NICE National Institute for Health and Care Excellence

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

Consultation on draft scope
Stakeholder comments table

13/02/2017 to 27/02/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

ID	Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
41	Addenbrookes Hospital	5	26	Include referral for endobronchial lung volume reduction(non-surgical LVR)	Thank you for your comment. The term 'surgery' used in this review question includes lung volume reduction (LVR) surgery using bronchoscopic methods, and therefore as part of the review on referral criteria for surgery, referral criteria for LVR by alternative methods (such as non-surgical LVR as you suggest) will be included. The new evidence identified as part of the NICE surveillance process which highlighted the need to update this topic, was actually conducted in patients undergoing bronchoscopic LVR (using endobronchial valves).
42	Addenbrookes Hospital	7	General	As above only surgery is mentioned- not no-surgical LVR	Thank you for your comment. The term 'surgery' used in this review question includes lung volume reduction (LVR) surgery using bronchoscopic methods, and therefore as part of the review on referral criteria for surgery, referral criteria for LVR by alternative methods will be included. The new evidence identified as part of the NICE surveillance process which highlighted the need to update this topic, was actually conducted in patients undergoing bronchoscopic LVR (using endobronchial valves).
43	Addenbrookes Hospital	7	General	Major omission regarding alpha-1 antitrypsin augmentation therapy- there is significant new evidence and the EMA has issues a licence for augmentation therapy. This evidence needs ot be reviewed in the new guideline development process as the comment in the previous NICE guidance states "augmentation therapy is	Thank you for your comment. The EMA decision was based on an RCT by Chapman (2015). A Cochrane review (Gotzsche 2016) was published which included the Chapman (2015) study. The Cochrane review concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant

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				not recommended"- this is out of date and nbew evidence has been published.	a change to the current recommendations, and the quality of the evidence was also unclear. We have also looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well as studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available related to the current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication) and may be included in the scope for the next update.
44	Addenbrookes Hospital	9 10	General	Inhaled therapy- significant new data on LABA/LAMA and role of ICS- it is essential this is reviewed and the new GOLD guidance is reviewed	Thank you for your comment. This comparison was supposed to be listed here as well, and so we have now amended the draft scope, and added the vs. LABA comparison in. Regarding ICS, the plan is to update the whole of the inhaled therapy pathway. We are planning to look in particular at the effectiveness of ICS/LABAs compared to LAMA/LABA as part of the guideline and this has been included in the scope. However, we are aware of safety issues concerning ICS, and therefore (as detailed in the draft scope), a footnote will be added to the guideline to outline potential adverse events related to inhaled steroids.

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					Information contained in the GOLD guidance may be discussed as part of the guideline committee's decision-making process.
45	Addenbrookes Hospital	11	General	New guidance based on evidence has been published by BTS	Thank you for your comment.
54	Alere International	General	General	Alere welcomes this NICE consultation on the draft scope of the proposed update to the Chronic Obstructive Pulmonary Disease (COPD) in over 16s Clinical Guidelines. Respiratory tract infections become more prevalent and more complex, particularly with an ageing patient population. Infective exacerbations of chronic obstructive pulmonary disease (COPD) are especially common among elderly people.[i, ii] It is important that practitioners have access to a wider set of cost-effective tools with an enhanced ability to accurately detect conditions. Alere therefore recommends that the guideline update review incorporates the inclusion of C-Reactive Protein Point of Care Testing (CRP POCT) as a means of supporting the accurate identification of patients with infective exacerbations of COPD, encouraging reductions in inappropriate antibiotic prescribing and generating cost savings for the NHS.	Thank you for your comment. Regarding point of care testing, The NICE guidelines on antimicrobial stewardship and on pneumonia were felt to sufficiently cover point of care testing, as specific recommendations have been made for people with suspected lower respiratory tract infections, which includes point of care testing with CRP. It would be expected that healthcare professionals would consult this guidance in order to address the issue of suspected respiratory tract infections, antibiotic resistance and overprescribing. Thank you for the references you have provided. If this topic is included in future updates of the guideline, then these studies will be considered if they meet the criteria set by the review protocol.

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				The prognosis of patients with infective exacerbations of COPD, declines with advancing age[ii] and in light of an increasingly ageing population, it is likely that the disease will impose an escalating burden on the healthcare system. It is therefore increasingly important that infective exacerbation of COPD is diagnosed promptly and accurately, to support more effective patient management. Evidence demonstrates that measuring C-Reactive Protein (CRP) can aid the differential diagnosis of bacterial acute exacerbations of COPD.[iii,iv] Further it could be shown that antibiotic overprescribing was significantly reduced using a CRP rapid test in these patients.[iii] When used alongside history taking and evaluation of signs and symptoms, CRP POCT is well-evidenced to support reductions in inappropriate antibiotic prescribing – outlined as the key priority in the final report of the Review on Antimicrobial Resistance (AMR)[v] – and thereby helping to address the rise of AMR, without producing a clinically significant increase in the risk of complications or missed diagnoses.[vi, vii] A 2014 study demonstrated for instance that CRP testing was associated with a 36.16% reduction in inappropriate antibiotic prescribing in patients presenting with acute cough and lower respiratory tract infections, including COPD.[viii] CRP POCT can reduce antibiotic prescribing for RTIs in primary care by up to	

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				42% (in suspected lower RTIs with a cough lasting less than four weeks together with one focal and one systemic symptom).[ix] Significantly the use of CRP POCT can also generate cost savings for the NHS. Greater uptake of CRP POCT in primary care could produce savings of £56m a year in prescription and dispensing costs alone, as well as lead to savings through reduced re-attendance rates.[vi] Including CRP POCT within the scope of this review would not only support the accurate diagnosis of infective exacerbations of COPD, contribute to effective antimicrobial stewardship strategies and lead to cost savings for the NHS, but would also bring CG 101 in line with the NICE Clinical Guidelines for Pneumonia (CG 191).[x] CG 191 recommends that for people presenting with symptoms of lower RTI in primary care, healthcare practitioners should consider using CRP POCT if after clinical assessment a diagnosis of pneumonia has not been made and it is not clear whether antibiotics should be prescribed. For the reasons set out above, Alere recommends therefore that the scope of the review for CG 101 includes the use of CRP POCT.	
22	Alpha-1 UK Support Group	Page 7	*General*	The draft scope excludes evidence review for alpha-1 antitrypsin replacement therapy and proposes to retain	Thank you for your comment. It is correct that the recommendation 1.2.11.1 has not been updated since 2004; this is not because the evidence was not looked

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				the current recommendations from the existing guidance, namely ***"1.2.11.1 Alpha-1 antitrypsin replacement therapy is not recommended for patients with alpha-1 antitrypsin deficiency (see also recommendation 1.1.3.3). [2004]".*** From the history of the NICE COPD Guideline it is apparent that, since its inception, not a single evidence review of alpha-1 antitrypsin (AAT) replacement therapy has been conducted. The last guideline update in 2010 did not include evidence review, and a review is seemingly not planned as part of the current guideline review either. This is concerning, as a large body of published evidence has become available in the last ten years that indicates clinical benefit of this therapy, at least in certain patient sub-groups. A number of clinical trials and registry studies have demonstrated the slowing of emphysema progression in AAT patient on replacement therapy compared to those on placebo (in RCTs) or on standard supportive therapy (in retrospective registry studies). Examples include: • The most recent pivotal RCT examining the efficacy of AAT replacement therapy has resulted in Respreeza being granted an EMA marketing	at, but because no new evidence was identified through the 2,4 and 6 year NICE surveillance process that was considered strong enough to change the current recommendation. Each update of the guideline is undertaken after a surveillance process at NICE where relevant literature that may affect the current recommendations is identified, assessed and consulted on. The most recent NICE surveillance review did not identify any systematic reviews (SR) data to inform an update of this clinical area. Thank you for highlighting these studies in your comment, we have responded to each one individually below. Chapman (2015) was not identified through the NICE surveillance process as the 6 year surveillance review searches for SRs. We understand that Chapman (2015) is relevant to the clinical area. This study showed some positive effects. It was found that there was a reduction in the loss of annual lung density (TLC only, not FRC alone or TLC and FRC combined). However, a Cochrane review published in 2016 (Gotzsche 2016), which included the Chapman study, concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant a change to the current recommendations, and the quality of the evidence was also unclear. We have also

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				authorisation in 2015 (***Intravenous augmentation treatment and lung density in severe α1 antitrypsin deficiency (RAPID): a randomised, double-blind, placebo-controlled trial*. Chapman KR, Burdon JG, Piitulainen E, et al. Lancet. 2015 Jul 25;386(9991):360-8).** The therapy has since been made available in several European countries. • AAT replacement therapy has been shown to reduce severe exacerbations and associated hospital admissions (***Reduction of severe exacerbations and hospitalization-derived costs in alpha-1-antitrypsin-deficient patients treated with alpha-1-antitrypsin augmentation therapy*. Barros-Tizón JC, Torres ML, Blanco I, et al. Ther Adv Respir Dis. 2012 Apr;6(2):67-78.)** • A retrospective registry study showed that AAT replacement therapy has a positive effect on patients' health-related quality of life (***Italian registry of patients with alpha-1 antitrypsin deficiency: general data and quality of life evaluation*. Luisetti M, Ferrarotti I, Corda L, et al.COPD. 2015 May;12 Suppl 1:52-7**.)	looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available related to the current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication) and may be included in the scope for the next update. The studies that were highlighted in your comment were not identified by the NICE surveillance searches because the 6 year surveillance process searches for meta-analysis / systematic reviews of RCT data only. More details on the NICE surveillance process for updating guidelines can be found in Chapter 14 of the methods manual https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf Barros- Tizon (2012) – n=172. This study was not identified in the NICE surveillance review because it is a case-series study (not a SR) and was outside of the

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				• Reviews of RTC demonstrate efficacy of AAT replacement therapy (***Compelling evidence for the efficacy of α1-antitrypsin augmentation treatment for α1-antitrypsin deficiency.*** **Crystal RG. Lancet Respir Med. 2017 Jan;5(1):7-8.**); ***Randomized, Placebo-Controlled Trials in Alpha-1 Antitrypsin Deficiency.*** **Sandhaus RA. Ann Am Thorac Soc. 2016 Aug;13 Suppl 4:S370-3.**) It is very surprising that these (and many other relevant) publications do not appear to have been either identified or considered in the process that results in the generation of the draft scope for the NICE COPD Guideline review. Every single one of the abovementioned publications contains sufficient evidence to warrant at least evidence review for AAT replacement therapy. This may indicate that the process used by NICE for identification of relevant evidence for the COPD Guideline review topic selection (presumably a systematic literature review based on a pre-defined keyword search) is inadequate to identify relevant papers in AAT deficiency. If the term "COPD" was a search term for the systematic literature review performed by NICE to identify topics for evidence review, this could explain why most of the compelling publications relevant to AAT replacement	surveillance search dates. The study concludes that augmentation therapy with AAT concentrates was associated with a reduction in the incidence and severity of exacerbations in AAT-deficient patients, which resulted in lower hospitalisation expenditures. However this study would be unlikely to change the current recommendation. Luisetti (2015) was not identified by the NICE surveillance review because it was not a SR of RCT data. This was a retrospective analysis of registry data with N=422. No further details were available from the abstract. Crystal (2017) refers to the open label extension trial of RAPID (Chapman 2015). This study was not identified in the NICE surveillance review as it is not a SR and it was out with the surveillance search dates. Sandhaus (2016) is a commentary on A1AT therapy and was not identified by the NICE surveillance review as it was not an SR.

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				therapy were not found – the term "COPD" is rarely used in publications relating to AAT deficiency. It is accepted by the scientific and clinical community that AAT deficiency is a separate, complex, multisystem condition, rather than a form of COPD. It may therefore not be appropriate to cover therapies relating to AAT deficiency in the NICE COPD Guideline altogether. Based on the above and the available evidence supporting efficacy of AAT replacement therapy that has been published since 2004, some of which has been included above, it is **not justifiable**: - to not review the substantive body of evidence available in the literature, and - to uphold the current blanket negative recommendation for use of AAT replacement therapy for all AAT deficiency patient, irrespective of their disease severity, disease progression and age. We therefore kindly request that all available evidence for AAT replacement therapy that has become available since publication of the current COPD Guideline in 2004, should to be reviewed. As an absolute minimum, the current blanket statement ***"1.2.11.1 Alpha-1 antitrypsin replacement therapy is not recommended for patients with alpha-1***	

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				antitrypsin deficiency (see also recommendation 1.1.3.3). [2004]" needs to be removed from the Guideline, as this statement ignores the substantial body of positive efficacy evidence and does not reflect the current standard of best evidence-based clinical care for this condition. This standard is applied in many other countries, where AAT augmentation therapy is routinely available, incl. France, Spain, Germany, Portugal, Austria, Switzerland, etc.	
65	Astrazeneca UK Ltd	4	14	**Groups that will be covered** We've noted that one of the groups that will be covered in this guideline update is adults (over 16 years) with COPD and asthma, bronchopulmonary dysplasia, or bronchiectasis. We welcome this new addition from the 2010 update, which only considered COPD patients with no other respiratory condition. We suggest however that this inclusion group could be written more clearly, for example: Adults (over 16 years) who have COPD with asthma; COPD with bronchopulmonary dysplasia; or COPD with bronchiectasis. This addition is to be welcomed as it reported that between 15 to 45% of patients with COPD have an element of asthma to their condition. [Postma DS & Rabe KF. N Engl J Med 2015;373:1241-9]	Thank you for your comment. We have amended the wording in the scope to make the population clearer. Regarding the evidence-base for these particular groups, we agree that they are often excluded from trial populations, however where evidence does exist, it will be included. If the evidence found for this group is very different to those with COPD alone, then the guideline committee will consider making separate recommendation(s) for these groups.

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				NICE should be aware that the inclusion of these COPD crossover patient groups may require a full review of the evidence, as outcomes for these patients have not been previously considered. In addition many of the COPD RCTs would specifically exclude patients with a co-diagnosis of asthma or bronchiectasis and therefore it may be challenging to identify a dataset that addresses these patient groups. Likewise asthma RCTs would likely exclude patients with COPD and a significant smoking history.	
66	Astrazeneca UK Ltd	6	Table section 1	**Differential diagnosis** The scope states that diagnosing and classifying the severity of COPD will not be subject to evidence review. However, the new addition in the 2017 scope of patients with COPD plus asthma or bronchopulmonary dysplasia or bronchiectasis means that a differential diagnosis is required in order to capture these additional subgroups of patients. We therefore suggest an evidence review for this section.	Thank you for your comments. Any evidence found that has been specifically conducted in these groups of people will be assessed as part of each evidence review for the guideline. If the evidence for these groups are different to the COPD alone population, then the guideline committee will be able to make specific recommendations for these subgroups.
67	Astrazeneca UK Ltd	7	Table section 2	**Management of stable COPD** It is important when considering management what the patient's clinical phenotype is i.e. predominantly symptoms or symptoms but with exacerbations. The evidence base for these two clinical phenotypes is likely	Thank you for your comment. The guideline committee will consider the clinical application of the evidence during the development of the guideline. If there is heterogeneity in treatment effects, then this may be explored by appropriate subgroup analysis to ascertain whether there is an explanation for the heterogeneity.

