

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Consultation report

Indicator area: COPD

Consultation period: 17 April – 16 May 2019

Date of Indicator Advisory Committee meeting: 4 June 2019

Output: New indicators for general practice

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Introduction

The [QOF review](#) recommended refreshing and renewing indicators with a focus on personalised care, addressing over- and under-treatment, and ensuring the best outcomes for patients.

In February and April 2019, a respiratory working group convened to consider what matters most to people with COPD and how best to help them achieve their best outcomes. The group had representation from:

- Asthma UK
- British Lung Foundation
- BMA'S GPC
- North East Quality Observatory Service
- NHS Digital
- NHS England
- RCGP
- NICE including IAC members
- Primary Care Respiratory Society

The results of these discussions were presented for public consultation in April 2019. The Indicator Advisory Committee is asked to consider this feedback and advise on inclusion on the NICE menu.

Summary of indicators included in the consultation

ID	Existing indicator	Proposed indicator	Evidence source
IND67	<p>COPD001: The contractor establishes and maintains a register of patients with COPD</p> <p>COPD002: The percentage of patients with COPD (diagnosed on or after 1 April 2011) in whom the diagnosis has been confirmed by post bronchodilator spirometry between 3 months before and 12 months after entering on to the register.</p> <p>NICE menu ID: NM103.</p>	<p>The contractor establishes and maintains a register of:</p> <ol style="list-style-type: none"> 1. Patients with a clinical diagnosis of COPD before (date of implementation), and 2. Patients with a clinical diagnosis of COPD on or after (date of implementation) whose diagnosis has been confirmed by a quality assured post bronchodilator spirometry FEV1/FVC ratio below 0.7 between 3 months before or 3 months after diagnosis. 	<p>Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2018) NICE guideline NG115, recommendations 1.1.4, 1.1.5, Table 4 Gradation of severity of airflow obstruction</p>
IND68	<p>COPD003: The percentage of patients with COPD who have had a review, undertaken by a healthcare professional, including an assessment of breathlessness using the Medical Research Council dyspnoea scale in the preceding 12 months.</p> <p>NICE menu ID: NM104.</p>	<p>The percentage of patients with COPD on the register, who have had a review in the preceding 12 months, including a record of the number of exacerbations and an assessment of breathlessness using the Medical Research Council dyspnoea scale.</p>	<p>Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2018) NICE guideline NG115, recommendation 1.1.3</p>

IND67 Objective testing to support diagnosis

The contractor establishes and maintains a register of:

- 1. Patients with a clinical diagnosis of COPD before (date of implementation), and*
- 2. Patients with a clinical diagnosis of COPD on or after (date of implementation) whose diagnosis has been confirmed by a quality assured post bronchodilator spirometry FEV1/FVC ratio below 0.7 between 3 months before or 3 months after diagnosis.*

Rationale

Demonstration of the presence of airflow obstruction is critical to making a diagnosis of COPD, with NICE guidance ([NICE NG115](#)) recommending spirometry. For people with a clinical diagnosis on or after the date of implementation the new indicator promotes a diagnosis of COPD supported by objective testing 3 months before or 3 months after initial diagnosis.

Evidence from Wales ([Fisk et al. 2019](#)) highlights that 25% of people on the COPD register had spirometry incompatible with COPD, similar data for England would be expected.

Linking diagnosis and objective testing to entry onto the QOF COPD disease register aims to contribute towards a reduction in both misdiagnosis and the risk of overtreatment in people with COPD.

Summary of consultation comments

- Multiple stakeholders gave comments of support for new indicator IND67. Specific comments referenced reducing the time to diagnosis and subsequent treatment as well as the specification of a FEV1/FVC ratio giving objective guidance to GPs and other staff involved in spirometry.
- Potential barriers to implementation identified by stakeholders included:
 - The need to address potential incorrect asthma diagnosis when COPD is subsequently diagnosed. Providing training to staff can help to address this potential barrier.
 - The need for adequate supply of spirometers in the chosen setting to conduct reviews in the 3-month time period, as well as a general concern about 3 months being a tight timescale.

- A concern about the workload involved to determine if a patient has had quality spirometry at the time of diagnosis
- Potential unintended consequences to introducing IND67 included:
 - Patients with emphysema who may have preserved FEV1/FVC ratio, and patients who have mixed obstruction and restrictive lung defects being removed from follow ups if they have a spirometry ratio above 0.7
- Potential differential impact across people with protected characteristics includes:
 - The need to take gender in to account when considering spirometry results
- No potential adverse impact across different groups in the community were identified.
- One stakeholder advocated the use of the lower limits of normal to quantify airflow obstruction rather than the fixed ratio of 0.7 or below. They felt that this would help address risks of over and under diagnosis at both ends of the age spectrum.
- One stakeholder queried if NICE would define 'quality assured spirometry' and if there would be a code solely for 'quality assured' spirometry.
- One stakeholder advocated for alternative wording, specifically using 'supported' rather than 'confirmed'

Considerations for the advisory committee

The committee is asked to consider:

- Availability of spirometry equipment
- Risks of under-treatment in people with spirometry ratio above 0.7
- Impact on workload

IND68 Annual review including recording of exacerbations

The percentage of patients with COPD on the register, who have had a review in the preceding 12 months, including a record of the number of exacerbations and an assessment of breathlessness using the Medical Research Council dyspnoea scale.

