its discussions:

- An estimated 3 million people are affected by COPD in the UK. About 900,000 have been diagnosed with COPD and an estimated 2 million people have COPD that remains undiagnosed. Current QOF indicators require practices to hold a register of people with COPD and practice are already required to record FEV₁ and MRC dyspnoea score.
- NICE has received topic suggestions for indicator development for the following: identification of early disease; oxygen therapy or pulse oximetry; pulmonary rehabilitation; self management; frequency of follow up.
- The proposed indicator for **identification of early disease** is:
 - The proportion of people aged 40 and above and documented as smokers or ex-smokers who have been assessed for the presence of airflow obstruction.
- This indicator is considered feasible and is supported by recommendation 1.1.7.1, which is based on level 2 evidence. There may be technical challenges defining chronic cough as mentioned the recommendation, and this could be explored as part of indicator development. However, chronic cough is not mentioned in the indicator proposed by the stakeholders.

- Indicators relating to **oxygen saturation measurement and the need for oxygen therapy** have been proposed:
 - The proportion of people with COPD with a Medical Research Council (MRC) dyspnoea score of 3 or higher who have had pulse oximetry recorded during the previous 15 months.
 - The percentage of all patients with COPD in whom there is a record of oxygen saturation value in the past 15 months.
 - The percentage of patients with COPD whose most recently measured forced expiratory volume in 1 second (FEV₁) is at or below 30% predicted in whom the result of a recording of oxygen saturation measured by pulse oximetry has been recorded within the past 15 months.
 - Proportion of people with COPD with a pulse oximetry reading of 92% or less on air who have been referred for clinical assessment for home oxygen.
- Indicators based on an initial assessment for oxygen therapy are considered feasible and there are several approaches that could be explored as part of indicator development. The indicators are supported by recommendations 1.2.5.4 and 1.2.5.5. The evidence base for the benefit for oxygen therapy is considered high.
- Indicators relating to **pulmonary rehabilitation** have been proposed. An indicator on referral to pulmonary rehabilitation is considered feasible and is supported by recommendations 1.2.8.1 and 1.2.8.2, which are based on level 1 evidence and are likely to be cost effective. The assessment of breathlessness using the MRC dyspnoea score is already incentivized in QOF indicator COPD 13. Consideration would need to be given to a prospective-based indicator.
- Indicators relating to **self management** have been proposed and are supported by recommendation 1.2.12.21, which is based on a moderate level of evidence. There may be technical challenges defining exacerbation as mentioned the recommendation and this could be explored as part of indicator development.
- An indicator relating to **frequency of follow up** for people with very severe COPD has been proposed and this is supported by recommendation 1.2.14.4, which is based on consensus. There would be technical challenges defining severe COPD and this could be explored as part of indicator development.

Assessment against NICE's prioritisation criteria

The condition is considered to have population prevalence that is high and fully meets the criteria for diagnosis, treatment and monitoring in primary care (by GPs or directly employed practice staff).

The recommendation for **identification of early disease** has feasibility issues to be considered by the Committee or during indicator development if progressed. The evidence of clinical effectiveness has been assessed as low. There is no evidence of cost effectiveness available. The expected change in practice is considered to be moderate.

The recommendations for **pulse oximetry** and **assessment for the need for oxygen therapy** have feasibility issues to be considered by the Committee or during indicator development if progressed. The evidence of clinical effectiveness for home oxygen therapy has been assessed as high. There is no evidence of cost effectiveness available. The expected change in practice is considered to be moderate.

The recommendations for **referral to pulmonary rehabilitation** are considered feasible. The evidence of clinical effectiveness has been assessed as high and is very likely to be cost effective. The expected change in practice is considered to be moderate.

The recommendation for **self management** has feasibility issues to be considered by the Committee or during indicator development if progressed. The evidence of clinical effectiveness has been assessed as moderate. There is no evidence of cost effectiveness available. The expected change in practice is considered to be moderate to high.