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				to be different and therefore needs to be considered in the evidence review, and reflected in the final guidance. This comment is also relevant to the section on page 14 starting on line 21.	
68	Astrazeneca UK Ltd	7	Table section 2	**Phosphodiesterase-4 inhibitors** We agree with the presence of PDE4 inhibitors in the guideline scope, and we have noted that the role of PDE4 inhibitors in COPD will be omitted from an evidence review. However, new data does exist for this drug class and has been reflected in the updated GOLD COPD guidelines for 2017. We agree that an evidence review is not necessary so long as the updated technology appraisal for roflumilast (expected June 2017), which considers this new evidence, is included in the guideline recommendations.	Thank you for your comments. Regarding PDE4 inhibitors, the NICE surveillance review identified new evidence, however it was considered insufficient to warrant a change in the current recommendation. NICE has published a TA (TA244, Roflumilast for the management of severe COPD) which will be cross-referred to in the new guideline update. In light of your comment, we have made this clearer in the scope, and added a sentence into the table that explains that the TA will be cross-referred to. The topic of PDE4 inhibitors was therefore not considered to need updating, and therefore excluded from the scope. A lack of implementation of the guideline recommendations is not an issue for guideline development, but should be addressed by local CCGs. The current recommendation will remain as it stands in the new updated guideline.
69	Astrazeneca UK Ltd	9	General	**Evidence review of inhaled therapy** If the scope of the guidance is being expanded to include patients with COPD plus asthma or bronchopulmonary dysplasia or bronchiectasis, then the evidence will require review to capture these sub-groups of patients to ensure robust guidance is produced.	Thank you for your comment. Regarding the evidence-base for these particular groups, where specific evidence does exist, (trials report data for this subgroup or are conducted wholly in these groups of people) it will be included. If the evidence found for this group is very different to those with COPD alone, then the guideline

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					committee will consider making separate recommendation(s) for these groups.
70	Astrazeneca UK Ltd	9	General	**Inhaled therapy** We agree with the need to review the inter-class evidence that exists for inhalers (i.e. LAMA+LABA vs. LAMA; LAMA+LABA vs. LABA+ICS). However the scope also outlines a possible objective to look at intra-class evidence: "long-acting anticholinergics: identifying which is the most effective and who should have treatment". Due to the rapidly changing nature of the inhaler market, this may not be practical for a guideline which will be in place for a number of years. We suggest that NICE focuses only on inter-class differences in inhaled therapies.	Thank you for your comment. We agree that this is a rapidly changing area, however if new evidence suggests that a particular type of LAMA is more effective than others, then it is important that the guideline recommends that people with COPD receive the best possible treatment option available. If new evidence for other agents is published showing them to be more effective, then this will be considered during the NICE surveillance review, who will review the need for the guideline to be updated at regular intervals. There is therefore an opportunity for new treatment options to be considered and recommendations updated, if appropriate.
71	Astrazeneca UK Ltd	10	General	**Inhaled therapy** We have noted that there will not be an evidence review of certain inhaled therapies. We are particularly concerned that the evidence for triple therapy is not going to be reviewed. There are a number of studies published since 2010 looking at free triple therapy, and more recently, the results of fixed triple therapy combinations have been published. Therefore an evidence review of triple therapy is justified.	Thank you for your comment. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or exacerbations persist on current therapy, irrespective of the patient's FEV1. During the NICE surveillance review no new evidence which would change the direction of these recommendations was identified. Triple therapy was therefore not included in the scope and the current recommendations will be retained in the updated guideline.

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72	Astrazeneca UK Ltd	6	Table section 1	**Referral for specialist advice** We agree that 'referral for specialist advice' should be within the guideline scope, and have noted that recommendations from the existing guideline will be retained. The 2010 COPD Clinical Guideline by NICE lists the reasons for referral in Table 5. We suggest that NICE considers the addition to this table of 'exacerbation frequency', as this may direct towards the severity of the COPD, and potentially appropriate interventions that may only be given or initiated in secondary care.	Thank you for your comment. The reasons listed in the table are not meant to be an exhaustive list, which is why we intentionally used the word 'including' intact fissures, Exacerbation frequency may well be another suitable referral criteria, and if there is evidence for this, then it will be picked up in the guideline literature review and assessed as part of the systematic review on this topic, if the studies meet the inclusion criteria set in the review protocol.
114	Birmingham CrossCity CCG	2	13	Evidence has been accumulating that the previous diagnostic criterion of FEV1/FVC<0.7 is incorrect leading to over diagnosis and missed diagnosis. This needs to be reviewed in line with page 3 line 1.	Thank you for your comment. Insufficient new evidence for using LLN measurements was identified as part of the NICE surveillance process, to justify making a change in the current recommendations which recommend FEV1/FVC ratio is used. The new GOLD guidelines have also not adopted this measurement either. LLN is also a measure already reported by spirometry readings so professionals are able to access this data and take it in consideration when making a diagnosis. This topic was therefore excluded from the scope, however the current recommendations on diagnosis as they stand, will appear in the update of the guideline.
115	Birmingham CrossCity CCG	4	1	The equality assessment completely ignores the age and sex discrimination inherent in the current diagnostic criterion of FEV1/FVC<0.7 to define airflow obstruction. This criterion misses true airflow obstruction in young	Thank you for your comment. We agree and have added the issue of this inequality, into the equality assessment form. However, consideration will be given to any

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				women and over diagnoses it in older men. Age and sex discrimination are illegal in the UK in the context of employment and it does not seem just or correct for NICE to allow it to occur in making clinical diagnoses. The paper Chronic obstructive pulmonary disease: missed diagnosis versus misdiagnosis. BMJ 2015; 351: h3021 gives an outline of the evidence behind this.	potential inequalities by the guideline committee, during their discussions on diagnosis.
116	Birmingham CrossCity CCG	6	6	The Table here suggests you will not be reviewing the diagnostic criteria. This is a serious omission. Current criteria greatly over diagnose COPD leading to inappropriate use of scarce resources for no benefit and leads to misdiagnosis. The previous diagnostic criterion of FEV1/FVC<0.7 is not based in science but is a purported convenience for clinical practice. This is not an approved justification for setting diagnostic criteria for any disease in humans. There is only one reference in support of this criterion where it was shown to approximate for men but not in women where the lower limit for this ratio was not constant. It was only constant in men due to poor sampling of older subjects. Every other paper in the literature shows this ratio to fall with age. I quote: “NICE guidelines make evidence-based recommendations….” If you do not review the diagnostic criteria then you are de facto not following the NICE principles. The recent literature references around this issue can be supplied to help you on this.	Thank you for your comment. We are planning to address aspects of diagnosis, including multidimensional assessment indices and further assessments to aid confirmation of diagnosis. This has been listed in the scope. Regarding alternative measures, insufficient new evidence was identified as part of the NICE surveillance process, to justify an update to the current recommendations which recommend FEV1/FVC ratio is used. The new GOLD guidelines have also not adopted this measurement either. Given all these factors, this topic was therefore excluded from the scope.

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29	British Infection Association	10 11	General	*There are studies suggesting that self-initiation of antibiotics and steroids during COPD exacerbation can shorten the duration of the exacerbation (Thorax. 66(1):26-31, 2011 Jan.) or reduce the frequency of hospital admissions (Copd: Journal of Chronic Obstructive Pulmonary Disease. 6(5):352-8, 2009 Oct.) but there are also studies pointing towards the need of appropriate patient selection (Primary and secondary care clinicians' views on self-treatment of COPD exacerbations: a multinational qualitative study. Patient Education & Counseling. 96(2):256-63, 2014 Aug.). COMMENT: we need a systematic review or meta-analysis to confirm there are benefits from self-management and possibly compare with the apparent benefits of alternative strategies such as long-term antibiotic prophylaxis.* **<u>The draft scope document SHOULD mention the desirability of:</u>** a) assessing the impact of self-management including early antibiotics ?beneficial at reducing duration of exacerbation or hospital admission or death or progressive loss of lung function b) comparing early antibiotic self-management versus long-term antibiotic prophylaxis: how do they compare in terms of • Frequency of hospital admissions	Thank you for your comment. The area of self-management has been included in the scope for the update. Early self -management compared to antibiotic prophylaxis will not be considered in the updated scope as no evidence was identified during the NICE surveillance review or scoping for the update that would change the current recommendations in the guideline. These recommendations will be carried forward into the updated guideline.

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				• Progressive loss of lung function • Mortality • Selection of antibiotic resistance	
30	British Infection Association	15	General	What is the clinical and cost effectiveness of prophylactic oral antibiotics for preventing exacerbations in people with stable COPD We are now more aware of the risks associated with long-term azithromycin prophylaxis. a) There are good epidemiological data linking antibiotic-resistance in pneumococci to overall antibiotic consumption: see for instance Eur J Clin Microbiol Infect Dis. 2007; 26(7):485-90. b) A few studies had demonstrated that azithromycin prophylaxis selects resistance: • higher macrolide resistance rate in azithromycin group (bronchiectasis study) JAMA 2013; 309: 1251-9 • COPD study: 81% resistance to macrolides in azithromycin group as opposed to 41% in placebo group ($p<0.001$) and some loss of hearing (N Eng J Med 2011; 365: 689-698) • COPD: increase in strep. Pneumoniae macrolide-R from 14% to 54% (COPD 2010; 7: 337-44) • CYSTIC FIBROSIS on long term azithromycin: 100% resistance to macrolides (JAMA 2010; 303: 1707-15) + increased risk of non-tuberculous mycobacterial infections (J Clin Invest 2011: 121: 3554-63)	Thank you for your comment. We agree. The issues surrounding antibiotic resistance the effects on long-term follow-up, and the adverse events associated with macrolides such as azithromycin, were three of the main reasons identified during the NICE surveillance review that led to this topic being included as a priority for update and therefore included in the draft scope. As part of the guideline evidence review on antibiotic prophylaxis, the impact on antibiotic resistance will be considered as one of the outcome measures and a factor taken into consideration when the guideline committee make recommendations. Both short-term and medium term outcomes will also be assessed as part of the evidence review for the guideline. It is standard practice for most evidence reviews in NICE guidelines, to look at both short and longer-term follow-up. Thank you for providing these references. They will be considered as part of the guideline evidence review on prophylaxis, if they meet the inclusion criteria set by the review protocol.

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				• Should COPD patients be screened for nontuberculous mycobacteria and not offered prophylaxis if culture positive? (N Eng J Med 2012; 367: 340-7) • Editorial in JAMA 2013; 309:1295-6 Macrolides & bronchiectasis: clinical benefit with a resistance price • Alternative to long-term azithromycin have been proposed: pulse treatment AND self-treatment of exacerbations (N Eng J Med 2012; 367:1865) c) Most of the azithromycin prophylaxis trials are short-term (6 months) studies. Are the benefits of prophylaxis sustained beyond 6 months, by which time the patients are colonised by resistant bacteria? In cystic fibrosis one trial examined outcomes beyond six months of azithromycin prophylaxis and did not demonstrate a significant improvement in relative change in FEV1 (Cochrane Database of Systematic Reviews. 2012.) d) Cardiac toxicity risks of macrolide antibiotics • Excess Sudden Cardiac Deaths after Short-Term Clarithromycin Administration in the CLARICOR Trial: Why Is This So, and Why Are Statins Protective? Cardiology 2011;118:63–67 • Cardiovascular events after clarithromycin use in lower respiratory tract infections: analysis of two prospective cohort studies. BMJ 2013;346:f1235 doi: 10.1136/bmj.f1235 • Azithromycin may also increase cardiovascular death risk !!! N Engl J Med 2012; 366:1881-1890	

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				• Wenzel (N Eng J Med 2012; 367: 340-7) proposed that patients at risk from cardiovascular disease should not receive azithromycin prophylaxis, but most COPD patients (smoker, ex-smokers) are at risk macrolides including azithromycin	
31	British Infection Association	15	General	**The scope of the review SHOULD be broadened to include:** a) The impact of long term antibiotic prophylaxis in terms of selection of resistance b) Whether the benefit of long term-antibiotic prophylaxis are sustained beyond the initial 6-months (most of the studies published were over 6-months): it is possible that the benefit may not be sustained due to the selection of resistance or other reasons c) Whether long-term antibiotic prophylaxis is more or less effective than alternative strategies (short azithromycin courses i.e. pulse treatment or self-management with early antibiotics) and whether the alternative strategies bring about a reduction in the selection of antibiotic resistance: if there were not any studies answering these questions, recommendations should be made for appropriate studies d) What are the risks (if any) in terms of cardiac toxicity, of long-term antibiotic prophylaxis with macrolides including azithromycin	Thank you for your comment. We agree the issues surrounding antibiotic resistance the effects on long-term follow-up, and the adverse events associated with macrolides such as azithromycin, were three of the main reasons identified during the NICE surveillance process that led to this topic being included as a priority for update and therefore included in the draft scope. As part of the guideline evidence review on antibiotic prophylaxis, the impact on antibiotic resistance will be considered as one of the outcome measures and a factor taken into consideration when the guideline committee make recommendations. Both short-term and medium term outcomes will also be assessed as part of the evidence review for the guideline. It is standard practice for most evidence reviews in NICE guidelines, to look at both short and longer-term follow-up.

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32	British Infection Association	2.7	General	What is the clinical and cost effectiveness of prophylactic oral antibiotics for preventing exacerbations in people with stable COPD We feel research is lacking in this particular area as illustrated above and more research is required in order to make recommendations.	Thank you for your comment. The NICE surveillance review as part of reviewing the original guideline for update, identified what was considered sufficient new evidence on the topic of prophylactic oral antibiotics, that warranted this being included in the scope as an area that needs addressing in the guideline. However, additional recommendations for future research can be made by the guideline committee when the evidence is reviewed for the guideline, if they find that the evidence is sufficiently inconclusive to make a definitive recommendation.
85	British Lung Foundation	General	General	The British Lung Foundation welcomes this consultation on the draft scope for NICE's clinical guideline on the diagnosis and management of COPD in over 16s. We believe that a robust clinical guideline will help support improved service provision for patients for COPD across a range of interventions. We are keen to ensure that the finalised scope for this guideline will: • Ensure that there is evidence review on pulmonary rehabilitation (PR), following the publication of the findings of the National COPD Audit and various BTS guidance documents • Ensure that while there can be a level of interaction between the two, there is recognition	Thank you for your comments. Regarding pulmonary rehabilitation, the NICE surveillance review identified new evidence for pulmonary rehabilitation, however it broadly supports the current recommendation (to provide PR). The topic of pulmonary rehabilitation, was therefore not considered to need updating, and therefore excluded from the scope. Lack of implementation is not an issue that can be addressed in guideline development, but is an issue for the local CCGs. The current recommendation will remain as it stands in the new updated guideline. Regarding self-management and telehealth, we agree with your comment and we have separated the terms in the scope. In terms of tele-healthcare, new evidence was identified for its effectiveness in COPD, and this will therefore be included in the guideline update. In terms of

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				that self-management and telehealth are distinct areas • Ensure that the evidence review for self-management will lead to better recognition of self-management	'true' self-management, NICE surveillance identified new evidence for the effectiveness of self-management interventions, which would lead to a change in the current recommendation, and therefore this will be included as an area for update in the scope. We understand that the definition of telehealthcare can be confusing and can be interpreted to mean different things Telehealthcare has different elements compared to a strict definition of self- management. We therefore agree with your comments and these differences will be highlighted in the scope; self- management and telehealth will be separated rather than grouped together. Teleheathcare may also be considered to have elements of self-management, when the treatment recommended by this type of remote monitoring, is administered by the person with COPD themselves. This is why we initially grouped telehealthcare together with self-management. We have amended the wording to say 'home' teleheathcare, since the studies that the NICE surveillance review identified, used home tele monitoring as their intervention.
86	British Lung Foundation	7	1-3	The draft scope currently specifies that there will not be a review of evidence PR, and that existing recommendations from current guidelines will be retained as they are.	Thank you for your comments. Thank you for providing these references, although these studies and reports show areas of change required in PR services, they do not report on the effectiveness of specific components of PR interventions, which is what would be required to update

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				We believe that an evidence review should be undertaken, with the view to introduce new and updated recommendations on PR. The principal pieces of new evidence are the two reports of the Royal College of Physician's National COPD Audit Programme - *Time to breathe better* and *Steps to breathe better*, which focus on PR services in England and Wales in 2015. These reports detail national data relating to the resourcing and organisation of PR services, and form the first comprehensive national audit of PR provision anywhere in the world. They also document attainment against relevant PR guidelines and quality standards, as published by the British Thoracic Society (BTS) in 2013 and 2014. Evidence from these reports suggest the need for improvements in clinical practice across a number of areas, which should be driven through new or updated recommendations in NICE guidance. Some of these recommendations are similar to existing recommendations within BTS guidelines published since 2010. These recommendations include: **The need to ensure that PR programmes include a defined, structured education programme, and that people completing PR are provided with an**	the current guideline recommendations to include the detail that you suggest needs adding. The NICE surveillance review identified new evidence for pulmonary rehabilitation, however it broadly supports the current recommendation (to provide PR). The topic of pulmonary rehabilitation, was therefore not considered to need updating, and therefore excluded from the scope. Lack of implementation and the development of SOPs is not an issue for guideline development, but should be addressed by local CCGs. The current recommendation will be carried forward and remain as it stands in the new updated guideline.