Rationale

Exacerbations affect morbidity in people with COPD, with evidence that people with COPD at the highest risk of exacerbations can be identified by exploring medical history for the presence of prior exacerbations ([Mullerova et al. 2014](#)). Evidence from the UK ([Quint et al. 2011](#)) reports that people with COPD remember the number of exacerbations that they have experienced, with the authors noting that patient recall is sufficiently robust to inform stratification to identify frequent and infrequent exacerbator groups for subsequent years.

Understanding the frequency of exacerbations can help when creating personalised management plans, identifying triggers and avoiding future exacerbations.

Summary of consultation comments

- Multiple stakeholders gave comments of support for new indicator IND68. Specific comments referenced the importance of the number of exacerbations in COPD reviews, the information clinicians will gain about the level of control of COPD from measuring exacerbations, reductions in hospital admissions and complications, and improvements in control.
- Potential barriers to implementation identified by stakeholders included:
 - Difficulty in monitoring the number of exacerbations, mainly due to more moderate exacerbations not leading to hospital admission and therefore not being formally recorded.
 - There was a need identified for consistent coding between COPD and asthma.
 - Exacerbations are likely to be remembered and interpreted differently by different individuals in different groups. A guide and clear definition could help reduce the likelihood of this.
- Potential unintended consequences to introducing IND68 included:

- Over recording of exacerbations leading to inappropriate increases in inhaled corticosteroid prescribing
- Routine issue of rescue packs to patients leading to overuse if they have not had appropriate education
- No differential impact across people with protected characteristics was identified.
- Stakeholders suggested additional breathlessness referral tools be added to the indicator, including:
 - oxygen saturation assessment, so that referrals to long term oxygen therapy can be triggered when appropriate
 - inhaler technique
 - CATest
- One stakeholder suggested alternative wording for the indicator as ‘The percentage of patients on the register with COPD...’

Considerations for the advisory committee

The committee is asked to consider:

- Difficulties defining and identifying exacerbations.
- Risks of over-treatment with corticosteroids / rescue packs.
- Use of other breathlessness referral tools.

General Comments

Issues raised by stakeholders

- Stakeholders commented that there should either be incorporation of malnutrition into all COPD indicators or suggested new indicators around COPD and malnutrition, referencing NICE QS24.
- The importance of aligning COPD indicators and coding with those used by the RCP National Audit of COPD and asthma programme (NACAP) primary care audit
- Some stakeholders commented that there should be an additional indicator addressing tobacco dependency in people with a COPD diagnosis
- One stakeholder commented that there should be an additional indicator addressing flu vaccination in people with a COPD diagnosis
- One stakeholder commented that there should be an additional indicator addressing referrals to pulmonary rehabilitation in people with a COPD diagnosis
- One stakeholder commented that there should be an additional indicator addressing frailty in people with a COPD diagnosis

Appendix A: Consultation comments

ID	Indicator	Stakeholder	Comment
1	General	Nutricia Advanced Medical Nutrition	<p>Advise the incorporation of nutrition screening and management into all indicators especially in relation to multimorbidity, frailty and COPD because for example in NICE QS24 it clearly states that</p> <ul style="list-style-type: none"> • People in care settings are screened for the risk of malnutrition using a validated screening tool • People who are malnourished or at risk of malnutrition have a management care plan that aims to meet their complete nutritional requirements • All people who are screened for the risk of malnutrition have their screening results and nutrition support goals (if applicable), documented and communicated in writing within and between settings
2	General	Nutricia Advanced Medical Nutrition	<p>NICE has shown that substantial cost savings can result from identifying and treating malnutrition – implementation of Clinical Guideline 32: Nutrition Support in Adults and supporting Quality Standard 24 have been shown to have a high impact with respect to cost savings and therefore this supports the integration of nutrition into care pathways an including some form of indicator ie screening for malnutrition risk (as stated above in multimorbidity/frailty/COPD) using a validated screening tool such as 'MUST' and implementing a Managing Malnutrition Pathway such as the Managing Adult Malnutrition in the Community Pathway www.malnutritionpathway.co.uk</p>
3	General	Primary Care Respiratory Society	<p>Every effort should be made to align indicators and coding with those being used in the RCP National Audit of COPD and asthma programme (NACAP) primary care audit , so that there is compatibility.</p>
4	General	Royal College of Nursing	<p>The Royal College of Nursing (RCN) welcome the consultation on the listed NICE QOF indicators. The RCN invited members who care for people with the listed conditions to review the draft indicators on our behalf.</p> <p>The comments below reflect the views of our reviewers.</p>
5	General	Royal College of Physicians	<p>The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the responses submitted by the British Association for Sexual Health & HIV (BASHH) and British Thoracic Society (BTS).</p>
6	COPD	Action on Smoking and Health (ASH)	<p>An important omission from the current proposals for COPD is an indicator relating to the treatment of tobacco dependency.</p>

