Managing Common Infections

Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing

Stakeholder comments table

09/07/2017 – 06/08/2018

ID	ORGANISATION NAME	DOCUMENT	PAGE NO.	LINE NO.	COMMENTS Please insert each new comment in a new row	DEVELOPER'S RESPONSE Please respond to each comment
1	British Infection Association	Draft Guideline	13		under second choice antibiotics, consider including oral chloramphenicol	Thank you for your comment. This was discussed further by the Committee and the recommendation has not been amended. Chloramphenicol is not commonly used in practice and the committee were concerned about serious haematological adverse effects and monitoring requirements when chloramphenicol is given systemically, when other safer alternatives are available. The BNF advises that it is reserved for the treatment of life-threatening infections.
2	British Infection Association	Draft Guideline	17		Second-line IV choice should include ceftriaxone for practical administration reasons (though with IV co-amoxiclav preferred). First choice IV should not include co-trimoxazole (which could be given orally or second-line).	Thank you for your comment. This was discussed further by the Committee and they agreed that second-choice intravenous antibiotics for an exacerbation of COPD would be an individualised decision after specialist advice, based on the severity of illness, likely pathogens or antibiotic susceptibilities from culture results when available, and local resistance patterns.

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3	British Infection Association	Draft Guideline			In the absence of evidence for regime and duration the best response from NICE would be to recommend further research.	Thank you for your comment. The evidence review for the efficacy of antibiotics was based on a systematic review and meta-analysis of RCTs (Vollenweider et al. 2012), which included a wide range of antibiotics. We also identified a systematic review and meta-analysis of RCTs assessing short course antibiotics (for less than 6 days) compared with long course antibiotics (for 7 days or more). The committee agreed that this was not a key research question and that that the main area of uncertainty was which people are more likely to benefit from antibiotics.
4	University Hospitals Birmingham NHS Foundation Trust (QE Hospital)	Guideline	1	Algor-othim	We are concerned that in an era of concern about antibiotic stewardship that this guideline will lead to an increase in use of antibiotics for acute exacerbations of COPD. Many exacerbations are viral in nature, due to air pollution, and perhaps unidentified cardiac failure. None of these will respond to antibiotic therapy. Sputum purulence correlates with neutrophilic inflammation and bacterial infection, and we believe that antibiotic should be reserved for patients with discoloured sputum i.e. yellow, yellow-green, green, or patients with very severe exacerbations requiring ventilatory support. The advice here contradicts what is said in the main COPD guideline see Page 41, Lines 18-23, pasted below:	Thank you for your comment. This was discussed further by the Committee and recommendations have been amended. The committee recognised that many exacerbations are not caused by bacterial infections, and this is included in the guideline. This antimicrobial prescribing guideline will replace recommendations 1.3.22–25 from the NICE guideline on COPD in over 16s (update). In response to stakeholder comments and following expert advice, the committee agreed that the presence of sputum colour changes and increases in volume or thickness beyond the person's normal day-to-day variation appear to be

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					"Antibiotics **1.3.22 Use antibiotics to treat COPD exacerbations associated with a history of 19 more purulent sputum. [2004] 20** **1.3.23 People who have exacerbations without more purulent sputum do not 21 need antibiotic therapy unless there is consolidation on a chest X-ray or 22 clinical signs of pneumonia. [2004]"** If an antibiotic is not prescribed on the algorithm but a sputum sample is sent, and grows something, you could interpret this as meaning that an antibiotic should be prescribed. If the sputum is whie, clear or colourless yet a bacteria is cultured, then this may simply represent colonisation – the patient should NOT have an antibiotic.	important factors. The committee agreed that an antibiotic should only be considered for people with an acute exacerbation of COPD on an individual patient basis. This should take into account the increased risk of harms and the risk of antimicrobial resistance with repeated courses, balanced against severity of their symptoms, their need for hospital treatment, their exacerbation and hospitalisation history, their risk of complications, and previous sputum culture results.
5	University Hospitals Birmingham NHS Foundation Trust (QE Hospital)	Guideline	4	Table 1	Does Erythromycin have sufficient activity against Haemophilus? If not, it shouldn't be a first line antibiotic choice.	Thank you for your comment. This was discussed further by the Committee and erythromycin has been removed from the prescribing table. While the committee agreed with the comment on theoretical grounds, the clinical relevance of this is unclear. However, it was felt that the inclusion of clarithromycin as the macrolide of choice was sufficient in this population.
6	The Royal College of Physicians and	Guideline	General	General	The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the	Thank you for your comment.