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				individualised structured written plan for ongoing exercise maintenance (discharge bundles) The report identified that a sizeable minority (35%) of programmes do not offer a clear, written plan for ongoing exercise and maintenance to all patients after completion of treatment. These plans help ensure that the benefits of PR are maintained for a longer period of time, which helps support patient quality of life and prevent further readmissions. According to the BTS quality standard on PR (2014), these plans should include aerobic and strength exercises alongside giving information about local gyms, walking clubs and local amenities. These plans are very important in ensuring that a patient is able to self-manage their condition. Self-management plays an important role in the prevention of exacerbations, but also in improving quality of life and mitigating against condition-related anxiety. **The need for pulmonary rehabilitation programmes to produce an agreed standard operating procedure.** The report identified that only 67% of programmes had a standard operating procedure (SOP), with 'considerable variation in the settings within which PR is provided and within the organisation of programmes'. A SOP covers	

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				areas such as accessibility, patient centre, minimum staffing, capacity, and environment and risk assessments. This suggests the need to clarify section 1.2.8.3 in the 2010 guideline, which calls for PR programmes to be 'effective', and to 'improve concordance' and to be 'held at times that best suit patients', to better outline what it means for a PR service to be 'effective'. This evidence suggests that there is some confusion regarding what constitutes effectiveness *Time to breathe* better is available via: https://www.rcplondon.ac.uk/file/2134/download?token=Aoa5vyiQ Steps to breathe better is available via: https://www.rcplondon.ac.uk/file/2767/download?token=HK0AKTbi The new BTS guidelines on PR are available here: Clinical guideline (2013) https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guideline-on-pulmonary-rehabilitation-in-adults/ Quality standard (2014) https://www.brit-thoracic.org.uk/document-library/clinical-	

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				information/pulmonary-rehabilitation/bts-quality-standards-for-pulmonary-rehabilitation-in-adults/	
87	British Lung Foundation	9	NA	We do not believe that self-management and telehealth should be defined in such close ways, as they are different by definition, which can be summarised below. This means that they should be discussed in distinct rather than combined terms when conducting an evidence review and developing the new guideline. Self-management – involves the provision of advice, guidance and support to help people self-manage their condition. It involves the provision of information on how to manage breathlessness, including mastering effective breathing and sputum clearance techniques. These are structured and personalised approaches which motivate, engage and support the positive adoption of healthy behaviours, with the development of skills to better manage conditions. Telehealth – involves using technology to enable healthcare professionals to remotely monitor data on certain aspects of a patient's health. It may include sensors that can monitor the amount of oxygen in a person's blood, or more straightforward examples, such as telephone check-ups.	Thank you for your comment. We understand that the definition of telehealthcare can be confusing and can be interpreted to mean different things. Telehealthcare has different elements compared to a strict definition of self- management. We therefore agree with your comments and these differences will be highlighted in the scope; self- management and telehealth will be separated rather than grouped together. Teleheathcare may also be considered to have elements of self-management, when the treatment recommended by this type of remote monitoring, is administered by the person with COPD themselves. This is why we initially grouped telehealthcare together with self-management. We have amended the wording to say 'home' teleheathcare, since the studies that the surveillance review highlighted as evidence, used home tele monitoring as their intervention.

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88	British Lung Foundation	9	NA	We are keen to ensure that NICE will conduct an evidence review that leads to the recognition that self-management is more than the process of spotting and responding to exacerbations. Rather, as described above, self-management refers to planned and supported actions to recognise, treat and manage their own health. The evidence base exploring types of self-management interventions can be found in a 2014 Cochrane Review of self-management for patients with COPD. This review is available below, and should be considered by NICE: Effing, T et al (2014) *Self-management for patients with chronic obstructive pulmonary disease* Cochrane Airways Group http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002990.pub3/full	Thank you for your comment. We understand that the definition of telehealthcare can be confusing and can be interpreted to mean different things. Telehealthcare has different elements compared to a strict definition of self- management. We therefore agree with your comments and these differences will be highlighted in the scope; self- management and telehealth will be separated rather than grouped together. Teleheathcare may also be considered to have elements of self-management, when the treatment recommended by this type of remote monitoring, is administered by the person with COPD themselves. This is why we initially grouped telehealthcare together with self-management. We have amended the wording to say 'home' teleheathcare, since the studies that the surveillance review highlighted as evidence, used home tele monitoring as their intervention.
33	British Society for Antimicrobial Chemotherapy (BSAC),	**9**	General	Table 2 Management of stable COPD – Oral Antibiotics Please can NICE discuss which antibiotics should be considered in order to reduce development of resistance and clostridium difficile.	Thank you for your comment. One of the main aims of the review question is to address this issue. Antibiotic resistance will be included as one of the main outcome measures in the review of the evidence for this topic.
35	British Thoracic Society	5	14	Role of inhaled corticosteroids (ICS): there is new evidence supporting use of stable state blood eosinophil counts (absolute count 0.3 or higher) to identify which patients are likely to gain additional benefit from ICS	Thank you for your comment.

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				(Pavord Thorax 2016; Watz Lancet Respir 2016). This data is relevant to the planned review of management of stable COPD (page 14) including: a) LABA/LAMA v ICS/LABA (FLAME showed LABA/LAMA was superior regardless of eosinophil status, however those with higher eosinophil counts may benefit from stepping up to triple therapy if further problems arise); and b) LABA/LAMA v ICS/LABA/LAMA. The potential cost saving is substantial: triple therapy with the market leading options (Seretide and Tiotropium) costs either side of £1,000 per year depending on the device selected. The new LABA/LAMA combinations cost £390 per year. Note: see page 10 (no current plans to review triple therapy).	Regarding blood eosinophil counts, this is an issue which could be covered and addressed by subgroup analysis of the data. We will be looking at the evidence for ICS/LABA, it was accidentally missed from the scope and has now been added in. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or exacerbations persist on current therapy, irrespective of the patient's FEV1. During the review for update process, the NICE surveillance review did not identify any new evidence which would change the direction of these recommendations. Triple therapy was therefore not included in the scope and the current recommendations will be retained in the updated guideline.
36	British Thoracic Society	6	6	Differential diagnosis – no plans to review evidence. Among patients on COPD registers, misdiagnosis rates raise concern. With increasing use of ICS-free regimes in COPD, identification of patients with primary or coexistent asthma is more important than ever. If such regimes are endorsed (as seems likely), this should be highlighted and existing patients should only be switched following clinical review, including re-confirmation of the diagnosis. Consider addressing Asthma and COPD Overlap Syndrome.	Thank you for your comments. Differential diagnosis: the current guideline already has recommendations around identification of early disease. Insufficient new evidence was identified as part of the NICE surveillance process, to justify making a change in the current recommendations This topic was therefore excluded from the scope, however the current recommendations on early identification as they stand, will appear in the update of the guideline. The population

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				Identification of Early Disease – no plans to review evidence. Diagnosis is often delayed, and opportunities to improve outcomes consequently missed. This is an area of concern. The decision not to review the severity classification for airflow obstruction is appropriate; arguably this was given too much weight previously. There is increasing recognition of the importance of symptom burden and exacerbation frequency in severity assessment; I assume this will be addressed under the remit of Assessing severity and prognostic factors. Simplicity is important to ensure adoption (e.g. GOLD 2017).	of COPD / Asthma has been included in the scope, and any evidence found in this group will be assessed. If the evidence for this group is different to the COPD alone population, then the guideline committee will be able to make specific recommendations for this group. Early disease identification: the current guideline already has recommendations around identification of early disease, we are unclear what you think should be changed in these recommendations? Insufficient new was identified as part of the NICE surveillance process, to justify making a change in the current recommendations This topic was therefore excluded from the scope, however the current recommendations on early identification as they stand, will appear in the update of the guideline. Regarding severity classification, under this section we are planning to look at the use of multidimensional assessment tools, such as BODE. Measures in this evidence review for the guideline are likely to include symptoms and exacerbation frequency.
37	British Thoracic Society	7	1	Theophylline: a randomised controlled trial of low dose theophylline in COPD is expected to be completed ~ June 2017 (TWICs). Roflumilast: consider including a statement, referencing the recent NICE review.	Thank you for providing this information. We will ensure that the guideline refers to other appropriate guidance in the relevant place. A referral to TA244 on Roflumilast will be included in the guideline. In light of your comment, we have made this clearer in the

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				NIV: there is important new data worthy of review: a) stable state COPD: Kohnlein Lancet Respiratory 2014: this RCT selected patients with a PaCO2 > 7kPa, and in the NIV arm ventilatory support was titrated aiming to achieve a reduction in PaCO2 of at least 20% or to <6.5kPa. The trial was halted prematurely due to a larger than expected 1 year mortality difference: NIV= 12% v control= 33%; b) post exacerbation requiring ventilation: The RESCUE trial (Thorax 2014) was negative, however a UK RCT of home NIV post COPD exacerbation requiring assisted ventilation (HOT HMV) showed NIV reduced the time to readmission or death (NNT = 6). In contrast to the RESCUE trial, patients were only included in HOT HMV if they had persistent hypercapnia two weeks after recovery. The results have been presented (ERS and BTS) and the primary paper is currently under review. A health economic analysis is in progress (expected to be completed May 2017). There are also two recent small single centre RCTs favouring NIV in this setting. Endobronchial valves and coils: recommend reviewing the evidence.	scope, and added a sentence into the table that explains that the TA will be cross-referred to. The current guideline already makes recommendations about when NIV should be given. Thank you for highlighting the studies in progress. These will be considered in further NICE surveillance reviews if they meet the review criteria. Regarding valves and coils for lung volume reduction surgery, the NICE surveillance review identified new evidence, however it was considered consistent with current guideline recommendations. Current guideline recommendations provide referral criteria for lung volume reduction surgery, but they do not specify the type of surgery that should be conducted. This would be considered a clinical judgement based on the expertise of the healthcare professional and the individual needs of the person with COPD who is presenting to them. The topic of surgery was therefore not considered to need updating, and therefore excluded from the scope. The current recommendation will remain as it stands in the new updated guideline.
38	British Thoracic Society	10 11	General	Assessment of the severity of an exacerbation and Hospital-at-home and assisted discharge schemes – no evidence review**.** I strongly recommend that new data in this area is considered. The last NICE guideline	Thank you for your comment and for providing details of this study. These studies were not included in the NICE surveillance review because they were not meta-analysis of RCT data. We already have a

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				recommended these services for low risk patients, but stated that there was insufficient data to make firm recommendations about which patients are most suitable for hospital at home. Subsequently, the DECAF prognostic score has been developed in 2,645 patients across 6 UK hospitals, showing excellent performance (Steer Thorax 2012; Echevarria Thorax 2016: AUROC 0.82 – 0.86). DECAF is superior to alternative tools. Moreover, in exacerbations of COPD complicated by pneumonia, CURB65 is unreliable (in-patient mortality for low risk scores: DECAF = 1.6%; CURB65 = 7.2%: Echevarria 2016). There is no loss in DECAF performance when limited to patients without co-existent consolidation. The 2014 National COPD Audit report recommended DECAF is scored in all patients admitted with an exacerbation and DECAF is included in the rolling audit. Of importance, 45-53% of admitted patients are low risk by DECAF, thus potentially suitable for Hospital at Home. The results of an RCT of hospital at home compared to inpatient care (RfPB) were presented at the British Thoracic Society Winter Meeting 2016 and will be submitted for publication shortly (I am the CI). Hospital at home was safe (no acute deaths), clinically effective (no increase in readmissions) and preferred by 90% of patients. Mean total health and social care cost over 90 days (capturing any transfer between health and social	recommendation which says that hospital at home is safe and effective for caring for people with exacerbations, and therefore this new evidence (also showing benefit), will not lead to a change in the current recommendation. This topic was therefore not included in the scope for the guideline update. However, the existing recommendations from the 2010 guideline will be carried forward into the updated guideline.

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				care budgets and the critical period for readmission risk) was £1,016 lower in the Hospital at Home arm. NHS England has agreed to support the creation of virtual wards to support this model of care. Selection by DECAF provides simple clear criteria to identify patients, and allows inclusion of at least double the proportion of patients compared to earlier models. The potential implications for patients and the wider NHS are large. Predictors of acute mortality risk differ from those for readmission. In the 2,417 patients across the DECAF cohorts who survived to discharge, a tool for risk of readmission within 90 days was developed (PEARL: Thorax in press). This may assist allocation of scarce resources post discharge, as well as informing future research trials in which readmission is an outcome.	
39	British Thoracic Society	11	Table	Non-invasive ventilation and COPD exacerbations: the current UK BTS/ICS NIV guideline (figure 1) states that NIV is “Not Indicated” in pneumonia. This statement is primarily aimed at patients with isolated pneumonia. However when pneumonia complicates an exacerbation of COPD NIV is of benefit. Most such patients are considered “not for intubation”, therefore risk being denied any form of ventilatory support. It would be useful to clarify that NIV should be considered in such cases: Confalonieri Am J Respir Crit Care Med 1999;160:1585–91; http://www.respiratoryfutures.org.uk/features/dyspnoea-	Thank you for your comment. Regarding criteria for starting NIV, the current guideline already makes recommendations about when NIV should be given and therefore we will not be updating this section of the guideline and it has not been included in the scope.

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				eosinopenia-consolidation-acidaemia-and-atrial-fibrillation-decaf-prognostic-score	
40	British Thoracic Society	8	General	Palliative care – no plans to review. Consider including palliative care and end of life issues within the remit. Patient selection is often challenging; clearer guidance in this respect may improve the current under provision of palliative care (e.g. Prognostic Indicator Guidance criteria for COPD).	Thank you for your comments. Regarding palliative care, no new evidence was identified that would affect recommendations. During the previous NICE surveillance review, it was considered that evidence identified was unlikely to change guideline recommendation on palliative care: patients with end-stage COPD and their family and carers should have access to the full range of services offered by multidisciplinary palliative care teams, including admission to hospices. The NICE surveillance review did identify new evidence for palliative care, however it was considered that it would be unlikely to lead to a change in the current recommendation. The topic of palliative care, was therefore not considered to need updating, and therefore excluded from the scope. . In light of your comment, we have made make this clearer in the scope, and added a sentence into the table that explains that the NICE end of life care guideline will be cross-referred to. Lack of implementation of the guideline recommendations is not an issue for guideline developers but is an issue for local CCGs to address. The current recommendation will remain as it stands in the new updated guideline.

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73	Chiesi Ltd	General	General	The draft guideline scope details key areas in which evidence and recommendations will be reviewed. We are concerned that in Section 2: Managing stable COPD and preventing disease progression, inhaled corticosteroid/ long-acting beta$_2$-agonist (ICS/LABA) combination inhalers have not been included as an area in which evidence will be reviewed or updated. Since the publication of the last NICE guideline on the management of COPD in June 2010, many clinical studies have been conducted and indeed published on the use of ICS/LABA combination inhalers for the management of COPD. Key studies such as Singh 2014 (FUTURE study)[1], Wedzicha 2014 (FORWARD study)[2], and Dransfield 2013[3]. Furthermore, since 2010 two new combinations of ICS/LABA inhalers have been developed, (fluticasone furoate/vilanterol and fluticasone propionate/formoterol), and many other ICS/LABA combinations have gained new devices or strengths. We believe that there is a wealth of new evidence for the use of ICS/LABA combination inhalers in COPD, which should be assessed when updating recommendations on the use of inhaled therapy in the management of COPD. [1] Singh D et al. BMC Pulm Med, 2014; 14: 43 [2] Wedzicha JA et al. Respir Med, 2014; 108: 1153-1162	Thank you for your comment. One of the topics included in the draft scope is ICS/LABA combination when compared to LABA/ LAMA. The whole of the treatment pathway is planned to be updated in the new guideline, which will include ICS. Thank you for providing these references, they will be considered as part of the evidence review for the guideline if they match the inclusion criteria set out in the guideline review protocol.