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			<p>Smoking accounts for 8 in 10 COPD deaths. Between 2015-17, 80,253 people in England died from COPD.</p> <p>As outlined in the Royal College of Physicians' recent report <i>Hiding in Plain Sight: Treating Tobacco Dependency in the NHS</i>, treating tobacco dependency amongst patients with COPD can deliver significant benefits to COPD prognosis. A 2008 systematic review of the effects of smoking cessation in people with COPD concluded that cessation reduces the rate of disease progression (generally measured as decline in one-second forced expiratory volume FEV1) and overall mortality. Further, the Lung Health Study provided strong evidence of a sustained 50% reduction in the rate of decline in FEV1 among people with COPD who succeed in quitting smoking, and a significant reduction (from 10.38 per 1,000 person-years to 8.83 per 1,000 person-year, $p=0.03$) in mortality.</p> <p>Treating tobacco dependency should be considered important to every health professional's role given the significant harm caused by smoking (the single largest preventable cause of death and disease in the UK) and the burden it places on the NHS (costing the health service around £2.5 billion annually). COPD is a major component of the financial. Of the £2.5 billion annual cost, £78 million is accounted for by COPD secondary care costs. Treating tobacco dependency in line with NICE guidance NG92 is a straightforward intervention which is highly cost-effective according to NICE's own economic analysis.</p> <p>Given the harm tobacco dependency has on COPD prognosis, treating it should be recognised as a priority. As detailed above, treating tobacco dependency is incredibly beneficial, proving both effective and cost-effective. An indicator encouraging the treatment of tobacco dependency amongst patients with COPD would ensure these benefits are reaped, significantly improving COPD outcomes and delivering savings to the NHS. It would also indicate to CCGs that restricting prescriptions of evidence-based pharmacotherapy for smoking cessation, behaviour identified by the British Lung Foundation's report <i>Less Help to Quit</i>, is unacceptable and that treating tobacco dependency remains rightfully a priority for the NHS as highlighted in the Long Term Plan.</p> <p><u>References</u> US Department of Health and Human Service. (2014). The Health Consequences of Smoking-50 years of progress: A report of the Surgeon General. Link: https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf Public Health England. Local tobacco control profiles. Accessed May 2019. Link: https://fingertips.phe.org.uk/profile/tobacco-control/data#page/3/gid/1938132887/pat/15/par/E92000001/ati/6/are/E12000007/iid/1204/age/1/sex/4 Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. June, 2018. Link: https://www.rcplondon.ac.uk/projects/outputs/hiding-plain-sight-treating-tobacco-dependency-nhs Godtfredsen NS, Lam TH, Hansel TT et al. COPD-related morbidity and mortality after smoking cessation: status of the evidence. <i>Eur Respir J</i> 2008;32:844–53. Link: https://www.ncbi.nlm.nih.gov/pubmed/18827152</p>
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7	COPD	British Dietetic Association	<p>Malnutrition is common in patients with COPD with reported prevalence rates between 30-60% for inpatients and 10-45 % in outpatients (1). People with COPD who are malnourished or at risk of malnutrition have greater healthcare needs - more GP visits, care at home, antibiotics, more hospital admissions and readmissions and longer length of hospital stay(2,3,4,5,6,7,8,9).</p> <p>We therefore recommend the following indicators in relation to COPD and malnutrition:</p> <ul style="list-style-type: none"> • The practice can produce a register of patients with COPD and their risk of malnutrition (based on results of a validated nutritional screening tool*). • The practice can produce a register of patients with COPD who are malnourished or at risk of malnutrition including their management care plan that aims to meet their complete nutritional requirements with nutrition screening goals and results documented and communicated in writing within and between settings (this is in line with NICE QS24) <p>* a validated nutritional screening tool, for example, the Malnutrition Universal Screening Tool (‘MUST’) (10) or Score Generated Subjective Global Assessment (PG-SGA) (11).</p> <ol style="list-style-type: none"> 1) Stratton et al. Disease related malnutrition: An evidence based approach to treatment. CABI Publishing Oxford 2003). 2) Collins PF et al. An economic analysis of the costs associated with weight status in chronic obstructive pulmonary disease (COPD). <i>Proc Nut Soc.</i> 2011; 70(OCE5): E3214. 3) Ezzell L and Jensen GL. Malnutrition in chronic obstructive pulmonary disease. <i>Am J Clin Nut.</i> 2000;72(6):1415-16 4) Gupta B et al. Nutritional status of chronic obstructive pulmonary disease patients admitted in hospital with acute exacerbation. <i>J Clin Med Res</i> 2010 Mar 20;2(2):68-74

			<p>5) Collins PF et al. 'MUST' predicts 1-year survival in outpatients with chronic obstructive pulmonary disease. Clin Nutr.2010;5(2): 17.</p> <p>6) Collins PF et al. The impact of malnutrition on hospitalisation and mortality in outpatients with chronic obstructive pulmonary disease. Proc Nutr Soc 2010; 69(OCE2)</p> <p>7) Landbo C et al. Prognostic value of nutritional status in chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1999; 160(6):1856-1861.</p> <p>8) Vestbo J et al. Body mass, fat-free body mass, and prognosis in patients with chronic obstructive pulmonary disease from a random population sample: findings from the Copenhagen City Heart Study. Am J Respir Crit Care Med 2006; 173(1):79-83.</p> <p>9) Vermeeren MA et al. Prevalence of nutritional depletion in a large outpatient population of patients with COPD. Respir Med,2006 Aug;100(8):1349-55</p> <p>10) British Association of Parenteral and Enteral Nutrition (BAPEN) Malnutrition Universal Screening Tool (MUST) http://www.bapen.org.uk/pdfs/must/must_full.pdf</p> <p>Ottery FD. Definition of standardized nutritional assessment and interventional pathways in oncology. Nutrition 1996;12(1 Suppl):S15-9</p>
8	COPD	British Lung Foundation	<p>We agree with PCRS that there is a significant omission in the indicators for COPD.</p> <p>The majority of people (an estimated 90%) who develop COPD have a past smoking history or are current smokers. Treating tobacco dependency through quitting smoking can halt the development of COPD and is the best available treatment for people who smoke. We therefore suggest that a specific indicator for COPD on treating tobacco dependency is included.</p> <p>Providing stop smoking support with pharmacotherapy for patients living with COPD costs just £2,000 per QALY. Yet we know from our 2018 British Lung Foundation report 'Less help to quit' that stop smoking support in primary care is often underused and not prioritised by CCGs. From our ongoing work in the area of primary care prescribing to support smoking cessation, a significant portion of health care professionals in the NHS don't see themselves as having a vital role to play in providing patients with support to quit.</p> <p>NICE guideline NG92 (stop smoking interventions and services) supports an indicator for treating tobacco dependency. The guideline suggests that if a person who smokes wants to quit health care professionals in primary care should discuss how to stop and set out pharmacotherapy options. They should then prescribe pharmacotherapy if the individual refuses a referral to a local stop smoking service – or if those services, which are funded by the local authority, are not in existence.</p> <p>Including a specific indicator on treating tobacco dependency in COPD would give a clear message to health care professionals in the NHS that treating tobacco dependency is their responsibility. This would make clear that they should</p>