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	Surgeons of Glasgow				United Kingdom who practice in the field of COPD. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. The College welcomes this review of Chronic Obstructive Pulmonary Disease (acute exacerbation): anti-microbial prescribing by NICE. It recognises that management protocols need to change with changes in the understanding of disease, its assessment and its treatment. It particularly notes that protocols need to take cognisance of anti-microbial resistance. It recognises the importance of working with Patients to manage their disease. It was considered that this is an excellent document which is well written and easy to read. It highlights the difficulties and challenges in giving advice around anti-microbial prescribing with current evidence available. The guideline will not produce any major challenges to implementation with appropriate support and education. It will have the biggest impact on primary care prescribing and have a large cost reduction whilst improving care and reducing potential harm to patients. The intention of reducing unnecessary antibiotic use is helpful. Healthcare professionals will have no issue with the technical wording but	

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					patients/families will struggle to follow some of the technical terms. They may be unnecessarily alarmed by the use of some terms – such as cardiorespiratory failure and sepsis when describing deteriorating symptoms. This may drive them to seek antibiotics in an attempt to avoid this. Despite this reservation, it was felt that overall the guideline is succinct, clear and could potentially have a massive effect in improving care.	
7	The Royal College of Physicians and Surgeons of Glasgow	Table 1	5	Table 1 point 1	Superscript point 1 – Our reviewer agrees with consulting the BNF, however the guideline could be made more "user-friendly" if some information was given as to where caution is needed when antibiotics are being considered in certain circumstances (it is appreciated that a further table may be needed).	Thank you for your comment. The committee agreed that users should refer to the BNF for appropriate use and dosing in specific circumstances.
8	The Royal College of Physicians and Surgeons of Glasgow	Summary review	7	11	A comment should be made about anti-viral therapy in acute COPD exacerbations.	Thank you for your comment. This is outside the scope of this guideline.
9	The Royal College of Physicians and Surgeons of Glasgow	Summary review	7	12	There should be a hyperlink to NICE Smoking cessation guideline to encourage discontinuing smoking.	Thank you for your comment. General management of acute exacerbations of COPD is covered in the NICE guideline on COPD in over 16s (update).
10	The Royal College of Physicians and	Summary of Evidence	9	25	Penicillin allergy is often over-diagnosed and can complicate choice of antibiotic – leading to an unnecessary choice of higher risk antibiotics.	Thank you for your comment. The information on penicillin allergy has been