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				[3] Dransfield M et al. Lancet Respir Med, 2013; 1: 210-223	
74	Chiesi Ltd	7	General	There is specific regulatory guidance from the European Medicines Agency[1] on how a pharmacological intervention should demonstrate a reduction in exacerbations. An important element is assessing the outcome of moderate or severe exacerbations, as these two sub-categories of exacerbation have been shown to be clinically relevant. For a pharmacological intervention to gain a licence for exacerbation risk reduction, it must be able to demonstrate that it's supporting clinical trials successfully meet the EMA requirements. We recommend that the scope of the guidance is broadened to include assessment of the clinically relevant exacerbation risk reduction data (those trials which measure moderate to severe exacerbations) across all pharmacological intervention classes. It should be considered that within a number of recently published studies assessing exacerbation reduction, it is not clear from the definition of an exacerbation, whether indeed moderate to severe exacerbations have been assessed. [1] European Medicines Agency. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000426.jsp&mid=WC0b01ac0580034cf6 [Accessed 23/02/17]	Thank you for your comment. The guideline has already included definitions of exacerbations that are evidence-based. The NICE surveillance review as part of reviewing the original guideline for update, did not identify sufficient new evidence that would change the current recommendations. The guideline definition is therefore not planned to be updated. However the guideline committee will be able to discuss the EMA criteria for trial definitions of a reduction in exacerbations when they look at the available evidence and what they consider to be a clinically relevant change. Thank you for highlighting this information

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75	Chiesi Ltd	10	General	A proposed outline for the new guideline is given, detailing specifically on page 10, that there is no new evidence for either dual therapy with ICS plus LABA or triple therapy (ICS plus LABA plus LAMA). We are concerned that there will be no evidence reviews undertaken in these areas, which mean that recommendations on the choice of inhaled therapy in COPD have not been based on an appraisal of all the evidence in this area. As highlighted in comment 1 above, we believe that there is sufficient new evidence for the use of ICS/LABA combination inhalers in the management of COPD in order that this evidence is considered for review. In addition, a number of phase III clinical trials for the use of novel triple therapy combinations have been recently published. [1,2,3,4] It can be seen from clinicaltrials.gov that many trials are currently on-going in this area, with a further influx of new data to be expected during the development of this guideline. Indeed, it is anticipated that two triple therapy combinations (extrafine beclometasone/formoterol/glycopyrronium and fluticasone furoate/vilanterol/umeclidinium) will likely be available in the next twelve months (please refer to the PharmaScan website for details of timelines).	Thank you for your comment. We will be looking at the evidence for ICS/LABA, it was accidentally missed from the scope and has now been added in. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or exacerbations persist on current therapy, irrespective of the patient's FEV1. During the review for update process, NICE surveillance did not identify any new evidence which would change the direction of these recommendations. Triple therapy was therefore not included in the scope and the current recommendations will be retained in the updated guideline. There will be further opportunities for the guideline to be updated based on new evidence that will be published after the guideline has been published. At regular intervals after publication, NICE surveillance reviews whether there is a need for the guideline or parts of the guideline to be updated. And so if there is substantive new evidence that is likely to lead to a change in the current recommendations, this will be picked up then. However, if you feel that new evidence demands more immediate consideration, this can be submitted to NICE and considered before the next scheduled NICE surveillance review. Thank you for making us aware of the studies that are currently being undertaken, this is helpful information that will be considered for future updates of the guideline.

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				It would be appropriate therefore that given the time which has elapsed since the publication of the previous NICE guideline on this topic, that this new evidence be considered for review. Please also consider delaying the publication of this guideline until the launch of these novel triple therapy combination products given that they will impact current practice. [1] Singh D et al. Lancet, 2016; 388: 963-973 [2] Siler TM et al. Respir Med, 2015; 109(9): 1155-63 [3] Pascoe SJ et al. Eur Respir J, 2016; 48(2): 320-30 [4] Sousa AR et al. NPJ Prim Care Respir Med, 2016; 26.	
76	Chiesi Ltd	5	30, 31	There is specific regulatory guidance from the European Medicines Agency[1] on how a pharmacological intervention should demonstrate a reduction in exacerbations. An important element is assessing the outcome of moderate or severe exacerbations, as these two sub-categories of exacerbation have been shown to be clinically relevant. For a pharmacological intervention to gain a licence for exacerbation risk reduction, it must be able to demonstrate that it's supporting clinical trials successfully meet the EMA requirements. We recommend that the scope of the guidance is broadened to include assessment of the clinically relevant exacerbation risk reduction data (those trials which measure moderate to severe exacerbations) across all pharmacological intervention classes. It should be	Thank you for your comment. The guideline has already included definitions of exacerbations . The NICE surveillance review as part of reviewing the original guideline for update, did not identify sufficient new evidence that would change the current recommendations. The guideline definition is therefore not planned to be updated. However the guideline committee will be able to discuss the EMA criteria for trial definitions of a reduction in exacerbations when they look at the available evidence and what they consider to be a clinically relevant change. Thank you for highlighting this information.

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				considered that within a number of recently published studies assessing exacerbation reduction, it is not clear from the definition of an exacerbation, whether indeed moderate to severe exacerbations have been assessed. [1] European Medicines Agency. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000426.jsp&mid=WC0b01ac0580034cf6 [Accessed 23/02/17]	
77	Chiesi Ltd	6	1, 2, 3	As above in comment 5	Thank you for your comment.
78	Chiesi Ltd	14	27, 28, 29	As above in comment 5	Thank you for your comment.
55	Cochrane Airways Group	General	General	I think that case finding and adherence are both very important challenges in primary care. The cost of starting people with very early COPD on treatment would need to be underpinned by strong evidence that this beneficial! Case finding needs to be appropriate. Adherence to inhalers is also a challenge with the increasing number of different inhalers that are available. I wonder if you should consider whether adherence is improved when all treatments are given through the same type of inhaler.	Thank you for your comment. We agree with your comment about case-finding needing to underpinned by very strong evidence. Regarding case-finding, in terms of case-finding within the primary care setting, there is an existing recommendation in the 2010 guideline (see recommendation 1.1.1.1 and 1.1.1.2 in the short version of the 2010 guideline) which covers this. These recommendations outlines criteria (including age, smoking status, and particular symptoms) that should lead a healthcare professional to suspect the person presenting may have COPD. If the person is considered as being suspected of having COPD, then the guideline

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					recommends spirometry to confirm the diagnosis (see recommendations in section 1.1.2). The current recommendations will be carried forward in the new updated guideline. We will however, be updating the recommendations on further investigations to confirm the diagnosis. Regarding case-finding in the general population, currently there is little evidence to suggest that control and progression of disease is improved if people are caught and treated early. There is currently no clear evidence for this being the case. A large recent trial on targeted case-finding (Jordan 2016), showed promising results but did not look at the effects on clinical outcomes and as such the effectiveness of the intervention remains unproven. Consequently, this area was not prioritised for update. Should further evidence become available, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication). Regarding adherence and inhaler type, we agree that these factors are important contributors to adherence. The guideline already contains recommendations pertaining to this and so we are not planning to update this.

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56	Cochrane Airways Group	15	12	I am not clear how you will address the most effective Long acting anticholinergic (LAMA) for COPD, when the LAMA will sometimes be in a single inhaler and sometimes combined with a long-acting beta-agonist (LABA), so perhaps this should be two separate effectiveness questions for single and combination LAMA inhalers.	Thank you for your comment. We have made the wording clearer in the scope to say LABA and LAMA in combination, and replaced the word 'anticholinergics' to say LAMA, where it refers to monotherapy. As part of the NICE surveillance process, new evidence was identified for specific LAMA monotherapies (under the review question of 'anticholinergics'), but was not compared to combination therapy (which is the content of the review questions in the section on inhaled therapy). We agree that terminology may be the source of confusion, and this will be checked by the guideline committee when the guideline is updated. In the original guideline, the term long-acting 'anticholinergics' was used to refer to LAMA.
89	CSL Behring	7	28	The draft scope for the update states "No evidence review: retain recommendations from existing guideline" in relation to alpha-1 antitrypsin replacement therapy (AAT). Currently, NICE CG101 states that AAT is not recommended for patients with alpha-1 antitrypsin deficiency (recommendation 1.2.11.1) which was based on an evidence review in 2004. This evidence review was therefore conducted 13 years ago, and as such, only identified one RCT (Dirksen, 1999) and one registry study group (The Alpha 1-Antitrypsin Deficiency Registry Study Group, 1998). Since this time, additional RCTs have been conducted and published and there is now a wealth of evidence	Thank you for your comment. We have been made aware of an updated Cochrane review on A1AT therapy (Gotzsche, 2016) which was published after the NICE surveillance searches were undertaken. This contains 3 RCTs, and concludes that there is no benefit to treatment with A1AT augmentation. Therefore the evidence is unlikely to have an impact on the current recommendation. Edgar (2016) is a systematic review on various interventions for A1AT treatment, with only 3 RCTs included in IV augmentation therapy, the same that were included in the Cochrane review. We understand that

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				relating to AAT. A recent systematic review was conducted using standard review methodology with meta-analysis and narrative synthesis (registered with PROSPERO-CRD42015019354: http://thorax.bmj.com/content/71/Suppl_3/A155.3). Eligible studies were those of any treatment used in severe alpha-1 antitrypsin deficiency, with RCTs as the primary focus. The authors analysed 51 trials with 5632 participants in total, including 26 AAT trials of which 3 were included in a meta-analysis. The meta-analysis demonstrated AAT slows lung CT density decline (p = 0.002) compared to placebo and therefore slows the progression of severity of emphysema. Furthermore, in 2015, EMA granted marketing authorisation for the first UK licensed AAT, Respreeza. Respreeza has been evaluated in the largest RCT of AAT to date, which is published (http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60860-1.pdf) along with the recent extension phase of the RCT demonstrating efficacy of Respreeza up to 4 years (http://www.thelancet.com/journals/lanres/article/PIIS2213-2600(16)30430-1/fulltext). Recommendation 1.1.3.3 of the current CG101 states that patients identified as having alpha-1 antitrypsin deficiency should be offered the opportunity to be referred to a	AAT has some beneficial effects, but there is not sufficient evidence to change the current recommendation. McEvaney (2017) was an open label extension of the RAPID trial and was not identified in the NICE surveillance review as it is not a SR and it was published after the surveillance search dates. Chapman (2015): this study was not identified by the NICE surveillance searches because we only looked for systematic reviews (SR) for the 6 year review. However Chapman (2015) was included in a Cochrane review by Gotzsche (2016) which concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant a change to the current recommendations, and the quality of the evidence was also unclear. We have also looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations, and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available that related to current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals

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				specialist centre to discuss the clinical management of this condition. Consequently, evidence relating to treatment options for alpha-1 antitrypsin deficiency should be considered in the review of CG101 to ensure optimal management of the condition.	after publication) and may be included in the scope for the next update.
79	GlaxoSmithKline, UK	General	General	GSK are grateful for the opportunity to comment on the draft scope of the NICE COPD management guideline. Please note that GSK can provide a dossier of key published clinical studies and abstracts upon request.	Thank you for your comment, and your offer to provide the dossier.
80	GlaxoSmithKline, UK	4	14	**Section 3.1: Who is the focus?** ***"****Adults (over 16 years) with COPD and asthma, bronchopulmonary 14 dysplasia, or bronchiectasis"* We believe it is important to also include patients where asthma and COPD coexist i.e. Asthma-COPD Overlap (ACO). This patient population is described in the GOLD 2017 Strategy Document and 2017 GINA guidelines.	Thank you for your comment. We will be looking at this population as part of the guideline update, and this was the intention of what was written in section 3.1 of the draft scope. The wording of section 3.1 has now been made clearer to reflect this.
81	GlaxoSmithKline, UK	5	General	**Section 3.3: Activities, services or aspects of care – key areas that will be covered in this update** *"Managing stable COPD and preventing disease progression"* GSK welcomes the decision to review current (and presumably emerging) evidence for the management of stable COPD using inhaled therapies. We note that bronchodilators are specifically mentioned as separate bullet points in this overview section (LABA/LAMA and	Thank you for your comment. We will be looking at the evidence for ICS/LABA, it was accidentally missed from the scope and has now been added back in. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or exacerbations persist on current therapy, irrespective of the patient's FEV1. During the review for update process, the NICE surveillance review did not identify any new evidence which would change the direction of these recommendations. Triple therapy was

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				LAMA). There is a robust evidence-base supporting the role of ICS/LABAs in managing COPD as well as a growing number of clinical trials assessing the safety and efficacy of triple therapy (ICS/LABA/LAMA); we believe that these interventions merit inclusion as separate bullet points. Please refer to the section entitled "*Proposed outline for the guideline*" below for further comment. **Section 3.3: Activities, services or aspects of care- Diagnosing and classifying the severity of COPD** "*assessing severity and prognostic factors (for example multidimensional severity assessment tools"* GSK supports a thorough evidence-based review of the criteria and tools used to diagnose and assess the disease severity and prognosis of patients with COPD. Moreover, given the heterogeneous nature of this progressive disease, we believe COPD is best managed by adopting a patient-centric approach, taking into consideration factors such as symptom-burden and exacerbation risk to pre-define subgroups and thereby recommend effective treatments. The other factors we would consider are patient preference/ability to use an inhaler device and their co-morbidities. As you are aware, the 2017 Global initiative for Chronic Obstructive Lung Disease (GOLD) guidelines has separated assessment of airflow limitation from	therefore not included in the scope and the current recommendations will be retained in the updated guideline. Multidimensional tools: thank you for your comment, we agree and this topic will be updated. Escalation and de-escalation of treatment: the plan for the new guideline is that the entire treatment pathway for inhaled therapy will be updated, and this will give the opportunity for the guideline committee to make recommendations on escalation and de-escalation where appropriate. Severity assessment tools: in this section we are planning to revisit the topic which will include looking at the use of multidimensional assessment tools, such as BODE and GOLD ABCD criteria as well as other measures. This will therefore not exclude other measures, and if the evidence- base supports a change which is in line with the new GOLD ABCD criteria or a different criteria, then the current recommendation will be updated. Early identification: the current guideline already has recommendations around identification of early disease, which includes the factors that you mention. We are unclear what you think should be changed in these

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				assessment of patient symptoms and risk of exacerbations. The symptoms and risk of exacerbations assessments now informs on which treatment options may be suitable for patients; thereby supporting the patient-centric approach. It would however, be useful to receive additional guidance for how to escalate or deescalate treatment in patients and what this would entail. Severity assessment tools like the COPD Assessment Test (CAT), has become widely accepted and an established method of collecting patient-oriented data on symptoms and impact of COPD (Karloh, Chest. 2016 Feb;149(2):413-25). It is adopted as a measure of COPD symptomatology by all major COPD professional associations and features as a measure of COPD assessment in the GOLD 2017 guide management of stable COPD. For early iidentification of disease, chronic mucus hypersecretion is a trait easily clinically ascertained either using chronic bronchitis questions from the Medical Research Council (MRC) measure or using the health status measures like the COPD Assessment Test (CAT) (Kim V, Ann Am Thorac Soc. 2015 Mar;12(3):332-9). It is associated with an increased risk of development of COPD and worse prognosis of COPD (Kim V, Ann Am	recommendations? Insufficient new evidence was identified as part of the NICE surveillance process, to justify making a change in the current recommendations This topic was therefore excluded from the scope, however the current recommendations on early identification as they stand, will appear in the update of the guideline. Biomarkers: this is an issue which could be covered and addressed by subgroup analysis of the data. Thank you for providing these references, they will be considered as part of the evidence review for the guideline if they match the inclusion criteria set out in the guideline review protocol.