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			<p>facilitate access to the most effective method of cessation, which is behavioural support and pharmacotherapy (varenicline or bupropion) or nicotine replacement therapy.</p> <p>This would also give a clear signal to CCGs that discouraging or refusing the prescription of pharmacotherapy and/or NRT for smoking cessation is unacceptable. We are aware of a number of areas where this is currently the case, and in practice this means patients can be refused support to quit smoking in primary care – despite this being the leading cause of morbidity and preventative mortality. This is counter to national public health policy and the ambitions of the Long Term Plan to treat tobacco dependency comprehensively.</p>
9	COPD	British Thoracic Society	<p>Flu vaccination is the most cost-effective intervention in COPD but is not included in current QOF indicators circulated. We have significant concerns about the existing QOF. Unfortunately in some practices a large proportion of the COPD population are exception reported, and nationally a large number of COPD patients are not vaccinated. As these patients are removed from the denominator the practice could still achieve the previous indicator and payment. We favour retention of flu vaccination within QOF, <u>but patients who decline vaccination or who cannot be contacted should be included in the denominator.</u> Both of these prior reasons for exception reporting can be influenced by practice. For example, patients can be reassured the vaccine is dead, and cannot give them flu.</p>
10	COPD	Elcena Jeffers Foundation	<p>There is a wish to know about self-care in general public education in life as different people has different diseases or ailments</p>
11	COPD	Managing Adult Malnutrition in the Community	<p>COPD – The Managing Malnutrition in COPD document is an endorsed resource under NICE NG115, NICE CG32 and NICE QS24 and it is endorsed by a number of multi-professional bodies (www.malnutritionpathway.co.uk/copd).</p> <p>It is estimated that around 21% of individuals with COPD are at risk of malnutrition¹ - it is recommended that nutrition screening, assessment and management are incorporated into the annual review.</p> <p><u>References</u> Collins PF et al., Prevalence of malnutrition in outpatients with chronic obstructive pulmonary disease. Proc Nut Soc. 2010; 69(Issue OCE2): E148</p>
12	COPD	NHS England	<p>Treating tobacco dependency is the business of all healthcare professionals because of the extensive harm it can cause, and the health benefits of quitting. Including a specific indicator on treating tobacco dependency in COPD would give a clear message to healthcare professionals that treating tobacco dependency is their responsibility – using the most effective method, which is support with medication.</p> <p>Inclusion of such an indicator will also give a clear signal to CCGs that a policy of prohibiting the prescribing of evidence based medication is unacceptable and runs counter to national public health policy and the need to address inequalities,</p>

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			and the NHS long term plan. The NHS public facing website supports this position – saying that prescription only meds are available from GP or NHS stop smoking service. https://www.nhs.uk/conditions/stop-smoking-treatments/ .
13	COPD	Nutricia Advanced Medical Nutrition	Malnutrition is common in patients with COPD with reported prevalence rates between 30-60% for in patients and 10-45 % in out-patients (Stratton RJ et al, Disease related malnutrition: An evidence based approach to treatment. CABI Publishing Oxford 2003).
14	COPD	Primary Care Respiratory Society	<p>There is an important omission in the indicators for COPD.</p> <p>The majority of people who develop COPD have a past smoking history or are current smokers. Treating tobacco dependency can halt the development of COPD and improve prognosis for people who smoke, which is obviously good both for the patient and the significant burden smoking places on the NHS. As tobacco dependency affects the lungs directly, it is logical to have a COPD indicator which addresses this specifically for these patients. Tobacco dependency causes harm, and is more prevalent than hypertension, so why would we not encourage healthcare professionals to see it as their responsibility to help smokers to quit?</p> <p>Treating tobacco dependency is the business of all healthcare professionals because of the extensive harm it can cause, and the health benefits of quitting. Including a specific indicator on treating tobacco dependency in COPD would give a clear message to healthcare professionals that treating tobacco dependency is their responsibility – using the most effective method, which is support with medication.</p> <p>Inclusion of such an indicator will also give a clear signal to CCGs that a policy of prohibiting the prescribing of evidence based medication is unacceptable, and runs counter to national public health policy and the need to address inequalities, and the NHS Long term plan. The NHS public facing website supports this position – saying that prescription only meds are available from GP or NHS stop smoking service. https://www.nhs.uk/conditions/stop-smoking-treatments/.</p>
15	COPD	PHE	<p>PHE does not have any comments on the proposed COPD indicators.</p> <p>However, there is an important omission in the QOF indicators for COPD. Most people who develop COPD have a past smoking history or are current smokers. QOF only includes COPD within a wider group of patients reported within the smoking indicators. Treating tobacco dependency can halt the development of COPD and improve prognosis for people who smoke. PHE would welcome the development of a COPD indicator which addresses this specifically for COPD patients.</p>
16	COPD	Royal College of Nursing	<p>Proposed changes to QOF for chronic obstructive pulmonary disease (COPD) seem appropriate and is a good starting point. However, the yearly review of exacerbations need to be part of a holistic assessment and treatment review including smoking cessation.</p> <p>There should also be access to services such as smoking cessation and pulmonary rehabilitation as there is still a big variance.</p>
17	COPD and General	British Thoracic Society	Assessment of smoking status is included as one of the asthma indicators, but not within COPD. Considering that most patients with COPD are undiagnosed, the optimum time for intervention is before harm has occurred and the wider adverse effects of smoking we recommend assessment of smoking status in all patients (not just COPD or Asthma), and