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	Surgeons of Glasgow				A comment should be considered about establishing the basis for the allergy and referral to specialist allergy services if in doubt.	updated to include information from the NICE guideline on drug allergy.
11	British Thoracic Society	Guideline	2	12-26	Both this and the COPD guideline (2018) should be consistent regarding which exacerbations require antibiotics: 1) This section does not recommend assessing sputum purulence and volume/viscosity to inform the decision whether to provide antibiotics. We recommend this is clarified. 2) Antibiotics are recommended in all severe (hospitalised) exacerbations. Not all exacerbations requiring hospitalisation are due to bacterial infection. Please amend. For simplicity, consider stating that sputum purulence and volume/ viscosity should be assessed to inform the decision to provide antibiotics in moderate and severe exacerbations (in this section).	This was discussed further by the Committee and recommendations have been amended. In response to stakeholder comments and following expert advice, the committee agreed that sputum colour changes and increases in volume or thickness beyond the person's normal day-to-day variation appear to be important factors. The committee agreed that an antibiotic should only be considered for people with an acute exacerbation of COPD on an individual patient basis. This should take into account the increased risk of harms and the risk of antimicrobial resistance with repeated courses, balanced against severity of their symptoms, their need for hospital treatment, their exacerbation and hospitalisation history, their risk of complications, and previous sputum culture results.
12	British Thoracic Society	Guideline	4-5	Table 1	We note the appropriate recommendation to consider the most recent sputum culture. The following comments are primarily in reference to patients without sputum culture and sensitivity data to guide choice. Patients with severe infective exacerbations requiring hospitalisation are more likely to have pseudomonas. The empirical options for	Thank you for your comments. The committee discussed your comments and have amended the choice of antibiotics to include piperacillin with tazobactam.

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					severely unwell patients do not cover pseudomonas. Those at high risk of death often show a short time to death (with the highest DECAF risk scores: median time to death among those not surviving to discharge = 2 days). Risk stratification to inform antibiotic choice is used in other conditions applying the pragmatic view that you may not get "a second bite at the cherry" in high risk patients. Empirical choice (no recent culture available) in patients with severe exacerbations (hospitalised) AND at high risk of inpatient mortality (e.g. high risk DECAF score): broad spectrum antibiotic with cover for pseudomonas e.g. piperacillin/tazobactam.	
13	British Thoracic Society	General			Please note that we had no prior knowledge of the production of this guideline and we also note that there is no specific respiratory input into the guideline group.	Thank you for your comment. Two respiratory specialists have been involved in the development of this guideline and we have worked closely with the committee developing the NICE guideline on COPD in over 16s (update).
14	The Royal Pharmaceutical Society	Draft Guideline	2	11	Whilst the visual summary mentions that patients may have a course of oral corticosteroids at home, this is not mentioned in the draft guideline.	Thank you for your comment. The recommendations have been amended to make clear that some people at risk of exacerbations may have antibiotics to keep at home as part of their exacerbation action plan (see the NICE guideline on COPD in over 16s [update]). The visual summary has been amended to reflect the guideline. The guideline

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						also states that 'The recommendations in this guideline are based on the evidence identified, which was for antibiotics for managing an acute exacerbation of COPD in adults. Non antimicrobial interventions, such as bronchodilators, corticosteroids and oxygen therapy are covered in the NICE guideline on COPD in over 16s (update).
15	The Royal Pharmaceutical Society	Draft Guideline	2	11	The guideline should mention that patients may need a course of oral corticosteroids for an exacerbation, co-prescribed with the antibiotic (and refer to the appropriate NICE guideline on this)	Thank you for your comment. Oral corticosteroids are outside the scope of this guideline. The NICE guideline on COPD in over 16s (update) includes recommendations on the use of oral corticosteroids. This guideline states that 'The recommendations in this guideline are based on the evidence identified, which was for antibiotics for managing an acute exacerbation of COPD in adults. Non antimicrobial interventions, such as bronchodilators, corticosteroids and oxygen therapy are covered in the NICE guideline on COPD in over 16s (update).
16	The Royal Pharmaceutical Society	Draft Guideline	3	9, 15	These sections refer to ***prescription*** of antibiotics. Antibiotics can be and are also supplied using a patient group direction (PGD) by community pharmacists for COPD exacerbations. The guideline should refer to the important role that community pharmacists can play in supporting patients with COPD in helping recognise and manage exacerbations at an early stage, including supplying rescue packs (with antibiotics) when appropriate, using a PGD.	Thank you for your comment. The committee discussed your comment and the guideline has been amended to remove the term 'prescription'. However, the NICE guideline on patient group directions (PGDs) recommends: 1.1.10 Do not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections. Ensure that an