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				Thorac Soc. 2016 Jul;13(7):1016-25; Allinson, Am J Respir Crit Care Med. 2016 Mar 15;193(6):662-72) Biomarkers have been gaining attention on how they may aid in guiding COPD treatment decisions. GSK would like to draw your attention to a growing body of evidence that supports the use of blood eosinophil counts in this area, especially when considering the risks and benefits of prescribing inhaled corticosteroids and its subsequent potential to improve cost effectiveness in healthcare costs: • Blood eosinophil counts, exacerbations, and response to the addition of inhaled fluticasone furoate to vilanterol in patients with chronic obstructive pulmonary disease: a secondary analysis of data from two parallel randomised controlled trials Pascoe S *et al. Lancet Resp Med* 2015;3(6):435-442 • Blood eosinophils and inhaled corticosteroid/long acting β-2 agonist efficacy in COPD Pavord ID *et al. Thorax* 2016; 71:118 -125 • Blood eosinophil count and pneumonia risk in patients with chronic obstructive pulmonary	

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				disease: a patient-level meta-analysis. Pavord ID et al. Lancet Respir Med. 2016 Sep;4(9):731-41 • Pre-license data in development (publication 2018): IMPACT (InforMing the PAthway of COPD Treatment). A 52 week evaluation of the efficacy (moderate/ severe exacerbations) and safety of ICS/LAMA/LABA vs. ICS/LABA or LAMA/LABA (n ~10 000) in COPD patients and pre-planned analysis on prospectively collected blood eosinophils. Published protocol: a phase III randomised controlled trial of single-dose triple therapy in COPD: the IMPACT protocol. Pascoe SJ. Eur Respir J 2016; 48: 320–330 Finally, in July 2015, the Food and Drug Administration (FDA) established plasma fibrinogen as the first biomarker to be qualified for use in COPD. Using a threshold of 350 mg/dL fibrinogen, risk of mortality and future exacerbations of COPD could be predicted (Miller, Am J Respir Crit Care Med. 2016 Mar 15;193(6):607-13.	
82	GlaxoSmithKline, UK	10	General	**Section 3.3 Activities, services or aspects of care.** Proposed outline for the guideline- Management of stable COPD therapy *"Inhaled therapy* *- monotherapy with SABA, LABA, or ICS*	Thank you for your comment. We will be looking at the evidence for ICS/LABA, it was accidentally missed from the scope and has now been added in. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or

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				- dual therapy with SABA plus SAMA, LAMA plus ICS, or LABA plus ICS (excluding LAMA + LABA) *- triple therapy with LAMA plus LABA plus ICS* *- delivery systems* *"No evidence review: amend recommendations if needed to fit with other parts of the update."* Since the NICE clinical guideline [CG101] was published in June 2010 there has been a notable increase in the evidence-base that assesses the clinical effectiveness of LAMA monotherapy, LABA/ICS, LABA/LAMA and triple therapy at managing patients with COPD. Although it is beyond the scope of this document to list all GSK clinical trials relating to umeclidinium 55mcg, umeclidinium/vilanterol 55/22mcg, fluticasone furoate/ vilanterol 92/22mcg, triple therapy, and the Ellipta inhaler, we would like to take this opportunity to draw your attention to a few representative studies (see below). We anticipate that the entire evidence base for these inhaled therapies will be considered as part of the NICE systematic review. • LAMA vs. LAMA o A randomized, blinded study to evaluate the efficacy and safety of umeclidinium 62.5 µg compared with tiotropium 18 µg in patients with COPD. Feldman G. Int J	exacerbations persist on current therapy, irrespective of the patient's FEV1. During the review for update process, NICE surveillance did not identify any new evidence which would change the direction of these recommendations. Triple therapy was therefore not included in the scope and the current recommendations will be retained in the updated guideline. There will be further opportunities for the guideline to be updated based on new evidence that will be published after the guideline has been published. At regular intervals after publication, NICE surveillance reviews whether there is a need for the guideline or parts of the guideline to be updated. And so if there is substantive new evidence that is likely to lead to a change in the current recommendations, this will be picked up then. However, if you feel that new evidence demands more immediate consideration, this can be submitted to NICE and considered before the next scheduled NICE surveillance review.. Thank you for making us aware of the studies that are currently being undertaken, this is helpful information that will be considered for future updates of the guideline. Thank you for providing us with details of the studies. Feldman (2016), Rheault (2016), Vestbo (2016) were published after the NICE surveillance searches had been undertaken. Maleki- Yazdi (2014) and Dransfield

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				Chron Obstruct Pulmon Dis. 2016; 11: 719730. ○ A randomised, open-label study of umeclidinium versus glycopyrronium in patients with COPD. Tara Rheault. ERJ Open Research 2016; 2: 00101-2015 • Fixed dose LABA/LAMA vs. Mono-components and tiotropium ○ Efficacy and safety of umeclidinium plus vilanterol versus tiotropium, vilanterol, or umeclidinium monotherapies over 24 weeks in patients with chronic obstructive pulmonary disease: results from two multicentre, blinded, randomised controlled trials. Decramer M, Lancet Respir Med 2014;2: 472–86 ○ Efficacy and safety of umeclidinium/vilanterol 62.5/25 mcg and tiotropium18 mcg in chronic obstructive pulmonary disease: Results of a 24-week, randomized, controlled trial. Maleki-Yazdi, M.R Respiratory Medicine 2014;108:1752-60 • Fixed dose ICS/LABA vs. LABA and vs. ICS/LABA	(2013) were identified in the NICE surveillance review. These studies will be considered by the guideline committee when they review the evidence on these topics during guideline development, if they meet the criteria outlined in the relevant review protocol. Thank you for your comment. Cost-effectiveness issues, such as reuse of inhalers will be considered as part of the guideline committee's discussions when looking at the care pathway for inhaled therapy. However, the use of specific devices is not being updated in the guideline. Thank you for your comment. One of the main outcomes for this update is adverse events, which could include pneumonia; the guideline committee will discuss and prioritise which outcomes will be extracted, and this information will be taken into account when they have those discussions.

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				○ Once-daily inhaled fluticasone furoate and vilanterol versus vilanterol only for prevention of exacerbations of COPD: two replicate double-blind, parallel-group, randomised controlled trials. Dransfield et al. Lancet Respir Med. 2013 May;1(3):210-23 ○ A comparison of the efficacy and safety of once-daily fluticasone furoate/vilanterol with twice-daily fluticasone propionate/salmeterol in moderate to very severe COPD. Agusti et al., Eur Respir J. 2014; 43: 763-772 ○ Effectiveness of Fluticasone Furoate–Vilanterol (FF/VI) for COPD in Clinical Practice. An effectiveness study set within regular UK clinical practice that compared FF/VI with usual care (GP choice of inhaler therapy- ICS and/or LAMA and/or LABA). Vestbo, J. NEJM 2016; 375:1253-1260. • Triple therapy ○ Efficacy and safety of umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: Results of two randomized studies. Siler	

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				TM, Respiratory Medicine . 2015;109:1155-1163 • Triple therapy (pre-license, in development): o Randomised controlled trial comparing the effectiveness of a single inhaler triple therapy (ICS/LAMA/LABA) vs. ICS/LABA. [FULFIL] Expected publication Q2 2017 o IMPACT (InforMing the PAthway of COPD Treatment) Publication 2018. Details as above. • Delivery systems o Open-label cross-over study of inhaler errors, preference and time to achieve correct inhaler use in patients with COPD or asthma: comparison of ELLIPTA with other inhaler devices. Van der Palen, J. npj Primary Care Respiratory Medicine. 2016;26:16079. Since the last publication of the NICE COPD guidelines, there has been an increase in the number of inhaler devices, with over 30 different combinations available for triple therapy alone. This raises the potential of recycling and reducing the carbon footprint of inhaler production as a consideration into comparing cost effectiveness from an environmental impact perspective.	

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				In addition to the above evidence, we also wish to highlight that in 2016, the European Medicines Agency (EMA) completed a review of the known risk of pneumonia in patients who use inhaled corticosteroid medicines for COPD: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Inhaled_corticosteroids_Article_31/European_Commission_final_decision/WC500210489.pdf. Finally, the Study to Understand Mortality and MorbidITy (SUMMIT) study provides further safety data on the effect of fluticasone furoate and vilanterol on survival, in patients with moderate COPD and heightened cardiovascular risk. Vestbo J. Lancet 2016; 387: 1817–26.	
83	GlaxoSmithKline, UK	14	General	**Section 3.5 Key issues and questions.** *"In people with suspected COPD, which tests (for example imaging or biomarkers) are the most accurate to identify whether they are at risk of poor outcomes and whether they will develop mild, moderate or severe COPD?"* Please refer to previous comments on assessing eosinophil blood counts as a potential biomarker to guide treatment of COPD patients with an ICS-containing regimen and plasma fibrinogen as a biomarker for mortality and risk of exacerbations.	Thank you for your comment. Regarding biomarkers, if the evidence found for particular subgroups of people is very different to those with COPD alone, then the guideline committee will consider making separate recommendation(s) for these groups. Regarding outcome measures, evidence will be looked at for many of the ones that you have mentioned. A non-exhaustive list of outcomes that will be used in the guideline has been included in the scope.

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				"2. Management of stable COPD" – cost effective comparisons" GSK anticipates that these comparisons are based on robust, clinically relevant outcomes such as lung function, rates of exacerbations and validated Patient Reported Outcomes (e.g. SGRQ, CAT, rescue medication use), which have demonstrated to be predictors of poor outcome.	
84	GlaxoSmithKline, UK	15	12	**3.5 Key issues and questions** *"2.6 Which is the most clinically and cost-effective long-acting anticholinergic for managing stable COPD, and which subgroups of people should receive treatment with it?"* Although long-acting anticholinergics forms the foundation of COPD treatments, GSK believe that comparisons of clinical and cost-effectiveness need to also be established in other treatment categories. ICS/LABAs are widely used in the UK due to its robust evidence base, therefore further guidance would be welcome for allocating which patient subgroups would be most amenable to ICS-containing treatments, in addition to anticholinergics.	Thank you for your comment. We are planning to look at the effectiveness of ICS/LABAs compared to LAMA/LABA as part of the guideline and this has already been included in the scope (please see the table in section 3.3 and also the review questions in section 3.5 where this is specifically outlined). Issues of patients who are most amenable to ICS treatments could be covered and addressed by subgroup analysis of the data.
91	Novartis Pharmaceuticals	9	Table 2, section 2	In the 'Inhaled therapy' section of the draft scope, Novartis recommends that published information on the following is considered as key review evidence when reviewing the 'LAMA plus LABA compared with LABA plus ICS treatment options':	Thank you for your comment. As part of the evidence review for the guideline, for these combinations, exacerbations, safety and lung function will all be important outcome measures that will be looked at. We are also aware of safety issues concerning ICS, and

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				• Reduction in risk of exacerbations • Safety considerations, particularly for inhaled corticosteroids (e.g. risk of pneumonia, osteoporosis, diabetes mellitus) • Lung function FLAME Study: A randomised, double-blind, double-dummy, non-inferiority trial investigating the efficacy and safety of indacaterol–glycopyrronium versus salmeterol–fluticasone in patients who had COPD has been published which demonstrated indacaterol–glycopyrronium was significantly more effective than salmeterol–fluticasone in preventing COPD exacerbations in patients with a history of exacerbation during the previous year (Wedzicha,JA. et al. N Engl J Med 2016;374:2222-34). If the evidence suggests that the LABA/LAMA class is more efficacious than the LABA/ICS class then recommendations could be made on how and when to withdraw LABA/ICS therapies and switch patients to LABA/LAMA therapies. A study investigating the efficacy and safety of the direct switch from various previous treatments to glycopyrronium or indacaterol-glycopyrronium: the CRYSTAL study, has recently been presented (Oral presentation, BTS Winter Meeting, London 07 December	therefore (as detailed in the draft scope), a footnote will be added to the guideline to outline potential adverse events related to inhaled steroids. Thank you for providing these references, they will be considered as part of the evidence review for the guideline if they match the inclusion criteria set out in the guideline review protocol. Regarding escalation, switching, and withdrawal, the plan is that the entire treatment pathway for inhaled therapy will be updated, and this will give the opportunity for the guideline committee to make recommendations including switching, withdrawal and escalation where appropriate. Current recommendations already state that LABA/LAMA combination should be used when LABA/ICS is declined or not tolerated. The guideline committee will review the evidence in this area and make recommendations as appropriate.

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				2016, Vogelmeier C. et al., Thorax 2016; 71 (Suppl 3): A22 (S35)). This study demonstrated superior improvement in lung function and dyspnoea after 12 weeks, in symptomatic patients with moderate COPD and a history of up to 1 exacerbation in the previous year. The widespread and inappropriate early use of ICS based regimens has been confirmed by numerous UK studies looking at real world prescribing patterns (Price D et al. Intl J Chron Obstruct Pulmon Dis. 2014;9:889–904) resulting in a significant cost to the NHS and unnecessary safety risks to patients. Therefore it would indeed be appropriate to give guidance on both escalation and de-escalation of ICS based therapy. The GOLD 2017 strategy document is a useful reference of current scientific strategy in this area (Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://goldcopd.org)	
92	Novartis Pharmaceuticals	5 8	12 Table 2, section 2	The Alliance recommends that the term 'stable COPD' is changed to 'Maintenance therapy for COPD'	Thank you for your comment. The guideline committee will consider terminology when they develop the update of the guideline.
93	Novartis Pharmaceuticals	8	Table 2, section 2	The Alliance recommends that in the 'Follow-up of patients with COPD' section there is consideration of annual reviews for people with COPD or when there is a	Thank you for your comments. Follow-up of people with differing severity of COPD is included in several recommendations in the current guideline, and includes

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				significant change in their symptoms, similar to annual asthma reviews. This review should include the review of treatments options and inhaler techniques and would help to ensure that people can be escalated and de-escalated from therapies as appropriate and avoid people being unnecessarily left on therapies, such as ICS, which will improve patient safety and ensure resources are used effectively.	detailed advice on what should be included in the review as well as how often reviews should take place. This includes assessing inhaler technique and symptom control (i.e. allows for a change in treatment options) amongst other things. The reviews have been recommended to be conducted at least annually, and more often when the COPD is very severe. These recommendations will be carried forward in the updated guideline.
94	Novartis Pharmaceuticals	11	Table 2, section 3	The Alliance recommends that the 'Maintenance inhaled pharmacotherapy after recovery from exacerbation' is also considered in this section.	Thank you for your comment. The original guideline looked at inhaled therapy for exacerbations, which included both short and medium-term therapy. As part of the guideline review for update process, the NICE surveillance review did not identify new evidence that would lead to changes in the current recommendations on inhaled therapy. The topic was therefore not included in the scope as a priority area requiring update.
117	Nutricia Advanced Medical Nutrition	General	General	Since the initial publication of this guideline in 2010, there have been a number of publications which assess the impact of nutritional intervention for patients with COPD. These publications provide evidence for the importance of nutritional management of patients with COPD to improve outcomes including hospital admissions and quality of life, as well as additional outcomes, including weight, respiratory and peripheral muscle strength and exercise performance. Appropriate nutritional management of patients with COPD may, in turn, result in cost saving recommendations if included in the guideline.	Thank you for your comment. Regarding nutrition, and the use of oral nutritional supplements in particular, the NICE surveillance review did identify new evidence on this section; however the new evidence was consistent with current recommendations and therefore this area did not require updating at this time. Please see below for individual responses to the studies referenced in your comments:

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				Malnutrition, and specifically under nutrition, is common in this patient group, with 21% of individuals with COPD identified as at risk of malnutrition using the Malnutrition Universal Screening Tool ('MUST') (Collins, 2010). This equates to up to 630,000 people in the UK. Malnutrition is associated with poor prognosis and increased mortality, independent of disease severity (Landbo et al, 1999), and outpatients who are identified as at risk of malnutrition are at increased risk of hospitalisation and increased mortality (Steer et al 2010). The implications of malnutrition for patients with COPD, and the wider healthcare economy, were further identified by Hoong and colleagues in 2016, who found that: • Malnutrition was independently associated with 1-year mortality and malnourished patients had a significantly higher 1-year mortality (27.7% vs 12.1%, p = 0.001) • Malnourished patients were hospitalised more frequently (1.11 SD 1.24 vs 1.51 SD 1.43; p = 0.051) • LOS was almost twice the duration in malnourished patients compared with those who were well nourished (11.57 days vs 6.67 days) and at almost double the cost. CG101 currently encourages healthcare professionals to monitor the weight and BMI of patients with COPD,	Cawood (2012) was not identified by the NICE surveillance searches because the population of the studies was not specifically COPD, and therefore would not be included in the evidence review for the guideline. Collins (2010) was not identified by the NICE surveillance searches because it was an abstract/ poster only, the 6 year NICE surveillance review only identified relevant systematic reviews (SR). Furthermore, abstracts would not be included in an evidence review for the guideline and therefore it would not change current recommendations. Collins (2012): This study was identified in the NICE surveillance review. It was concluded that this study was unlikely to change the current recommendation to give ONS if BMI is low. Collins (2013): This study was identified in the NICE surveillance review. It was concluded that this study was unlikely to change the current recommendation to give ONS if BMI is low. Ferreira (2012): This Cochrane review was identified by the NICE surveillance review, and it was concluded that it was unlikely to change the current recommendations.