			<p>to include the offer smoking cessation support with pharmacotherapy in the indicator. It is worth keeping this lean and simple, so rather than including smoking assessment in Asthma, COPD +/- multimorbidity sections, a separate addiction section addressing smoking and alcohol (?+ other drugs – cannabis, crack, cocaine and heroin) should be considered. Alcohol and smoking indicators in other areas could be moved into this section.</p>
<p>18</p>	<p>Nutrition and COPD</p>	<p>Abbott</p>	<p>It has been estimated that around 21% of individuals with COPD (up to 630,000 people in the UK) are at risk of malnutrition¹. Malnutrition may develop gradually over several years or might develop or progress following exacerbations. Muscle loss is a large part of malnutrition, and in COPD, the condition is often associated with muscle wasting and weakness, both of which predict morbidity and mortality ^{2,3}.</p> <p>Nutrition can play a vital role in minimising muscle loss and thus having positive effects on clinical and functional outcomes, particularly protein, vitamin D and Beta-hydroxy-beta-methylbutyrate (HMB).</p> <p>Protein intake is essential to help minimise declines in strength and function⁴ and high protein oral nutritional supplements have been clinically proven to reduce hospital readmissions by 30%, as well as improve weight and grip strength.⁵</p> <p>Vitamin D supplementation has shown to substantially reduce the rate of moderate/severe COPD exacerbation in patients with baseline serum vitamin D levels of <25 nmol/L.⁶</p> <p>Beta-hydroxy-beta-methylbutyrate (HMB) is also of interest in maintaining muscle, as HMB has been shown to have anticatabolic properties and contribute to the preservation of muscle through increased protein synthesis and decreased protein degradation.^{7,8,9}</p> <p>A study of over 600 malnourished patients, which included patients over the age of 65 years, hospitalised with respiratory disorders (such as COPD) and heart disorders, investigated the impact of an oral nutritional supplement (ONS) high in protein and containing HMB and additional vitamin D, vs placebo on readmissions and mortality through 90 days post hospital discharge. The study did not observe a significant effect for the primary composite endpoint of non-elective readmissions or death at 90 days. It did show:¹⁰</p> <ul style="list-style-type: none"> -The risk of 90 day mortality was significantly lower in the experimental group compared with the placebo group (4.8% vs 9.7%) -Significant improvement in nutritional status in 90 days (consistently greater in the experimental group vs placebo). - Significantly higher serum vitamin D in the experimental group vs placebo at day 30 and 60. -Increased life expectancy by 8.5 months and being cost effective as a management solution.

			<p>A further analysis of data from the study showed that the experimental group had significantly improved hand-grip strength vs placebo. ¹¹</p> <p>Therefore, the inclusion of an indicator involving the nutritional assessment (including a parameter of measuring muscle mass/strength) and the appropriate nutritional management of patients with COPD, which may include offering an ONS high in protein, with HMB and additional vitamin D) would contribute to improved outcomes in COPD patients.</p> <ol style="list-style-type: none"> 1. Collins PF et al., Prevalence of malnutrition in outpatients with chronic obstructive pulmonary disease. Proc Nut Soc. 2010; 69(Issue OCE2): E148 2. Barreiro E and Jaitovich A. <i>J Thorac Dis</i> 2018;10(Suppl 12):S1415-S1424. 3. Wust RC and Degens H. <i>Int J Chron Obstruct Pulmon Dis</i> 2007;2(3):289-300. 4. Deutz NE et al. <i>Clin Nutr</i> 2014;33(6):929-936 5. Cawood AL et al. <i>Ageing Res Rev</i> 2012;11(2):278-296. 6. Joliffe DA et al. <i>Thorax</i> 2019;10.1136/thoraxjnl-2018-212092. 7. Wilson GJ et al. <i>Nutr Metab (Lond)</i> 2008;5:1 8. Manzano M et al. Presented at 31st ESPEN Congress. 29 August-1 Sept 2009, Vienna, Austria. 9. Eley HL et al. <i>Am J Physiol Endocrinol Metab</i> 2008;295(6):E1417-1426. <p>Deutz NE et al. <i>Clin Nutr</i> 2016;35(1):18-26.</p>
<p>19</p>	<p>Multimorbidity, Frailty, Falls, COPD</p>	<p>Managing Adult Malnutrition in the Community</p>	<p>In light of the fact that the QOF aims to increase likelihood of improved patient outcomes, decrease likelihood of harm from overtreatment and improve the personalisation of care it should be noted that people who are <u>malnourished</u> :</p> <ul style="list-style-type: none"> • have greater healthcare needs (more GP visits, care at home, antibiotics), more hospital admissions and readmissions and longer length of hospital stay¹ • have increased risk of falls^{2,3}, impaired recovery from illness and surgery⁴, poorer clinical outcomes⁴, impaired immune response⁴, reduced muscle strength⁴ and frailty^{5,6}, impaired wound healing⁴ and impaired psycho-social function⁴ • have health and social care costs that are more than 3 times greater than a non- malnourished patient¹ (the cost of healthcare for a malnourished patient is estimated as £5763 compared to £1715 for a non-malnourished patient, the cost of social care for a malnourished patient is estimated as £1645 compared to £440 for a non-malnourished patient) <p>Malnutrition affects 11% of people at GP practices⁷, 35% of people recently admitted to care homes⁸, 29% of adults on admission to hospital⁹, 30% of those attending hospital outpatients¹⁰.</p>