The recommendation for **frequency of follow up for people with severe COPD** has feasibility issues to be considered by the Committee or during indicator development if progressed. The evidence of clinical effectiveness has been assessed as low. There is no evidence of cost effectiveness available. The expected change in practice is considered to be moderate.

References

Roberts CM, Bugler JR, Melchor R et al. (1993) Value of pulse oximetry in screening for long-term oxygen therapy requirement. *European Respiratory Journal* 6: 559–62

Royal College of Physicians (1999) Domiciliary oxygen therapy services. Clinical guidelines and advice for prescribers. A report of the Royal College of Physicians: commissioned by the Department of Health. London: Royal College of Physicians.

Royal College of Physicians (2008) [The National Chronic Obstructive Pulmonary Disease Audit](#).

Appendix A: Evidence summary

Selected recommendations from NICE clinical guideline 101

	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
Identification of early disease					
1.1.7.1	Spirometry should be performed in patients who are over 35, current or ex-smokers, and have a chronic cough.	GDG consensus.	n/a	In the early stages airflow limitation may be present without producing symptoms or that symptoms may not be recognised as being abnormal by the individual. In a cross sectional study of opportunistic case finding in general practice, 27% of patients who were aged over 35 years, were current or ex-smokers and had a chronic cough had reduced FEV ₁ . Opportunistic case finding should be based on the presence of risk factors (age and smoking) and symptoms. The diagnosis should be confirmed using spirometry.	None related to specific recommendation. A simple cost effective model developed by the GDG showed that opportunistic case finding in primary care and using spirometry is a relatively cost effective strategy when linked with smoking cessation therapy.
Long-term oxygen therapy (LTOT)					
1.2.5.4	The need for oxygen therapy should be assessed in: <ul style="list-style-type: none"> • all patients with very severe airflow obstruction (FEV₁ <30% predicted) 	2 RCTs.	Survival in patients with COPD.	Two major randomised controlled trials – the British Medical Research Council (MRC) Working Party and the American Nocturnal Oxygen Therapy Trial Group (NOTT) both show that long term oxygen therapy, when used	None presented.

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	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
	<ul style="list-style-type: none"> • patients with cyanosis • patients with polycythaemia • patients with peripheral oedema • patients with a raised jugular venous pressure • patients with oxygen saturations $\leq 92\%$ breathing air. <p>Assessment should also be considered in patients with very severe airflow obstruction (FEV₁ 30–49% predicted).</p>			for at least 15 hours daily, improved survival in patients with COPD. The precise mechanism of the improvement in survival with oxygen therapy is unknown.	
1.2.5.5	To ensure all patients eligible for LTOT are identified, pulse oximetry should be available in all healthcare settings.	Existing guidelines and GDG consensus.	n/a	The GDG deemed there was sufficient consensus to recommend that pulse oximetry should be available in all healthcare settings.	None presented.
Pulmonary rehabilitation					
1.2.8.2	Pulmonary rehabilitation should be offered to all patients who consider themselves functionally disabled by COPD (usually MRC grade 3 and	Meta-analysis of RCTs.	Hospitalisations, exacerbations, mortality, A&E attendance, Health related quality of life (St	In the studies reviewed, a statistically significant improvement in health related quality of life, functional and maximum exercise capacity was reported for pulmonary rehabilitation, compared to either usual care or	There is good evidence that pulmonary rehabilitation is cost effective in the outpatient setting

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	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
	above). Pulmonary rehabilitation is not suitable for patients who are unable to walk, have unstable angina or who have had a recent myocardial infarction.		George's Respiratory Questionnaire score), exercise performance.	education. There was also GDG consensus that the magnitude of the effects of pulmonary rehabilitation on exercise capacity, dyspnoea and health-related quality of life are significantly greater than the effects of bronchodilator drugs. There is currently no justification for selection on the basis of age, impairment, disability, smoking status or use of oxygen. Some patients with serious comorbidity such as cardiac or locomotor disability may not benefit as much. The GDG considered that the introduction of rehabilitation becomes appropriate when patients become aware of their disability. The GDG considered that there is limited evidence about the benefits of attendance at further pulmonary rehabilitation programmes.	compared with usual care.
1.2.8.1	Pulmonary rehabilitation should be made available to all appropriate people with COPD (see 1.2.8.2) including those who have had a recent	As above.	As above.	As above.	As above.