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				however more recent guidelines encourage a more comprehensive nutritional screening. In July 2016, *Managing Malnutrition in COPD* was published. This guideline was written and agreed by a multi-professional panel with expertise in Malnutrition and COPD and has been endorsed by ten key patient and professional organisations, including the British Lung Foundation, National Nurses Nutrition Group, Royal College of General Practitioners, Primary Care Respiratory Society, Association of Respiratory Nurse Specialists, British Dietetic Association and Royal College of Nursing. It has also been given the following NICE endorsement statement: *this guide supports some of the recommendations on identification and management of malnutrition in the NICE guideline on nutrition support in adults and chronic obstructive pulmonary disease in over 16s. It also supports the statements about identifying and managing malnutrition in the NICE quality standard for nutrition support in adults.* Therefore, inclusion of this guideline, and/or it's recommendations, within CG101 should be considered. This guideline provides healthcare professionals with an up-to-date consensus of evidence and expert opinion for identifying and managing malnutrition in patients with COPD. It incorporates a malnutrition screening tool, 'MUST', which assesses a patient's weight and BMI, as	Hoong (2016): This was not identified by the NICE surveillance review because it was published outside of the dates of the surveillance searches and is not a SR. This study is a prospective cohort of association between malnutrition and hospital costs, which is not the intervention of interest and therefore would not be included in the evidence review for the guideline. Landbo (1999): This study was not identified in the NICE surveillance review because it was outside of the search dates and not a SR. This is a prospective study examining the value of BMI as a predictor of mortality; this is not the intervention of interest and would not be included in an evidence review on nutrition for the guideline in COPD. Managing malnutrition in COPD: Thank you for highlighting this resource, however it would not have been picked up by the NICE surveillance searches as it is not a SR and would not be included in any evidence review for the guideline on this subject. Snider (2015): This study was not identified by the NICE surveillance review because it is a retrospective cohort, not a SR. The evidence within this study is consistent with the current recommendations.

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				well as recent weight loss and nutritional intake. Dependent on the degree of nutritional risk identified, the guideline informs the level of nutritional intervention required. For patients identified as at high risk of malnutrition, it is recommended that oral nutritional supplements are prescribed two per day for a 12 week duration. Due to the symptoms of COPD, a low volume, high energy/high protein oral nutritional supplement is suggested for patients with COPD. To further support the above, recent publications since CG101 was published, including two systematic reviews and meta-analyses and one Cochrane review, highlight that nutrition intervention, including the use of oral nutritional supplements in patients with COPD can: - Improve Quality of Life - Significantly improve length of stay and readmissions to hospital - Significantly improve hand grip strength - Significantly improve respiratory muscle strength - Significantly improve exercise performance - Significantly improve patients' nutritional intake - Significantly improve weight (Collins PF et al, 2012; Collins PF et al, 2013; Snider JT et al, 2015; Ferreira IM et al, 2012)	Steer (2010): This study was not identified in the NICE surveillance searches because it is an incorrect study type (poster) and as such would not be included in any evidence review for the guideline.

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				Furthermore, the advantages of high protein oral nutritional supplements are recognised in the literature. A recent systematic review and meta-analysis suggests that ONS high in protein (with ≥ 20% of total energy from protein) can significantly reduce both length of stay and hospital readmissions compared with routine care, with economic implications (Cawood, 2012). To improve care in this patient group, we believe that the early detection using a comprehensive screening tool, such as 'MUST' and appropriate management of malnutrition should be more comprehensively highlighted within the guideline and this is supported by publications since CG101 was initially published in 2010. Cawood AL, Elia M, Stratton RJ. Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. Ageing Research Reviews 11 (2012) 278– 296 Collins PF et al., Prevalence of malnutrition in outpatients with chronic obstructive pulmonary disease. Proc Nut Soc. 2010; 69(Issue OCE2): E148 PF Collins, RJ Stratton, M Elia. Nutritional support in chronic obstructive pulmonary disease: a systematic review and meta-analysis American Journal of Clinical Nutrition. 2012; 95: 1385-93 PF Collins, M Elia, RJ Stratton. Nutritional support and functional capacity in chronic obstructive pulmonary	

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				disease: A systematic review and meta-analysis Respirology. 2013; 18: 616-629 Ferreira IM, Brooks D, White J, Goldstein R. Nutritional supplementation for stable chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2012 Dec 12;12:CD000998. doi: 10.1002/14651858. CD000998.pub3. Review. Hoong JM, Ferguson M, Hukins C et al. Economic and operational burden associated with malnutrition in chronic obstructive pulmonary disease. Clinical Nutrition. 2016; 1-5. Landbo C, Prescott E, Lange P, Vestbo J, Almdal TP. Prognostic value of nutritional status in chronic obstructive pulmonary disease. Am J Respir Crit Care Med, 1999 Dec; 160(6): 1856-61. Clinical Nutrition, 2006; 25: 311-31. Managing Malnutrition in COPD - Including a pathway for the appropriate use of ONS to support community healthcare professionals. Available at: http://malnutritionpathway.co.uk/copd/. Accessed 23/02/2017. Snider JT, Jena AB, Linthicum MT, Hegazi RA, Partridge JS, LaVallee C, Lakdawalla DN, Wischmeyer PE. Effect of hospital use of oral nutritional supplementation on length of stay, hospital cost, and 30day readmissions among Medicare patients with COPD. Chest. 2015 Jun;147(6):147784.	

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				Steer J, Norman E, Gibson GJ, Bourke SC (2010) Comparison of indices of nutritional status in prediction of inhospital mortality and early readmission of patients with acute exacerbations of COPD. *Thorax* 65: A127	
57	Primary Care Respiratory Society UK	6	6	Table …Diagnosis - No evidence review and retain recommendations… ? 1. See next comments re LLN versus fixed ratio in diagnosis. Late onset asthma is an importance differential diagnosis for COPD – and patients with both asthma and COPD (overlap syndrome?) are explicitly included in the guideline – but reversibility testing is not currently recommended in COPD diagnosis. How will clinicians pick up patients with late onset asthma (or with a substantial degree of reversibility)? The GDG might review this section of the guideline to ensure that they feel that this issue is adequately discussed or whether it needs to be revised.	Thank you for your comment. Reversibility testing is not included for most people, however there is a further recommendation on differential diagnosis between COPD and asthma, and which outlines specific criteria to aid clinicians in their diagnosis of these conditions. The NICE surveillance review did not identify sufficient new evidence that would lead to a change in the current recommendation. The topic of differential diagnosis, was therefore not considered to need updating, and therefore excluded from the scope. Lack of implementation of the guideline is not an issue that guideline development can address, this is an issue for local CCGs. The current recommendation will remain as it stands in the new guideline update.
58	Primary Care Respiratory Society UK	14	8-18	The recommendation regarding using the Fixed ratio of Fev-1/FVC for diagnosis of COPD should be revisited. The BTS/Asthma Guidelines recommend using the Lower limit of normal to diagnose airways obstruction and new population tables are now available since 2010 so this recommendation urgently needs to be revisited.	Thank you for your comment. Insufficient new evidence for using LLN measurements was identified as part of the NICE surveillance process, to justify making a change in the current recommendations which recommend FEV1/FVC ratio is used. The new GOLD guidelines have also not adopted this measurement either. LLN is also a measure already reported by spirometry readings so professionals are able to access

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				The issue of whether lower limit normal for the FEV1/FVC ratio should be used as a diagnostic criterion for COPD is an ongoing controversy of major importance, since the protagonists of using LLN argue that using a fixed ration leads to significant over diagnosis of COPD in older people. Even if the GDG were to choose not to include this question in the evidence review, the issue should be mentioned and a justification given for not making new recommendations.	this data and take it in consideration when making a diagnosis. This topic was therefore excluded from the scope, however the current recommendations on diagnosis as they stand, will appear in the update of the guideline.
59	Primary Care Respiratory Society UK	7	6	See above	Thank you for your comment.
60	Primary Care Respiratory Society UK	14	21- 30	Management of stable COPD. In Section 2.2 L 27-30, LAMA/LABA is to be compared with LAMA alone but not with LABA alone – only with LABA + ICS. Should this comparison also be included? (In Section 2.1 LAMA alone IS to be compared with LABA alone)	Thank you for your comment. We also spotted this error. Both comparisons were supposed to be listed here as well, and so we have now amended the draft scope, and added the vs. LABA comparison in.
61	Primary Care Respiratory Society UK	15	1-28	Many medicines management groups are recommending the step down of people on “Unnecessary” ICS – containing therapies. The evidence regarding the effect of this need to be examined and recommendations regarding appropriate step down be made. If there is no evidence available the guideline should say this but offer advice to health professionals on how to step down and stop ICS if thought to be unnecessary for ongoing management.	Thank you for your comment. As part of the guideline review for update process, the NICE surveillance review identified evidence relating to withdrawal of ICS, however it was not deemed sufficient to lead to changes in the current recommendations on inhaled therapy. The topic was therefore not included in the scope as a priority area requiring update. However, we are aware of safety issues concerning ICS, and therefore (as detailed in the draft scope), a footnote

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					will be added to the guideline to outline potential adverse events related to inhaled steroids.
62	Primary Care Respiratory Society UK	15	30	The NICE COPD quality Standard 2016 recommends that research be carried out on the effectiveness of discharge bundles. There is now evidence available regarding this and the new GDG should analyse this.	Thank you for your comment. New evidence for discharge bundles was not identified as part of the NICE surveillance process, and it was concluded that the current recommendations on assisted discharge did not need updating. Since the quality statement also suggests that there is insufficient evidence, and this statement was made in 2016, we have also not identified or been informed that sufficient new evidence exists to warrant this topic being covered. This topic was therefore excluded from the scope, however the current recommendations on assisted discharge as they stand, will appear in the update of the guideline.
63	Primary Care Respiratory Society UK	General	General	With respect to Alpha1 antitrypsin deficiency the current guideline states: 1.2.11 Alpha-1 antitrypsin replacement therapy Alpha-1 antitrypsin replacement therapy is not recommended for patients with alpha-1 antitrypsin deficiency (see also recommendation 1.1.3.3). **[2004]** Our attention has been drawn by Alpha-1 Awareness UK to an RCT showing possible benefit for iv augmentation therapy in this condition (the RAPID trial http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60860-1/fulltext): the agent in question	Thank you for your comment and for highlighting these studies. Chapman (2015) was not included in the NICE surveillance review because the 6 year NICE surveillance review only includes systematic reviews (SR). The study by Chapman (2015) is an RCT with a population of eligible non-smokers (aged 18–65 years) in 28 international study centres in 13 countries if they had severe α1 antitrypsin deficiency (serum concentration <11 μM) with a forced expiratory volume in 1 s of 35–70% (predicted). N=180 randomised to placebo or augmentation therapy. It was found that there

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				has received marketing authority from the EMA on the basis of this evidence. Professor Robert Stockley has argued that this is a therapeutic option that warrants further assessment (http://ojrd.biomedcentral.com/articles/10.1186/1750-1172-8-149). Should the GDG consider whether this evidence on the effects of a new but expensive agent for a rare but serious condition warrants assessment with a view to modifying this statement in the existing guideline?	was a reduction in the loss of annual lung density (TLC only, not FRC alone or TLC and FRC combined). Stockley (2013) was not included in the NICE surveillance review because it is a non – systematic review. It is unlikely that this study would be included in an evidence review for the guideline and therefore would not change recommendations. However, a Cochrane review published in 2016 (Gotzsche 2016) concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant a change to the current recommendations, and the quality of the evidence was also unclear. We have also looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available related to the current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication) and may be included in the scope for the next update.

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1	Royal College of General Practitioners	7	6	The recommendation regarding using the Fixed ratio of FEV1/FVC for diagnosis of COPD should be revisited. The BTS/Asthma Guidelines recommend using the Lower limit of normal to diagnose airways obstruction and new population tables are now available since 2010 is this recommendation urgently needs to be revisited	Thank you for your comment. Insufficient new evidence for using LLN measurements was identified as part of the NICE surveillance process, to justify making a change in the current recommendations which recommend FEV1/FVC ratio is used. The new GOLD guidelines have also not adopted this measurement either. Given all these factors, this topic was therefore excluded from the scope. However, the current recommendations on diagnosis as they stand, will appear in the update of the guideline.
2	Royal College of General Practitioners	14	8-18	The recommendation regarding using the Fixed ratio of FEV1/FVC for diagnosis of COPD should be revisited. The BTS/Asthma Guidelines recommend using the lower limit of normal to diagnose airways obstruction and new population tables are now available since 2010 is this recommendation urgently needs to be revisited	Thank you for your comment. Insufficient new evidence for using LLN measurements was identified as part of the NICE surveillance process, to justify making a change in the current recommendations which recommend FEV1/FVC ratio is used. The new GOLD guidelines have also not adopted this measurement either. LLN is also a measure already reported by spirometry readings so professionals are able to access this data and take it in consideration when making a diagnosis. This topic was therefore excluded from the scope, however the current recommendations on diagnosis as they stand, will appear in the update of the guideline.
3	Royal College of General Practitioners	15	1-28	Many medicines management groups are recommending the step down of people on “Unnecessary” inhaled corticosteroids –containing therapies. The evidence regarding the effect of this need to be examined and	Thank you for your comment. As part of the guideline review for update process, the NICE surveillance review identified evidence relating to withdrawal of ICS, however it was not deemed sufficient to lead to changes in the current recommendations on inhaled therapy. The

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				recommendations regarding appropriate step down be made	topic was therefore not included in the scope as a priority area requiring update. However, we are aware of safety issues concerning ICS, and therefore (as detailed in the draft scope), a footnote will be added to the guideline to outline potential adverse events related to inhaled steroids.
4	Royal College of General Practitioners	15	30	The NICE COPD quality Standard 2016 recommends that research be carried out on the effectiveness of discharge bundles. There is now evidence available regarding this and the new GDG should analyse this	Thank you for your comment. New evidence for discharge bundles was not identified as part of the NICE surveillance process, and it was concluded that the current recommendations on assisted discharge did not need updating. Since the quality statement also suggests that there is insufficient evidence, and this statement was made in 2016, we have also not identified or been informed that sufficient new evidence exists to warrant this topic being covered. This topic was therefore excluded from the scope, however the current recommendations on assisted discharge as they stand, will appear in the update of the guideline.
5	Royal College of General Practitioners	General	General	• It seems confusing to be reviewing causes of exacerbations (often viral) but not on the basis of this make the clinical side of things more clear - there is plenty of evidence accruing around lung microbiomes and impact of antibiotic prescribing. Also quite a few hospitals are following the 40mg for 5 days steroid course after a study in 2015 by Leuppi rather than the 30mg for 7-14 days which NICE currently recommends. The role of	Thank you for your comments. Regarding antibiotic prescribing, we are updating this topic and so depending on what the new evidence shows, the current recommendations may change. When the evidence for causes of exacerbations is looked at, the guideline committee will take this into consideration in terms of the impact it has on treatment options.

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				phosphodiesterase-4 inhibitors is probably clearer now • It would seem sensible to update oxygen too - on the basis of new BTS O2 guidelines and on the impact of smoking and other areas to help to inform safe commissioning and delivery - there has also been a large trial published in NEJM which should impact on clinical practice (Group TL-TOTTR. A Randomized Trial of Long-Term Oxygen for COPD with Moderate Desaturation. New England Journal of Medicine. 2016;375(17):1617-27) • There appears to a lot of interest in valves and lung volume reduction surgery - but NICE is proposing not to review this area (will leave a patch work of up to date and out of date advise which will impact on credibility) - similarly new evidence on A1AT treatments • As finding spirometry in patients with symptoms in primary care there is evidence for particularly in areas with high smoking rates now or historically and should be part of scope	Regarding PDE4 inhibitors, the NICE surveillance review identified new evidence, however it was considered insufficient to warrant a change in the current recommendation. NICE has published a TA on Roflumilast, which will be cross-referred to in the new guideline update. The topic of PDE4 inhibitors was therefore not considered to need updating, and therefore excluded from the scope. In light of your comment, we have made this clearer in the scope, and added a sentence into the table that explains that the TA will be cross-referred to. Additionally, the lack of implementation of the guideline cannot be addressed through an update to the guideline, but is an issue for local CCGs to address. The current recommendations will be carried forward in the new updated guideline. Long-term oxygen: Yes we are planning to update long-term oxygen as you state. Thank you for providing these references, they will be considered as part of the evidence review for the guideline if they match the inclusion criteria set out in the guideline review protocol. Regarding valves and lung volume reduction surgery, the NICE surveillance review identified new evidence, however it was considered consistent with current guideline recommendations. Current guideline recommendations provide referral criteria for lung volume reduction surgery, but they do not specify the type of surgery that should be conducted. This would be

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					considered a clinical judgement based on the expertise of the healthcare professional and the individual needs of the person with COPD who is presenting to them. The topic of surgery was therefore not considered to need updating, and therefore excluded from the scope. The current recommendation will remain as it stands in the new updated guideline. Regarding A1AT, we understand that there is new evidence on A1AT treatments. However, a Cochrane review published in 2016 (Gotzsche 2016) concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant a change to the current recommendations, and the quality of the evidence was also unclear. We have also looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available related to the current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication) and may be included in the scope for the next update.