			<p>We would therefore recommend that nutrition screening (using a validated screening tool such as ‘MUST’¹¹), assessment and management are incorporated into all indicators (and particularly in relation to multimorbidity, frailty, falls and COPD in relation to the issue of malnutrition).</p> <p>References:</p> <ol style="list-style-type: none"> 1. Elia M, on behalf of the Malnutrition Action Group (BAPEN) and the National Institute for Health Research Southampton Biomedical Research Centre. The cost of malnutrition in England and potential cost savings from nutritional interventions (full report). 2015. http://www.bapen.org.uk/pdfs/economic-report-full.pdf 2. Brotherton, Simmonds and Stroud on behalf of BAPEN (2010), Malnutrition Matters. Meeting quality standards in nutritional care, UK: BAPEN 3. Meijers et al (2012). Predicting falls in elderly receiving home care: The role of malnutrition and impaired mobility, Journal of Nutrition, Health and Aging 16(7): 654-658 4. Stratton RJ et al. Disease-related malnutrition: an evidence-based approach to treatment. Oxford: CABI publishing; 2003. 5. Gossier S, Guyonnet S and Volkert D. The Role of Nutrition in Frailty: An Overview. The Journal of Frailty & Aging 2016; 5(2) 6. JAMDA. Frailty Consensus: A Call To Action. 2013; 14: 391-397 7. McGurk P et al. The burden of malnutrition in general practice. Gut 2012; 61 (Suppl 2): A18 (OC-042) 8. Russell C, Elia M on behalf of BAPEN and collaborators. Nutrition Screening Surveys in Care Homes in the UK: A report based on the amalgamated data from the four Nutrition Screening Week surveys undertaken by BAPEN in 2007, 2008, 2010 and 2011. 2015 http://www.bapen.org.uk/pdfs/nsw/care-homes/care-homes-uk.pdf 9. Russell C, Elia M on behalf of BAPEN and collaborators. Nutrition Screening Surveys in Hospitals in the UK, 2007-2011: A report based on the amalgamated data from the four Nutrition Screening Week surveys undertaken by BAPEN in 2007, 2008, 2010 and 2011. 2014. http://www.bapen.org.uk/pdfs/nsw/bapen-nsw-uk.pdf 10. Stratton RJ et al. Malnutrition in hospital outpatients: prevalence, concurrent validity and ease of use of the ‘malnutrition universal screening tool’ (‘MUST’) for adults. Br J Nutr (2004);92, 799-808. 11. The ‘MUST’ report. Nutritional screening for adults: a multidisciplinary responsibility. Elia M, editor. 2003. Redditch, UK, BAPEN.
<p>20</p>	<p>Multimorbidity, Frailty, Falls, COPD</p>	<p>Managing Adult Malnutrition in the Community</p>	<p>NICE QS24¹ Nutrition Support in Adults should be incorporated into all aspects of care. NICE QS24¹ recommends:</p> <ul style="list-style-type: none"> • People in care settings are screened for the risk of malnutrition using a validated screening tool • People who are malnourished or at risk of malnutrition have a management care plan that aims to meet their complete nutritional requirements

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			<ul style="list-style-type: none"> • All people who are screened for the risk of malnutrition have their screening results and nutrition support goals (if applicable), documented and communicated in writing within and between settings • People receiving nutrition support are offered a review of the indications, route, risks, benefits and goals of nutrition support at planned intervals. <p>NICE has shown that substantial cost savings can result from identifying and treating malnutrition – implementation of Clinical Guideline 32²: Nutrition Support in Adults and supporting Quality Standard 24¹ have been shown to have a high impact with respect to cost savings – estimating savings of £71,800 per 100,000 people by implementing screening and management of malnutrition.</p> <p>However despite this nutrition continues to be ignored as a key indicator in many disease areas.</p> <p>References:</p> <ol style="list-style-type: none"> 1. National Institute for of Health and Care Clinical Excellence (NICE). Nutrition support in adults. Quality Standard 24. 2012. 2. National Institute of Health and Care Excellence (NICE). Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition. Clinical Guideline 32. 2006.
21	IND01	KSS AHSN Respiratory Programme	This is very welcome and will help support a holistic approach identifying patients who require services supporting multi-morbidity. Agree frailty is missing from these indicators and I would also like to see it added to the indicators in regards to COPD
22	IND67	Boehringer Ingelheim Limited	<p><i>Do you think there are any barriers to implementing the care described by these indicators?</i></p> <p>It is well recognised that spirometry is an essential part of diagnosis (although should not be the sole means of diagnosis). What does however require monitoring and prove more problematic to implement is when there is potential for COPD/Asthma overlap, as NICE recommendations differ when patients have a clinical diagnosis of asthma: however, it is considered probably that there are many patients who have historically and incorrectly diagnosed with asthma which should be reassessed if a positive diagnosis of COPD is made.</p> <p>Robust training and support will need to be funded and in place to ensure equity of access to the same ‘quality assured’ assessment.</p>
23	IND67	Boehringer Ingelheim Limited	<p><i>Do you think there are potential unintended consequences to implementing/ using any of these indicators?</i></p> <p>This is a minor change to an existing indicator and the use of quality spirometry can only be positive as long as there are adequate spirometers/HCPs to deliver in the chosen settings given the 3 month time period for review.</p>
24	IND67	Boehringer Ingelheim Limited	<p><i>Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.</i></p>