ITEM 10.2

	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
	hospitalisation for an acute exacerbation.				
Multidisciplinary management - Self management					
1.2.12.21	Patients at risk of having an exacerbation of COPD should be given self-management advice that encourages them to respond promptly to the symptoms of an exacerbation.	One systematic review and one additional RCT.	Increase in use of oral steroids, use of rescue medication, reduction in COPD-related hospital admissions, lung function, symptom scores, visits.	The GDG concluded that the effects of self management were promising but further studies are needed to refine the content of self management plans. In the studies reviewed, there was no evidence that self management plans similar to those used in asthma are of value in COPD.	None presented.
Follow up of patients with COPD					
1.2.14.4	When patients with very severe COPD are reviewed in primary care, they should be seen at least twice a year, and specific attention should be paid to the issues listed in table 6.	GDG consensus.	n/a	The GDG acknowledged the difficulty of conducting studies in this area and noted that there are no data to guide decisions on how frequently patients should be reviewed, and this will depend on the individual and the severity.	None presented.

Appendix B: Related QOF indicators

Related existing QOF indicators from 2009/10 indicator set

COPD relates to an existing QOF clinical domain as defined in the 2009/10 GMS Contract guidance. The QOF indicators for this domain are outlined below.

QOF domain 2009/10: COPD

Indicator	Points	Payment stages
Records		
COPD 1. The practice can produce a register of patients with COPD	3	
Initial diagnosis		
COPD 12. The percentage of all patients with COPD diagnosed after 1 April 2008 in whom the diagnosis has been confirmed by post bronchodilator spirometry	5	40-80%
Ongoing management		
COPD 10. The percentage of patients with COPD with a record of FeV ₁ in the previous 15 months	7	40-70%
COPD 13. The percentage of patients with COPD who have had a review, undertaken by a healthcare professional, including an assessment of breathlessness using the MRC dyspnoea score in the preceding 15 months	9	50-90%
COPD 8. The percentage of patients with COPD who have had influenza immunisation in the preceding 1 September to 31 March	6	40-85%

QOF domain 2009/10: Smoking

Indicator	Points	Payment stages
Ongoing management		
SMOKING 3. The percentage of patients with any or any combination of the following conditions: coronary heart disease, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the previous 15 months	30	40-90%
SMOKING 4. The percentage of patients with any or any combination of the following conditions: coronary heart disease, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses who smoke whose notes contain a record that smoking cessation advice or referral to a specialist service, where available, has been offered within the previous 15 months	30	40-90%

Related indicators from the NICE menu of indicators

There are no COPD related indicators on the NICE menu of indicators (at June 2010), which is available online: www.nice.org.uk/aboutnice/qof/indicators.jsp

Appendix C: Assessment and classification of severity of airflow obstruction

Assessment and classification of severity of airflow obstruction

NICE recommendation 2.1.1

The severity of airflow obstruction should be assessed according to the reduction in FEV₁ as shown in table 4. [New 2010]

2010 update table

This expands the NICE 2004 definition of airflow obstruction to include people with an FEV₁ more than 80% predicted (with an FEV₁/FVC ratio less than 0.7). It also expands the clinical diagnosis of COPD to include people in this mild airflow obstruction group who are also symptomatic.

Table 4 Gradation of severity of airflow obstruction

		NICE clinical guideline 12 (2004)	ATS/ERS ¹ 2004	GOLD 2008 ²	NICE clinical guideline 101 (2010)
Post-bronchodilator FEV₁/FVC	FEV₁ % predicted	Severity of airflow obstruction			
			Post-bronchodilator	Post-bronchodilator	Post-bronchodilator
<0.7	≥80%		Mild	Stage 1 – Mild	Stage 1 – Mild ³
<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 ⁴	Stage 4 – Very severe ⁴

¹ 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 236: 932–46.