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					Regarding case-finding, in terms of case-finding within the primary care setting, there is an existing recommendation in the 2010 guideline (see recommendation 1.1.1.1 and 1.1.1.2 in the short version of the 2010 guideline) which covers this. These recommendations outlines criteria (including age, smoking status, and particular symptoms) that should lead a healthcare professional to suspect the person presenting may have COPD. If the person is considered as being suspected of having COPD, then the guideline recommends spirometry to confirm the diagnosis (see recommendations in section 1.1.2). The current recommendations will be carried forward in the new updated guideline. We hope that this answers your question of why case-finding in primary care has not been specifically mentioned as needing updating in the scope for the new update of the guideline. We will however, be updating the recommendations on further investigations to confirm the diagnosis. Regarding case-finding in the general population, this makes the assumption that response to treatment and progression of disease is improved if people are caught early. There is currently no clear evidence for this being the case. A large recent trial on targeted case-finding (Jordan 2016), showed promising results but did not look at the effects on clinical outcomes and as such the effectiveness of the intervention remains unproven.

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					Consequently, this area was not prioritised for update. Should further evidence become available, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication).
95	Royal College of Nursing	General	General	This is a joint submission from the Association of Respiratory Nurse Specialists and the Royal College of Nursing. We invited respiratory nurses who care for people with chronic obstructive pulmonary disease (COPD) to review the document on our behalf. The comments below reflect the views of our reviewers.	Thank you for your comments.
96	Royal College of Nursing	2	30	There is no mention on nutritional importance of patients with COPD.	Thank you for your comment. The NICE surveillance review did not identify any new evidence which would lead to a change in the current guideline recommendations on nutrition for patients with COPD. Nutrition has therefore not been included as an area requiring update in the scope.
97	Royal College of Nursing	5	27	Need to be clear on what is meant by telehealth monitoring. Very little evidence to show that this works and appears to be a drive from NHS England with regards to this issue.	Thank you for your comment. The NICE surveillance review, as part of reviewing the original guideline for update, identified sufficient new evidence on the topic of teleheathcare, that warranted this being included in the scope as an area that needs addressing in the guideline. We understand that the definition of telehealthcare can be confusing and can be interpreted to mean different

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					things Telehealthcare has different elements compared to a strict definition of self- management. We therefore agree with your comments and these differences will be highlighted in the scope; self- management and telehealth will be separated rather than grouped together. Teleheathcare may also be considered to have elements of self-management, when the treatment recommended by this type of remote monitoring, is administered by the person with COPD themselves. This is why we initially grouped telehealthcare together with self-management. We have amended the wording to say 'home' teleheathcare, since the studies that the NICE surveillance review highlighted as evidence, used home tele monitoring as their intervention.
98	Royal College of Nursing	5	28	Is this going to include Feno testing, Sputum samples, pollution etc.?	Thank you for your comment. The NICE surveillance review,as part of reviewing the original guideline for update, did not identify sufficient new evidence on these topics that would change the current recommendations. These topics are therefore not included in the scope to be updated. However the recommendations made in the previous guideline will still be retained and appear in the updated guideline document.
99	Royal College of Nursing	7	1	There is a New GOLD classification stating only Spirometry on diagnosis. Ideal to parallel with GOLD classification.	Thank you for your comment. The classification criteria outlined in GOLD contains the same criteria as listed in the current NICE guideline. We therefore do not think it is necessary to change this since they contain the same information.

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100	Royal College of Nursing	7	1	It may be essential to discuss case finding for identification of early disease. Evidence states that this is not about finding the patients rather than ad hoc identification when patients come to see their GP for chest infection or are smokers, for example.	Thank you for your comment. Early disease identification: the current guideline already has recommendations around identification of early disease, insufficient new evidence was identified as part of the NICE surveillance process, to justify making a change in the current recommendations This topic was therefore excluded from the scope, however the current recommendations on early identification as they stand, will appear in the update of the guideline. In terms of case-finding within the primary care setting, there is an existing recommendation in the 2010 guideline (see recommendation 1.1.1.1 and 1.1.1.2 in the short version of the 2010 guideline) which covers this. These recommendations outlines criteria (including age, smoking status, and particular symptoms) that should lead a healthcare professional to suspect the person presenting may have COPD. If the person is considered as being suspected of having COPD, then the guideline recommends spirometry to confirm the diagnosis (see recommendations in section 1.1.2). The current recommendations will be carried forward in the new updated guideline. We hope that this answers your question of why case-finding in primary care has not been specifically mentioned as needing updating in the scope for the new update of the guideline. We will

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					however, be updating the recommendations on further investigations to confirm the diagnosis. Regarding case-finding in the general population, this makes the assumption that response to treatment and progression of disease is improved if people are caught early. There is currently no clear evidence for this being the case. A large recent trial on targeted case-finding (Jordan 2016), showed promising results but did not look at the effects on clinical outcomes and as such the effectiveness of the intervention remains unproven. Consequently, this area was not prioritised for update. Should further evidence become available, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication).
101	Royal College of Nursing	9	General	Inhaled therapy – need to mention LABA/LAMA and also importance of checking technique at every opportunity	Thank you for your comment. The evidence for LABA/LAMA will be reviewed as part of the update, and has already been included in the scope. Regarding inhaler technique, this is included in several recommendations in the current guideline, including retraining and reassessment. As part of reviewing the guideline for update, the NICE surveillance review identified new evidence on inhaler technique and adherence (under the self-management topic of the guideline). However, it was considered

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					consistent with current guideline recommendations. The topic of adherence and inhaler technique was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward in the updated guideline.
102	Royal College of Nursing	9	General	We welcome that the guideline will consider the review of medication. This is important because of the availability of newer combinations of medicines since the last medicines update and also emerging evidence on risk/benefit for practice.	Thank you for your comment.
103	Royal College of Nursing	9	General	The review of biomarkers and multidimensional tools seems appropriate as does the review of who should receive oxygen.	Thank you for your comment.
104	Royal College of Nursing	10	1	Need to emphasise the importance of education and repeated training for both staff and patients on inhaler technique. UK Inhaler Group (UKIG) has data on this and a competency framework	Thank you for your comments. Inhaler technique is included in several recommendations in the current guideline, including retraining and reassessment. As part of reviewing the guideline for update, the NICE surveillance review identified new evidence on inhaler technique and adherence (under the self-management topic of the guideline). However, it was considered consistent with current guideline recommendations. The topic of adherence and inhaler technique was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward in the updated guideline.

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					Regarding training of HCPs, it is assumed that HCPs who are involved in providing care would be sufficiently trained to be able to deliver the interventions outlined in the guideline. It is not in the remit of NICE guidelines to provide advice on the specifics of how and which professionals should be trained.
105	Royal College of Nursing	10	3	There is no mention of psychological interventions during an exacerbation period.	Thank you for your comment. As part of the guideline review for update process, the NICE surveillance review did not identify sufficient evidence that would justify adding this new topic area into the scope of the guideline.
27	Royal College of Radiologists (RCR)	9		As well as “Lung surgery “ consider evidence review for bronchoscopic lung volume reduction therapies	Thank you for your comment. Regarding valves and coils for lung volume reduction surgery, the NICE surveillance review identified new evidence, however it was considered consistent with current guideline recommendations. Current guideline recommendations provide referral criteria for lung volume reduction surgery, but they do not specify the type of surgery that should be conducted. This would be considered a clinical judgement based on the expertise of the healthcare professional and the individual needs of the person with COPD who is presenting to them. The topic of surgery was therefore not considered to need updating, and therefore excluded from the scope. The current recommendation will remain as it stands in the new updated guideline.

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28	Royal College of Radiologists (RCR)	15	27	Re: 2.11 In people with stable COPD, what are the referral criteria (for 27 example intact fissures) for lung surgery? The following questions could be also considered: What are the referral criteria for bronchoscopic lung volume reduction and what is the appropriate work up?	Thank you for your comment. The term 'surgery' used in this review question includes lung volume reduction (LVR) surgery using bronchoscopic methods, and therefore as part of the review on referral criteria for surgery, referral criteria for LVR by alternative methods will be included. The new evidence identified as part of the NICE surveillance process which highlighted the need to update this topic, was actually conducted in patients undergoing bronchoscopic LVR (using endobronchial valves).
6	The Royal College of Anaesthetists	general	General	There is no mention in the document of the missing millions of COPD patients waiting for surgical operations (non-cardiothoracic) and who have not been diagnosed as having COPD. These are currently been picked up at Preassessment clinics where standard testing before major surgery now includes pulmonary function testing. The RCOA would like to see consideration of care pathways in this group to include –screening program, diagnosis, inhaler therapy commencement, rehabilitation prior to surgery and postoperative management	Thank you for your comment. Regarding perioperative pathways, it is expected that guideline recommendations on diagnosis and management would be applied to all stages of the care pathway for a person with COPD or suspected COPD. NICE guidelines do not usually make specific recommendations stating every scenario where individual recommendations may apply.
7	The Royal College of Anaesthetists	General	General	There is an evidence base for a higher rate of smoking cessation when referred to cessation pathways prior to surgery. There is an evidence base for early intervention in the potential 'treatable moment' i.e. when patients have been referred for surgery.	Thank you for your comment. There a multiple recommendations in the current guideline, encouraging people with COPD to stop smoking and for the healthcare professional to provide them with advice and help to do so. As part of the process for reviewing the guideline for update, the NICE surveillance review identified new evidence on smoking cessation strategies, however it was considered consistent with

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					current guideline recommendations. The topic of smoking cessation therapy was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward, in the new updated guideline. We are also planning to cross-refer to the NICE guideline on smoking cessation which is due to be published November 2017, and the TA on Varenicline for smoking cessation (TA123) will be linked to this guidance in the NICE pathway. New evidence identified on Varenicline during the NICE surveillance review and scoping for the guideline update has been passed to the NICE Technology Appraisal team.
8	The Royal College of Anaesthetists	General	General	Case finding (screening programs) should be linked into perioperative pathways	Thank you for your comment. Regarding perioperative pathways, it is expected that guideline recommendations on diagnosis would be applied to all stages of the care pathway for a person with COPD or suspected COPD. NICE guidelines do not usually make specific recommendations stating every scenario where individual recommendations may apply. Regarding case-finding, in terms of case-finding within the primary care setting, there is an existing recommendation in the 2010 guideline (see recommendation 1.1.1.1 and 1.1.1.2 in the short version of the 2010 guideline) which covers this. These

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					recommendations outlines criteria (including age, smoking status, and particular symptoms) that should lead a healthcare professional to suspect the person presenting may have COPD. If the person is considered as being suspected of having COPD, then the guideline recommends spirometry to confirm the diagnosis (see recommendations in section 1.1.2). The current recommendations will be carried forward in the new updated guideline. We hope that this answers your question of why case-finding in primary care has not been specifically mentioned as needing updating in the scope for the new update of the guideline. We will however, be updating the recommendations on further investigations to confirm the diagnosis. Regarding case-finding in the general population, this makes the assumption that response to treatment and progression of disease is improved if people are caught early. There is currently no clear evidence for this being the case. A large recent trial on targeted case-finding (Jordan 2016), showed promising results but did not look at the effects on clinical outcomes and as such the effectiveness of the intervention remains unproven. Consequently, this area was not prioritised for update. Should further evidence become available, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication).

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9	The Royal College of Anaesthetists	General	General	Adherence to inhaler therapy prior to surgery is likely to be an issue – involvement of pharmacy in perioperative pathways results in cost savings if postoperative respiratory complications are reduced	Thank you for your comment. Inhaler technique is included in several recommendations in the current guideline, including retraining and reassessment. Regarding perioperative pathways, it is expected that guideline recommendations would be applied to all stages of the care pathway for a person with COPD or suspected COPD. NICE guidelines do not usually make specific recommendations stating every scenario where individual recommendations may apply.
10	The Royal College of Anaesthetists	General	General	1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? *a. Optimising communication between primary and secondary care and within the multi professional teams (which should include community pharmacist) to avoid unnecessary hospital admission, but ensure timely recognition and action when specialist secondary care intervention is needed.* b. *Systems to ensure prescription and supply, especially of inhalers and antibiotics, is based on the supplies the patient has and not an automatic repeat. Also ensure continuity of supply when patient moves between primary and secondary care and vice versa – "green bags" may be helpful*	Thank you for your comments. The current guideline recommends multidisciplinary care, and we agree that good communication should form an essential part of interdisciplinary working. Regarding prescriptions and supplies of antibiotics and inhalers, the whole section on prophylactic antibiotic therapy is being updated which will give the guideline committee an opportunity to address issues which they consider as being important. However, providing guidance to commissioners on how they should supply medications and prescriptions for patients is outside the remit of this guideline. It is an implementation issue that should be addressed by CCGs.
11	The Royal College of Anaesthetists	General	General	2. Please give us your opinion on whether either or both of the following two topics are a challenge in current practice, and therefore guidance addressing the	Thank you for your comments. Inhaler technique is included in several recommendations in the current guideline, including retraining and reassessment.

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				issue, would be helpful for professionals to have included in the update of the guideline. 1. Case-finding : *unable to comment* 2. Adherence to treatment with inhaler: *adherence to treatment, especially ensuring patients are using the correct technique is critical and all HCPs who come into contact with patients should be able to check and if necessary retrain patients in the use of inhalers. The guidance should signpost to practical training for HCPs.*	As part of reviewing the guideline for update, the NICE surveillance review identified new evidence on inhaler technique and adherence (under the self-management topic of the guideline). This evidence was considered consistent with current guideline recommendations. The topic of adherence and inhaler technique was therefore not considered to need updating, and therefore excluded from the scope of the update. The current recommendations will be carried forward in the updated guideline. Regarding training of HCPs, it is assumed that HCPs who are involved in providing care would be sufficiently trained to be able to deliver the interventions outlined in the guideline. It is not in the remit of NICE guidelines to provide advice on the specifics of how and which professionals should be trained.
12	The Royal College of Anaesthetists	General	General	Early and simple diagnosis will only be of benefit if linked to effective action to reduce or stop disease progression - essentially smoking cessation. Simply labelling patients seems of little benefit as many of the medical interventions do little to affect disease progression. It would be helpful to improve guidance on chronic oral and inhalation therapy. The complexity and number of single and combined treatments available is confusing and may not be evidenced based. The use of phosphodiesterase 4	Thank you for your comments. Regarding smoking cessation, there a multiple recommendations in the current guideline, encouraging people with COPD to stop smoking and for the healthcare professional to provide them with advice and help to do so. As part of the process for reviewing the guideline for update, the NICE surveillance review identified new evidence on smoking cessation strategies, however it was considered consistent with current guideline recommendations. The topic of

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				inhibitors is not supported by evidence and there is a significant doubt when considering B2 agonists.	smoking cessation therapy was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward, in the new updated guideline. We are also planning to cross-refer to the NICE guideline on smoking cessation which is due to be published November 2017, and the TA on Varenicline for smoking cessation (TA123) will be linked to this guidance in the NICE pathway . New evidence identified on Varenicline during the NICE surveillance review and scoping for the guideline update has been passed to the NICE Technology Appraisal team In terms of the treatment options and combinations of treatments recommended in the guideline, we assume that you are referring to inhaled therapy. This section is going to be updated and recommendations will be brought in line with new evidence that has emerged since they were made. All NICE guideline recommendations are evidence-based, and the section on treatment options is no exception. Regarding PDE4 inhibitors, the NICE surveillance review identified new evidence, however it was considered insufficient to warrant a change in the current recommendation. NICE is currently updating the TA (TA244: Roflumilast for the management of severe chronic obstructive pulmonary disease) which will be