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			Only factors that may prevent successful spirometry taking place should have an impact. When considering spirometry results gender is taken into consideration (particularly when assessing % predicted FEV1) so sensitivity would need to be exercised relating to gender.
25	IND67	Boehringer Ingelheim Limited	<i>If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities?</i> No adverse impact of spirometry would be anticipated.
26	IND67	British Medical Association	The contractor establishes and maintains a register of: 1. Patients with a clinical diagnosis of COPD before (date of implementation), and 2. Patients with a clinical diagnosis of COPD on or after (date of implementation) whose diagnosis has been confirmed by a quality assured post bronchodilator spirometry FEV1/FVC ratio below 0.7 between 3 months before or 3 months after diagnosis. We support the changes to this indicator.
27	IND67	British Thoracic Society	Objective testing & diagnostic accuracy: we recommend changing to FEV1/(F)VC, explaining that both forced (FVC) and relaxed vital capacity (VC) should be measured and the ratio of FEV1/FVC compared to FEV1/VC to avoid missing true airflow obstruction due to technical reasons, in line with ARTP guidance on quality assured spirometry. Some patients stop forced manoeuvres prematurely; in this setting airflow obstruction will be missed by reliance on FEV1/FVC alone. Relaxed VC should always be performed for diagnosis. Please note that the ARTP guidelines on quality assured spirometry should be followed currently.
28	IND67	British Thoracic Society	The requirement for annual spirometry has been removed. NICE 2019 1.1.4 includes performing spirometry “to monitor disease progression” without stipulating frequency. We agree with removal of the requirement for <u>routine</u> annual spirometry as this placed excessive burden on primary care for limited gain (72% of nurse time for the annual review in one study; time better spent on other aspects of disease management once the diagnosis has been confirmed). However this is a big change and perhaps it is worth clarifying that a) routine annual spirometry is no longer required by QoF (otherwise primary care clinicians may not realise that it is not routinely required), and more importantly b) spirometry should be repeated after optimising treatment (this will improve diagnostic accuracy - misdiagnosed asthma) and if there is a substantial change in symptoms (if no decline this will help prompt consideration of other causes such as heart failure). We appreciate that this does not lend itself to a separate measurable indicator, but could be included within the rationale for objective testing.
29	IND67	KSS AHSN Respiratory Programme	The ARTP course & subsequent registered practitioners advise using the LLN rather than <70% ratio for COPD diagnosis as per NICE 2018 update to avoid misdiagnosis. The Guide to Performing Quality Assured Diagnostic Spirometry a document validated by the BLF, Asthma UK, NHS, BTS, PCRS, PCC, ARTP, Education for Health supports this approach to diagnosis of obstruction. Guidance and QoF should align. Would prefer to see LLN used for quantifying airflow obstruction not a fixed ratio given the risk of over and under diagnosis at either end of the age spectrum.

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30	IND67	KSS AHSN Respiratory Programme	The 3 month timescale after diagnosis is tight to be able to get people in after an exacerbation for full spirometry. There could also be a large work load to try and discover if a patient has had quality spirometry at the time of diagnosis- e.g. may have been done at a hospital and notes not transferred with change of GP
31	IND67	KSS AHSN Respiratory Programme	Concern re patients with significant emphysema who may have preserved FEV/FVC ratio, and those who have mixed Obstruction and Restrictive lung defects - they would be removed from follow up if they have a normal ratio
32	IND67	KSS AHSN Respiratory Programme	There is coding in place for recording spirometry but will NICE define 'quality-assured' spirometry further (and who will assess this). Will there be a separate code for "quality-assured spirometry"?
33	IND67	NHS England	This is a sensible change. Although it would be better to say that the diagnosis was SUPPORTED rather than CONFIRMED by a ratio of 0.7 – because of the issue of lower limits of normal in over (and under) diagnosis of COPD and the existence of other causes (notably asthma) of obstructive spirometry. COPD is primarily a CLINICAL diagnosis and the indicator should acknowledge this.
34	IND67	National Pharmaceutical Advisers Group (PAG)	The implementation of a register that would include the date of clinical diagnosis and the second date of confirmation diagnosis confirms the time frame for objective diagnosis. The introduction of the 3 month (reduced from 12 months) from clinical to confirmation diagnosis speeds up diagnosis and possible treatment. The specification of FEV1/FVC of 0.7 provides guidance to GPs and other practice staff who do spirometry of obstructive airways disease and gives an objective figure for confirmation rather than spirometry without proper interpretation.
35	IND67	Primary Care Respiratory Society	This is a sensible change It would be better to say that the diagnosis was SUPPORTED rather than CONFIRMED by a ratio of 0.7 – because of the issue of lower limits of normal in over (and under) diagnosis of COPD and the existence of other causes (notably asthma) of obstructive spirometry. COPD is primarily a CLINICAL diagnosis and the indicator should acknowledge this.
36	IND67	Royal College of General Practitioners	IND67: The contractor establishes and maintains a register of: 1. Patients with a clinical diagnosis of COPD before (date of implementation), and 2. Patients with a clinical diagnosis of COPD on or after (date of implementation) whose diagnosis has been confirmed by a quality assured post bronchodilator spirometry FEV1/FVC ratio below 0.7 between 3 months before or 3 months after diagnosis We support this change
37	IND67	PHE	PHE welcomes the inclusion of objective testing of COPD within the QOF, however notes that there is a disparity between the asthma QOF (which separates the maintenance of a register with the percentage of those who have had objective testing – IND-63 and 64). Within IND 67 it is possible that those COPD patients who had been diagnosed with objective testing, but outside the three months before or after timeframes, may be missed off the register?