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					A paper on COPD support service (can be found via the link below on the main CPF website) evidences the health economic value of this. www.communitypharmacyfuture.org.uk Community pharmacies in Scotland have been providing rescue medication, including antibiotics using a PGD for several years. http://www.communitypharmacy.scot.nhs.uk/nhs_boards/NHS_Forth_Valley/redesign/LNS/pharmacy_first.html	antimicrobial is included in a PGD only when: • clinically essential and clearly justified by best practice guidance • a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 1.3.2) • use of the PGD is monitored and reviewed regularly (see recommendations 1.6.4 and 1.8.5). 1.1.4 Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis. Self-management is outside the scope of this guideline. A recommendation has been added to make clear that people with an acute exacerbation of COPD who have an exacerbation action plan may have antibiotics to keep at home, in line with the NICE guideline on COPD in over 16s (update).
17	The Royal Pharmaceutical Society	Visual Summary			The summary paper only refers to ***prescription*** of antibiotics. Antibiotics can be and are also supplied using a patient group direction (PGD) by community pharmacists for COPD exacerbations. The visual summary should refer to the important role that community pharmacists can play in supporting patients with COPD in helping recognise and manage exacerbations at	Thank you for your comment. The committee discussed your comment and the guideline has been amended to remove the term 'prescription'. However, the NICE guideline on patient group directions (PGDs) recommends: 1.1.10 Do not jeopardise local and national strategies to combat

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					an early stage, including supplying rescue packs (with antibiotics) when appropriate, using a PGD. A paper on COPD support service (can be found via the link below on the main CPF website) evidences the health economic value of this. www.communitypharmacyfuture.org.uk Community pharmacies in Scotland have been providing rescue medication, including antibiotics using a PGD for several years. http://www.communitypharmacy.scot.nhs.uk/nhs_boards/NHS_Forth_Valley/redesign/LNS/pharmacy_first.html	antimicrobial resistance and healthcare-associated infections. Ensure that an antimicrobial is included in a PGD only when: • clinically essential and clearly justified by best practice guidance • a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 1.3.2) • use of the PGD is monitored and reviewed regularly (see recommendations 1.6.4 and 1.8.5). 1.1.4 Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis. Self-management is outside the scope of this guideline. A recommendation has been added to make clear that people with an acute exacerbation of COPD who have an exacerbation action plan may have antibiotics to keep at home, in line with the NICE guideline on COPD in over 16s (update).
18	The Royal Pharmaceutical Society	Visual Summary			Section 1.5.1 of the evidence review mentions that: *Medicines adherence may be a problem for some people with medicines that require frequent dosing (for example, some antibiotics) (NICE guideline on medicines adherence [2009]).* The Visual Summary contains guidance	This guideline does not include recommendations on the general principles of antimicrobial stewardship. This guideline has not searched for, or reviewed evidence for the benefits and risks of completing the full course. The

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					for ***When an antibiotic is given, advise:*** This should also include the importance to complete the course of antibiotics as part of antimicrobial stewardship.	visual summary reflects the content of the guideline recommendations. See the NICE guidelines on Antimicrobial stewardship: changing risk-related behaviours in the general population (2017) and Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use (2015).
19	Royal College of General Practitioners		4	25	The course length for amoxicillin in this guideline is 5 days whilst that in the new guideline for bronchiectasis is 7 days. This may lead to some confusion	Thank you for your comment. This was discussed further by the Committee and the recommendation has not been amended as it is in line with the evidence considered for people with an acute exacerbation of COPD.
20	Royal College of General Practitioners	General			There is no mention in the guideline about the guideline committee's view on the use of delayed scripts or prophylactic long-term antibiotics	Thank you for your comment. No evidence was identified on back-up antibiotics and the committee was not able to make any recommendations on their use. This is now stated in the committee rationale section of the guideline. Antibiotic prophylaxis is outside the scope of this guideline, this is covered in the NICE guideline on COPD in over 16s (update).
21	Royal College of General Practitioners	General			There is no mention of the role of testing C reactive protein (CRP) or procalcitonin (PCT) in the decision to prescribe antibiotics	Thank you for your comment. The remit of the guideline does not cover diagnostic tests.
22	The British Society for Antimicrobial Chemotherapy (BSAC)	Draft guideline Visual summary	n/a	n/a	The definition of severe exacerbation is different to the full guideline.	Thank you for your comment. The committee discussed the recommendation for people with a severe exacerbation and this has now been amended. There is no longer a separate recommendation for people with a severe