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					cross-referred to in the new guideline update. In light of your comment, we have made this clearer in the scope, and added a sentence into the table that explains that the TA will be cross-referred to. The topic of PDE4 inhibitors was therefore not considered to need updating, and therefore excluded from the scope. Lack of implementation of the guideline is not an issue for guideline development, but for local CCGs. The current recommendation will remain as it stands in the new updated guideline. The evidence regarding long-acting beta2 agonists in combination with other inhaled therapy, is going to be updated in the guideline. For short-acting beta 2 agonists or long-acting beta2 agonists as monotherapy, the NICE surveillance review found insufficient new evidence to warrant an update to the current recommendations, and therefore these will not be included in the update of the guideline.
13	The Royal College of Anaesthetists	General	General	Early diagnosis and risk stratification will cost money unless behaviour modification is properly addressed. Otherwise it will simply result in increased prescribing. A proper evaluation of medical intervention is long overdue. It may well be that much of the prescribed medication is of little, if any, long term benefit and the side effects may outweigh the gain from symptom control. If	Thank you for your comment. We are unclear what you are specifically referring to by 'behaviour modification'. The current guideline makes recommendations about clinical assessment to be done at least annually, and this includes assessing smoking status and desire to quit, inhaler technique and other things that would be considered behaviour modification). There are also a number of recommendations addressing smoking

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				this is realistically addressed, adherence to treatment may also improve.	cessation. We therefore do not plan to update this section of the guideline. We could perhaps further emphasise the recommendations around smoking, and we are planning to cross-refer to the NICE smoking cessation guideline, which is due to be published November 2017 and the TA on Varenicline for smoking cessation (TA123) will be linked to this guidance in the NICE pathway. This has been made clearer in the wording of the table in the scope.
14	The Royal College of Anaesthetists	5	16-19	Muscarinic antagonists and anticholinergic agents are listed separately but in this context they are essentially the same drugs.	Thank you for your comment. We have clarified the wording in the scope as the first bullet point was referring to combination therapy of LAMA and LABA, and the second bullet point was referring to LAMA monotherapy. We have now changed the scope to say LAMA instead of anticholinergics. We agree that terminology may be the source of confusion, and this will be checked by the guideline committee when the guideline is updated. In the original guideline, the term long-acting 'anticholinergics' was used to refer to LAMA.
15	The Royal College of Anaesthetists	7		Similarly theophylline and phosphodiesterase antagonists are listed separately. Theophylline is a member of this group.	Thank you for your comment. We disagree with combining PDE4 inhibitors with theophyllines. Theophyllines are less selective than PDE4 inhibitors and in the BNF they are listed under a different heading.
16	UK Inhaler Group	General	General	The UK Inhaler Group recognise that there is a thorough inclusion of inhaler technique/issues within the content to date. However, it appears in the master document that	Thank you for your comments. Inhaler technique is included in several recommendations in the current guideline, including retraining and reassessment.

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				this has not been reviewed and updated since the 2004 consultation We would recommend that NICE highlights the importance of the inhaler technique Quality statement in relation to the management of this group of patients and draws the attention to.https://www.nice.org.uk/guidance/qs10/chapter/Quality-statement-2-Inhaler-technique as part of this review	As part of reviewing the guideline for update, the NICE surveillance review identified new evidence on inhaler technique and adherence (under the self-management topic of the guideline). However, it was considered consistent with current guideline recommendations. The topic of adherence and inhaler technique was therefore not considered to need updating, and therefore excluded from the scope of the update. The current recommendations will be carried forward in the updated guideline.
17	UK Inhaler Group	General	General	Prescribing devices – patients should have their ability to use the prescribed inhaler device (particularly for any change in device) assessed by a competent healthcare professional at initiation of an Inhaled therapy Reassessing inhaler technique should be a routine part of structured clinical review Generic prescribing of inhalers should be avoided as this might lead to people being given an unfamiliar inhaler device which they are not able to use properly. The UK Inhaler group would also like to share our recently published Inhaler Standards and competency document intended to be used as a framework to set, assess and support the standards of those initiating	Thank you for your comments. Inhaler technique is included in several recommendations in the current guideline, including prescribing, ability, retraining and reassessment. As part of reviewing the guideline for update, the NICE surveillance review identified new evidence on inhaler technique and adherence (under the self-management topic of the guideline). However, it was considered consistent with current guideline recommendations. The topic of adherence and inhaler technique was therefore not considered to need updating, and therefore excluded from the scope of the update. The current recommendations will be carried forward in the updated guideline.

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				inhaler therapies and checking inhaler techniques, in order that they can demonstrate competency in prescribing medications via an inhaled route and teaching the correct technique for the inhaler device prescribed to optimise drug administration. It also provides an outline basis for competency assessment. UKIG Inhaler and Competecy document can be found at; http://bit.ly/2lLoRtt	Regarding choice of devices, we consider that the recommendations in the current guideline are sufficiently broad to allow an appropriate device to be selected and changed, depending upon the requirements of individual patients. No other evidence was found by the NICE surveillance review when they reviewed whether the guideline needed updating. The topic of inhaler devices was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward in the updated guideline.
18	UK Inhaler Group	General	General	it is good that there is a review of medications. This is required because of newer combinations of medicines since the last medicines update and emerging evidence on risk/benefit for our practice. The review of biomarkers and multidimensional tools seems appropriate to update as does the review of who should receive oxygen	Thank you for your comments.
106	UKCPA	General	General	The scoping document should ensure there is consistency in terminology used, e.g. where long-acting anticholinergics is used interchangeably with long acting muscarinic antagonosts.	Thank you for your comment. We agree that terminology may be the source of confusion, and this will be checked by the guideline committee when the guideline is updated. In the original guideline, the term long-acting 'anticholinergics' was used to refer to LAMA. LAMA has

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					now been added to replace the word 'anticholinergics' in the scope, to make this clearer.
107	UKCPA	General	General	We would propose that there is some consideration of the evidence for the role of pharmacists in managing patients with COPD to improve cost-effective treatments are used.	Thank you for your comment. It is not the usual practice for guidelines to make recommendations about specific professional groups, but more about the experience and competence needed to deliver the interventions. The focus of the guideline is to ensure that people receive the best care by competent and supervised practitioners. The current guideline has made recommendations about care of COPD involving a multidisciplinary team, and it would be expected that a pharmacist would be included as part of this.
108	UKCPA	2 General	20	The document identifies that "the range and complexity of the inhaled therapies available (drugs and devices) has also increased enormously". This should prompt a review of the evidence of the risks associated with non-consented switch of inhaler devices, as different devices are not interchangeable and generics launched with a hybrid license have a dm+d prescribing status of VMP not suitable to prescribe – patient training required. We would propose that the updated guideline should consider a recommendation that mirrors the BTS/SIGN asthma guideline good practice recommendation "Generic prescribing of inhalers should be avoided as this might lead to people with asthma being given an unfamiliar inhaler device which they are not able to use properly."	Thank you for your comment. Regarding choice of devices, we consider that the recommendations in the current guideline are sufficiently broad to allow an appropriate device to be selected and changed, depending upon the requirements of individual patients. . No other evidence was found by the NICE surveillance review when they reviewed whether the guideline needed updating.The topic of inhaler devices was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward in the updated guideline.

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109	UKCPA	9	Table	We would have thought a review of ICS therapy in COPD would be worthwhile. Perhaps there is no new evidence for ICS therapy, but surely there is new safety data,. Failure to consider the safety risks of ICS in terms of pneumonia creates a mismatch with EMA advice (see http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Inhaled_corticosteroids_for_chronic_obstructive_pulmonary_disease/human_referral_prac_000050.jsp&mid=WC0b01ac05805c516f). On page 10, the scoping document reports that "footnotes highlighting safety considerations will be added to the recommendations on ICS monotherapy and delivery systems. This is because of Drug Safety Updates published: – in 2010, covering psychological and behavioural side effects associated with inhaled corticosteroids", so it is interesting that the scoping document fails to comment on pneumonia risk with ICS, which is of high importance in COPD.	Thank you for your comment. One of the topics included in the draft scope already is ICS/LABA combination when compared to LABA/ LAMA. The whole of the treatment pathway is planned to be updated in the new guideline, which will include ICS. Safety issues associated with ICS, would include pneumonia and this will be taken into consideration in the guideline committee's discussions, and footnotes will be added in where appropriate.
110	UKCPA	10	Table	We consider that there is a significant oversight within the evidence review of Management of Stable COPD. With the anticipated launch of the first triple combination inhalers (long-acting muscarinic antagonist + long-acting beta2-againost + inhaled corticosteroid), it is a significant failing of the scope that an evidence review of triple inhalers is not planned, and risks the updated COPD guideline being irrelevant at the point of publication. The 6- year surveillance document used to inform the scoping document	Thank you for your comment. We will be looking at the evidence for ICS/LABA, it was accidentally missed from the scope and has now been added in. Regarding triple therapy, the guideline recommends that triple therapy should be offered as step-up treatment if symptoms or exacerbations persist on current therapy, irrespective of the patient's FEV1. During the review for update process, NICE surveillance did not identify any new evidence which would change the direction of these recommendations. Triple therapy was therefore not

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				(https://www.nice.org.uk/guidance/cg101/evidence/appendix-a-decision-matrix-april-2016-2425366766) is dated 2015, and so new important data has not been reviewed e.g. Singh et al. Lancet 2016, 388(10048):963-73. http://dx.doi.org/10.1016/S0140-6736(16)31354-X	included in the scope and the current recommendations will be retained in the updated guideline.
111	UKCPA	10	Table	We note that no review of delivery systems is proposed. We consider this to be wrong. A review of the evidence of the risks associated with non-consented switch of inhaler devices, as different devices are not interchangeable and generics launched with a hybrid license have a dm+d prescribing status of VMP not suitable to prescribe – patient training required. We would propose that the updated guideline should consider a recommendation that mirrors the BTS/SIGN asthma guideline good practice recommendation "Generic prescribing of inhalers should be avoided as this might lead to people with asthma being given an unfamiliar inhaler device which they are not able to use properly."	Thank you for your comment. Regarding choice of devices, we consider that the recommendations in the current guideline are sufficiently broad to allow an appropriate device to be selected and changed, depending upon the requirements of individual patients. No other evidence was found by the NICE surveillance review when they reviewed whether the guideline needed updating. The topic of inhaler devices was therefore not considered to need updating, and therefore excluded from the scope. The current recommendations will be carried forward in the updated guideline.
112	UKCPA	10	Table	A review of subgroups and cohorts of patients that may respond to inhaled corticosteroids should be considered. There is increasing evidence that COPD patients with high eosinophil counts are more likely to respond to ICS than those with low counts (eg Watz et al. Lancet Resp Med 2016;4:390-8).. The updated guideline should consider how patients prescribed ICS inappropriately should be stepped down	Thank you for your comment. We are planning to look at the effectiveness of ICS/LABAs compared to LAMA/LABA as part of the guideline and this has been included in the scope. If the evidence found for particular subgroups of people is very different to those with COPD alone, then the guideline committee will consider making separate recommendation(s) for these groups. As part of the guideline review for update process, the NICE surveillance review identified evidence relating to

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				and have their ICS withdrawn (e.g. Magnusson et al. New Engl J Med 2014;371:1285-94)	withdrawal of ICS, however it was not deemed sufficient to lead to changes in the current recommendations on inhaled therapy. The topic was therefore not included in the scope as a priority area requiring update. However, we are aware of safety issues concerning ICS, and therefore (as detailed in the draft scope), a footnote will be added to the guideline to outline potential adverse events related to inhaled steroids. Thank you for providing this reference for the large RCT by Magnusson et al. It will be considered as part of the guideline evidence review on ICS, if it meets the inclusion criteria set by the review protocol.
113	UKCPA	10	Table	We would propose that there should be some consideration of the role of rescue packs and addressing the overuse of oral corticosteroids and antibiotics.	Thank you for your comment. There is currently a recommendation on the use of rescue packs (recommendation 1.2.12.23) and this recommendation will be carried forward into the updated guideline.
46	University Hospital Birmingham	General	1.2.11	Alpha1Antitrypsin augmentation. Since 2004 there has been a lot of published work on both the pathophysiology, natural history and observational studies as well a powered and controlled trial demonstrating benefit in preserving lung structure. Many ex smokers remain stable but others show progression despite optimal COPD therapy and management. I think Nice should pay attention to the wealth of new data rather than referring to the 2004 evidence	Thank you for your comment. We are aware of an RCT on A1AT augmentation therapy (Chapman 2015), which showed some positive effects. It was found that there was a reduction in the loss of annual lung density (TLC only, not FRC alone or TLC and FRC combined). However, a Cochrane review published in 2016 (Gotzsche 2016), which included the Chapman study, concluded that there was no significant change in outcomes of those undergoing A1AT therapy to warrant a change to the current recommendations, and the

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					quality of the evidence was also unclear. We have also looked at the evidence both during the NICE surveillance review of whether to update the guideline, as well studies submitted to us during scoping of this update. The evidence identified did not impact current recommendations and therefore A1AT therapy was not prioritised for update in this scope. Should further evidence become available related to the current recommendation, then this will be considered by the NICE surveillance review when the guideline is reviewed for need to update (which is done at regular intervals after publication) and may be included in the scope for the next update.
47	University Hospital Birmingham	5	11 and 12	Agree assessment of prognosis/severity eg BODE/ADO	Thank you for your comment.
48	University Hospital Birmingham	5	21	Including advice on Azithromycin in anti-inflammatory doses – hearing, QTc interval, NTM, and duration of treatment – may overlap with forthcoming BTS guideline on low dose macrolide use.	Thank you for your comment. The advice provided in the NICE guideline includes cost-effectiveness as well as clinical effectiveness, and so the recommendations may differ because they are based on more factors than those considered by the BTS guidance.
49	University Hospital Birmingham	5	26	Not just lung surgery but other lung volume reduction procedures – eg valves +/- coils	Thank you for your comment. Regarding valves and coils for lung volume reduction surgery, the NICE surveillance review identified new evidence, however it was considered consistent with current guideline recommendations. Current guideline recommendations provide referral criteria for lung volume reduction surgery, but they do not specify the type of surgery that

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					should be conducted. This would be considered a clinical judgement based on the expertise of the healthcare professional and the individual needs of the person with COPD who is presenting to them. The topic of surgery was therefore not considered to need updating, and therefore excluded from the scope. The current recommendation will remain as it stands in the new updated guideline.
50	University Hospital Birmingham	6	Table	Need to reiterate importance of quality-assured spirometry for diagnosis and forthcoming accreditation procedure for performance and interpretation of mspiro – ARTP.	Thank you for your comment. Although we are not planning to update this topic in the new guideline, the recommendations from the original guideline will be retained and will appear in the updated guideline. There is already a recommendation stating that spirometry services should be supported by quality control processes. The specific process followed and adhering to accreditation procedures, is an implementation issue which needs to be addressed by individual CCGs, and is therefore not within the remit or scope of this guideline to do this.
51	University Hospital Birmingham	7	Table	Look at evidence on starting NIV soon after an admission if hypercapnia persists; and evidence base for early post exacerbation pulmonary rehab.	Thank you for your comment. Regarding criteria for starting NIV, the current guideline makes recommendations about when NIV should be given. One of these includes hypercapnia. Regarding pulmonary rehabilitation, the NICE surveillance review identified new evidence for pulmonary rehabilitation, however it broadly supports the

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					current recommendation (to provide PR). The topic of pulmonary rehabilitation, was therefore not considered to need updating, and therefore excluded from the scope. Lack of implementation is not an issue that can be addressed in guideline development, but is an issue for the local CCGs. The current recommendation will remain as it stands in the new updated guideline.
52	University Hospital Birmingham	10	3	Assessment of severity of acute exacerbations - DECAF	Thank you for your comment. We are aware of the publications relating to DECAF prognostic scoring (Steer, 2012 and Echivarria, 2016); however these were not identified in the NICE surveillance review as they were out with the search dates used, and were not meta-analyses or systematic reviews. It was concluded that there is currently not enough evidence to change the recommendation on prognostic scoring for COPD: however this area will remain under NICE surveillance (which is done at regular intervals once the updated guideline is published) and consideration will be given to updates in future. However, if you feel that new evidence demands more immediate consideration, this can be submitted to NICE and considered before the next scheduled NICE surveillance review. Thank you for making us aware of the studies that are currently being undertaken, this is helpful information that will be considered for future updates of the guideline.

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Registered stakeholders

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