² Global Initiative for Chronic Obstructive Lung Disease (GOLD) (2008) Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease.

³ Symptoms should be present to diagnose COPD in people with mild airflow obstruction (see recommendation 1.1.1.1).

⁴ Or FEV₁ <50% with respiratory failure.

Appendix D: Assessment of topic and recommendations against prioritisation checklist criteria status

This appendix provides assessment of the overall topic and recommendation that has been produced by the QOF programme team. This takes into account information presented in this briefing paper against the revised prioritisation checklist as agreed at the July 2009 Advisory Committee.

Topic status

This topic meets the prioritisation criteria for prevalence, primary care management and disease severity as outlined in 1A, 1B and 1C below.

1A Population	
The condition is considered to have population prevalence that is high	<input checked="" type="checkbox"/>
The condition is considered to have population prevalence that is medium	<input type="checkbox"/>
The condition is considered to have population prevalence that is low	<input type="checkbox"/>

1B Management				
	Fully meets criteria	Partly meets criteria	Doesn't meet criteria	
	Score:	[3]	[2]	[1]
The condition is diagnosed in primary care*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The condition is treated in primary care*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The condition is monitored in primary care*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>* by GPs or directly employed practice staff</i>				

1C Disease severity		
Score	Scoring criteria	
1	Minor quality-of-life impact, no disability, limited morbidity impact	<input type="checkbox"/>
2	Definite quality-of-life impact, no disability, limited morbidity impact	<input type="checkbox"/>
3	Definite quality-of-life impact, some disability and/or intermediate morbidity impact	<input checked="" type="checkbox"/>
4	Definite quality-of-life impact, significant disability and/or significant morbidity impact	<input type="checkbox"/>

Recommendation status

The individual recommendations are assessed on feasibility, strength of clinical and cost effectiveness evidence and expected change in practice.

Feasibility of each recommendation from NICE clinical guideline 101	
Recommendation 1.1.7.1	Amber
Recommendation 1.1.7.1	Amber
Recommendation 1.2.5.5	Amber
Recommendation 1.2.8.1	Green
Recommendation 1.2.8.2	Green
Recommendation 1.2.12.21	Amber
Recommendation 1.2.14.4	Amber

Scores for each recommendation from NICE clinical guideline 101			
Recommendation	Evidence of clinical effectiveness	Evidence of cost effectiveness	Expected change in practice
1.1.7.1	Low	No data available	Moderate
1.1.7.1	High	No data available	Moderate
1.2.5.5	High	No data available	Moderate
1.2.8.1	High	Very likely to be cost effective	Moderate
1.2.8.2	High	Very likely to be cost effective	Moderate
1.2.12.21	Moderate	No data available	Moderate–High
1.2.14.4	Low	No data available	Moderate

Appendix E: Minutes of June 2010 Advisory Committee discussion

Taken from minutes of day 2 of the June 2010 AC meeting:

www.nice.org.uk/media/23A/19/QOFMinutes3June2010.pdf.

The Committee was presented with the QOF briefing paper for COPD.

Committee summary

The Committee considered a briefing paper, including an equalities impact assessment form, on the topic of COPD.

The expert technical adviser stated that the recording of symptoms can be poor and that, as a result, the definition 'chronic cough' would pose some technical difficulties, as would the frequency of follow up.

The NICE external contractor advised that there are feasibility and definition issues with all the recommendations in terms of indicator development, which would require considerable further work before potential indicators could be developed.

The Committee noted that COPD was a clinically important area and agreed that the topic as a whole required further preliminary development to build on the existing COPD QOF domain. The Committee agreed that it would consider potential indicators – based on a review of the recommendations and related evidence by the NICE External Contractor. The Committee noted that this review would include a review of the feasibility and definition issues.