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						exacerbation. The content of the visual summary has been amended to reflect the guideline.
23	The British Society for Antimicrobial Chemotherapy (BSAC)	Guideline and visual summary	Guideline pg 5 Visual summary pg 2	25 table 1	Concerned re use of macrolides with risk of cardiac toxicity in patients with COPD who are are at higher risk of IHD	Thank you for your comment. The choice of antibiotics takes account of the balance between risks and benefits and the committee agreed that macrolides are an appropriate first-choice empirical treatment. A statement about using macrolides with caution in people with a predisposition to QT interval prolongation has been added to the safety of antibiotics section in the guideline. However, the prescribing table states 'See BNF for appropriate use and dosing in specific populations, for example, hepatic impairment, renal impairment, and administering intravenous antibiotics. The guideline also states 'See the summaries of product characteristics for information on contraindications, cautions and adverse effects of individual medicines.
24	The British Society for Antimicrobial Chemotherapy (BSAC)	COPD (acute exacerbation): antimicrobial prescribing Full guideline	5	General	We are concerned that the recommendation to use co-amoxiclav first line may have a negative impact on *Clostridium difficile* rates. Some centres are using IV benzylpenicillin or IV amoxicillin + single dose IV gentamicin for these cases which provides sufficient cover without CDI risk The inclusion of IV co-trimoxazole is welcome, but the lack of availability of a licensed product	Thank you for your comment. The choice of IV antibiotics has been amended following discussion with the committee and includes a range of options. Amoxicillin has been added for people who may not need a broader spectrum antibiotic, for example because they are unable to take oral medicines. Piperacillin with tazobactam has been added for when specific activity against

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					(due to recurrent product shortage) is a practical factor We are concerned that moxifloxacin is included as it is subject to an EMEA warning for its oral use, and is recommended only where other antibiotics cannot be used.	pseudomonas aeruginosa may be required. In some people exacerbations of COPD may be life threatening which may necessitate the use of a broader spectrum antibiotic such as co-amoxiclav. As therapeutic drug monitoring and dose adjustment is required for gentamicin, the committee did not feel that this was an appropriate first-choice intravenous antibiotic, when many people with an acute exacerbation of COPD are treated in the community. This was discussed further by the Committee and the recommendation has not been amended. The committee does not base its decisions on medicines supply issues as these change over time, and alternative options are given. The committee discussed your comment and moxifloxacin has been removed from the prescribing table.
25	The British Society for Antimicrobial Chemotherapy (BSAC)	COPD (acute exacerbation) : antimicrobial prescribing Full guideline	7	9	Previous NICE guidance says to use antibiotics for an exacerbation associated with increased purulent sputum. This new guidance says to use antibiotics for a severe exacerbation, which is defined as needing hospitalisation. I am concerned that this implies that all COPD exacerbations requiring antibiotics needs to be referred first to secondary care?	Thank you for your comment. This was discussed further by the Committee and recommendations have been amended. This guideline will replace recommendations 1.3.22–25 from the NICE guideline on COPD in over 16s (update). In response to stakeholder comments and following expert advice, the