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38	IND68	AstraZeneca	AstraZeneca supports the update to this indicator and agrees that number of exacerbations is an important part of a COPD review. As recognised by the advisory committee, exacerbation history influences COPD morbidity, and therefore the update to this indicator is an important step in improving the management of COPD patients in England.
39	IND68	Boehringer Ingelheim Limited	<i>Do you think there are any barriers to implementing the care described by these indicators?</i> Recording both breathlessness and exacerbations is a positive step and is helpful in determining the appropriate treatment. However, there is potential difficulty in terms of monitoring the number of exacerbations that patients have: exacerbations resulting in hospitalisation should be easy to measure as primary care should be notified of the admission, however what we may term 'moderate' exacerbations that are generally managed by the patient at home with rescue packs of antibiotics or oral corticosteroids may be more difficult to record.
40	IND68	Boehringer Ingelheim Limited	<i>Do you think there are potential unintended consequences to implementing/ using any of these indicators?</i> It will be important to clearly define what an exacerbation is. Any over recording of exacerbations is likely to lead to an inappropriate overall increase in inhaled corticosteroid prescribing, which is not recommended for infrequent exacerbators (GOLD 2019) or patients who neither show asthmatic features nor features of steroid responsiveness (NICE 2018). ICS use is associated with a number of well-established adverse events, including pneumonias, and therefore only patients who would genuinely benefit from ICS should have them prescribed.
41	IND68	Boehringer Ingelheim Limited	<i>Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.</i> None anticipated
42	IND68	Boehringer Ingelheim Limited	<i>If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities?</i> Exacerbations are likely to be handled and remembered differently by different individuals, let alone different groups in the community, based on the communication with their primary care team. A practical guide to knowing what an exacerbation is and how it should be recorded by the HCP (taking into account whether the exacerbations should be classified as mild, moderate or severe) will be important.
43	IND68	British Medical Association	IND68: The percentage of patients with COPD on the register, who have had a review in the preceding 12 months, including a record of the number of exacerbations and an assessment of breathlessness using the Medical Research Council dyspnoea scale. We support the changes to this indicator.
44	IND68	British Thoracic Society	Annual review: please add oxygen saturations (measured at rest for at least 10 minutes breathing room air or usual LTOT). Rationale – LTOT is one of the few interventions that improves survival - this will trigger appropriate referral for assessment for LTOT. We agree with the importance of capturing exacerbations. There is a risk that routine issue of rescue packs to patients who have not received appropriate education, or are unable to understand and implement this advice, will lead to

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			overuse. Not all exacerbations require both antibiotics and steroids and overuse of either causes harm. We need “steroid stewardship” as well as antibiotic stewardship. Please consider making a reference to education on exacerbation recognition and management, including appropriate use of rescue packs within the rationale.
45	IND68	National Pharmaceutical Advisers Group (PAG)	Addition of exacerbations to the indicators informs the clinicians of the level of control of COPD, reduce hospital admissions, complications and indicate action to be taken to improve control of COPD.
46	IND68	Primary Care Respiratory Society	This is sensible in principle, since exacerbations are an indicator of poor control. There needs to be a very clear definition of what constitutes an exacerbation and a method of coding “number of exacerbations in the last year” which is universally and consistently applied We suggest that the same approach is taken to coding this as is used for the National audit for COPD and asthma, to ensure consistency.
47	IND68	Royal College of General Practitioners	IND68: The percentage of patients with COPD on the register, who have had a review in the preceding 12 months, including a record of the number of exacerbations and an assessment of breathlessness using the Medical Research Council dyspnoea scale We support this change
48	IND68	KSS AHSN Respiratory Programme	Pleased to see exacerbation frequency has been added as this supports customising the care to follow the appropriate guideline for treatment of COPD. Would like option of additional breathlessness assessment tools as MRC does not reflect change well compared to CATest. Need to add check and correct inhaler technique. Concern that oxygen saturation assessment does not feature now as although it is assumed to be commonplace now there is concern that if not specifically listed it may well cease to be checked.
49	IND68	NHS England	This is sensible in principle, since exacerbations are an indicator of poor control. There needs to be a very clear definition of what constitutes an exacerbation and a method of coding “number of exacerbations in the last year” which is universally and consistently applied. The Primary Care Respiratory Society would suggest that the same approach is taken to coding this as is used for the National audit for COPD and asthma, to ensure consistency.
50	IND65 IND66 IND68 IND72	Resuscitation Council (UK)	The proposed initial wording of these indicators is ‘The percentage of patients with asthma/COPD/heart failure on the register...’ We believe that these sentences would be better worded ‘The percentage of patients on the register with asthma/COPD/heart failure...’. This is a minor point relative to our other more important comments.