The Committee noted that the recommendations presented in the briefing paper were taken from the pre-publication check of the guideline. The Committee noted that the recommendations in the final published guideline were unlikely to change but agreed that any development work would need to be based on the recommendations in the final guideline.

Committee decision

The Committee agreed that further preliminary development work was needed by the NICE External Contractor across the set of clinical recommendations presented before a recommendation to progress for indicator development could be made. The

NICE External Contractor agreed to explore a number of potential indicators for consideration at the December 2010 meeting of the Committee.

Appendix F: Indicators generated by the NICE external contractor

The following indicators have been generated by the NICE External Contractor following the outcomes of the June 2010 AC meeting discussion.

Identification of early disease

- The percentage of patients who smoke aged ≥ 35 or ≥ 40 whose notes contain a record of smoking status in the previous months (to be confirmed) with a documentation that they are current smokers or ex smokers who have been assessed for the presence of airflow obstruction.
- The percentage of patients who smoke aged ≥ 35 whose notes contain a record of smoking status in the previous 15 months with a documentation that they are current smokers or ex smokers who have been assessed for the presence of airflow obstruction.

Oxygen therapy or pulse oximetry

- The percentage of patients with COPD with a record of a Medical Research Council (MRC) dyspnoea score of ≥ 3 at any time in the previous 15 months who have subsequently had pulse oximetry recorded during the previous 15 months
 - (NB: at any time but the most recent recorded ≥ 3 .)
- The percentage of patients with COPD with a record of oxygen saturation value at any time in the in the previous 15 months.
 - (NB: This is any record irrespective of whether there is more than one; in which case the most recent will do.)
- The percentage of patients with COPD with a record (at any time in the previous 15 months) of measured forced expiratory volume in 1 second (FEV_1) at $\leq 30\%$ predicted, in whom there is a subsequent record of oxygen saturation measured by pulse oximetry, within the previous 15 months.
 - (NB: at any time in the previous 15 months but the 'most recent' that is $\leq 30\%$. So if there are 4 and the second to last was $\leq 30\%$ that is the one that counts, **not** the most recent.)

- The percentage of patients with COPD with a record (at any time in the previous 15 months) of a pulse oximetry reading of $\leq 92\%$ on air with a record of subsequent referral for clinical assessment for home oxygen.

Pulmonary rehabilitation

- The percentage of patients with COPD and Medical Research Council (MRC) Dyspnoea Scale ≥ 3 at any time in the previous 15 months in whom there is a subsequent record of referral to an approved pulmonary rehabilitation programme.
 - (NB: at any time in the previous 15 months but the ‘most recent’ that is ≥ 3 . So if there are 4 Dyspnoea Scale scores recorded with the most recent < 3 but the second to last ≥ 3 that is the one that counts, **not** the most recent.)
- The percentage of people with COPD with an Medical Research Council (MRC) dyspnoea score of ≥ 3 with a subsequent record of referral to pulmonary rehabilitation
 - (NB: referral period to be confirmed.)

Self management

- The percentage of people with COPD who at any time in the previous 15 months have a record of a structured COPD educational discussion that includes a written COPD self-management plan.
- The percentage of patients with COPD with a record of $FEV_1 > 80\%$ predicted (with an FEV_1/FVC ratio < 0.7) at any time in the previous 15 months who have a subsequent record of a COPD self management plan that includes advice on how to respond promptly when symptoms worsen (for example, treatment with home supply of antibiotics and steroids).

Frequency of follow up

- The percentage of patients with very severe COPD (FEV_1 of less than 30% predicted?) who have had a clinical review in the past 9 months.

NICE External Contractor suggestions for indicators following discussion with a representative from the General Practice Airways Group (GPIAG)

- The percentage of patients with COPD and Medical Research Council (MRC) Dyspnoea Scale ≥ 3 with a record of oxygen saturation value in the previous 15 months.
- The percentage of patients with COPD and Medical Research Council (MRC) Dyspnoea Scale ≥ 3 at any time in the previous 15 months and who have been offered referral to a pulmonary rehabilitation programme.