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					It is not clear from the evidence base why the above change in practice has been made.	committee agreed that sputum colour changes and increases in volume or thickness beyond the person's normal day-to-day variation appear to be important factors. The committee agreed that an antibiotic should only be considered for people with an acute exacerbation of COPD on an individual patient basis. This should take into account the increased risk of harms and the risk of antimicrobial resistance with repeated courses, balanced against severity of their symptoms, their need for hospital treatment, their exacerbation and hospitalisation history, their risk of complications, and previous sputum culture results.
26	Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups	Visual Summary			Will it be useful to highlight levo/moxifloxacin as choices for pseudomonas eradication with sputum cultures as this is suggestive of colonising with suspected infective organism. Cost of levo/moxi vx cipro also an issue? If considered the durations of antibiotic courses seem too short - some patients do not respond to one week only. Higher dose therapy with respect to penicillins (amox) may also be needed depending on clinical picture of those suggested.	Thank you for your comments. The committee discussed this further and has not highlighted pathogen specific antibiotic choices. Sputum culture is not recommended routinely in people with an acute exacerbation of COPD, therefore in most cases empirical treatment will be required. However, the prescribing table has been amended to give more clarity on when a broader spectrum antibiotic, or an antibiotic with specific activity against a pathogen such as pseudomonas aeruginosa may be required. The committee agreed that levofloxacin was the appropriate choice of quinolone

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						for people with an acute exacerbation of COPD, based on the evidence identified. Moxifloxacin has been removed from the prescribing table to take account of EMEA advice. The recommended course length is based on a systematic review and meta-analysis of RCTs which found that short-course antibiotics (for less than 6 days) were as effective as long course antibiotics (for 7 days or more). The committee did not find any evidence that specific subgroups of people would benefit from a longer course. The committee also agreed that symptoms may not be fully resolved when the antibiotic course has been completed, and this has been added to the advice that should be given to the person. A footnote has been added to the antibiotic prescribing table to show were the dosage may be increased in severe infections.
27	Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups	Guideline			There is a lack of clarity re anti-pseudomonal choices of oral treatment	Thank you for your comments. The committee discussed this further and has not highlighted pathogen specific antibiotic choices. Sputum culture is not recommended routinely in people with an acute exacerbation of COPD, therefore in most cases empirical treatment will be required. However, the prescribing table has been amended to give more clarity

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						on when a broader spectrum antibiotic, or an antibiotic with specific activity against a pathogen such as pseudomonas aeruginosa may be required, guided by susceptibilities when available.
28	Scottish Antimicrobial Prescribing Group	Key questions 1-4			The guidance on the whole reflects current practice so implementation of the recommendations should not present many challenges. Key learning point for professional groups will be adopting a 'no antibiotic' approach when patients present with increased symptoms as this may not be current practice for some clinicians.	Thank you for your comment.
29	Scottish Antimicrobial Prescribing Group	Visual summary	1		Given that this is for members of public as well as HC professionals not sure the term 'antimicrobial' will be understood - should 'antibiotic' be used or inserted in brackets Also unsure if the public would understand the term 'purulence' in relation to sputum. Where patients do not get an antibiotic should it include 'advise patient to monitor symptoms over next few days' i.e. a watch and wait approach? Consider antibiotic after prescribing considerations – unclear that you need to look at box on right side of summary to see what these are. It may be helpful to note that a short course of steroids should also be considered. May also be helpful to include concurrent medication and potential drug interactions.	Thank you for your comment. This guideline is written for health professionals. Wording was considered by the NICE publishing team. No evidence was identified regarding a wait and watch approach. If no antibiotic is given, the recommendations include advice for the person about when to seek medical help without delay. Wording and formatting was considered by the NICE publishing team. The visual summary states 'consider an antibiotic, **but only after prescribing considerations**'. Corticosteroids are outside the scope of this guideline. The NICE guideline on COPD in over 16s (update) includes

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					If sputum is sent when results are available review antibiotic – suggest add 'if one has already been started'. Severe exacerbations box on right refers to 'more symptoms' it would be helpful to include somewhere earlier in the summary what key symptoms and GOLD criteria for an exacerbation.	recommendations on the use of oral corticosteroids, including people with an exacerbation action plan. It is not possible to include full prescribing information about possible drug interactions in a short 2-page summary of the recommendations. The committee agreed that users should refer to the BNF for appropriate use and dosing in specific circumstances. The remit of this guidance is the management of common infections not diagnosis, and further detail on diagnostic signs and symptoms, or criteria is out of scope. The guideline does include information in the 'terms used in the guideline' section.
30	Scottish Antimicrobial Prescribing Group	Visual summary	2		First line IV treatment co-amoxiclav – this is not current practice in Scotland.	Thank you for your comment. The committee agreed that this is an appropriate first-line intravenous choice for people who are severely unwell, or unable to take oral medicines.
31	Scottish Antimicrobial Prescribing Group	Draft guideline	4-5		Formatting – table split over 2 pages	Thank you for your comment. The final guideline will be presented as a web-based product and the table will not be split across pages.
32	Royal College of Nursing	General			Advised that they have no comments to submit on this occasion	Thank you
33	NHS England	Guideline	General		This covers the antibiotic treatment of COPD exacerbations separately from the other aspects of exacerbation management described in the	Thank you for your comment. This guideline is part of a suite of antimicrobial prescribing guidelines with a remit for optimising antimicrobial use and

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					COPD guideline. The rationale for doing this is not clear (CLR)	minimising antimicrobial resistance. The guideline states 'The recommendations in this guideline are for the use of antibiotics for managing an acute exacerbation of chronic obstructive pulmonary disease (COPD). See the NICE guideline on COPD in over 16s (update) for other recommendations on preventing and managing an acute exacerbation of COPD, including self-management'. The NICE pathway will incorporate both guidelines.
34	NHS England		General		This guideline will help inform the prescribing practice of AHPs which is most welcomed.(CAHPO)	Thank you for your comment.
35	NHS England		General		The recommended antibiotics could result in a resource implication for some organisations/professions if the current use of PGDs for exacerbations of COPD do not include these medicines. There would be a need for organisations to review and update their PGDs in line with the guidance provided but this is quite routine requirement for many conditions/medicines and therefore should not be an issue. (CAHPO)	Thank you for your comment. The majority of clinical care involving supplying and/or administering medicines should be made on an individual, patient-specific basis. Organisations have a responsibility to ensure that patient group directions (PGDs) are appropriate and reviewed and updated, in line with best practice. The NICE guideline on PGDs recommends: 1.1.10 Do not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections. Ensure that an antimicrobial is included in a PGD only when:

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						• clinically essential and clearly justified by best practice guidance • a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 1.3.2) • use of the PGD is monitored and reviewed regularly (see recommendations 1.6.4 and 1.8.5). 1.1.4 Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.
36	NHS England		General		This is a good adjunct to the NICE COPD guidance and NICE Sepsis guidance. The guidance is highly relevant to primary care. The table 1 (commencing on page 4 line 21) is particularly clear and helpful. The guidance is helpful in advising when sputum microbiology should be used. It would be helpful to have advice on the present or future role of blood tests such as CRP (either lab or near patient testing) in determining the decision to prescribe antibiotics. (PC)	Thank you for your comment. The remit of the guideline does not cover diagnostic tests.
37	NHS England		1.1.4		Sputum colour has been suggested in the past? (CLR)	Thank you for your comment. This was discussed further by the Committee and the recommendation has been amended. This guideline will replace recommendations 1.3.22–25 from the NICE guideline on COPD in over 16s (update).

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						This was discussed further by the Committee and recommendations have been amended. In response to stakeholder comments and following expert advice, the committee agreed that sputum colour changes and increases in volume or thickness beyond the person's normal day-to-day variation appear to be important factors. The committee agreed that an antibiotic should only be considered for people with an acute exacerbation of COPD on an individual patient basis. This should take into account the increased risk of harms and the risk of antimicrobial resistance with repeated courses, balanced against severity of their symptoms, their need for hospital treatment, their exacerbation and hospitalisation history, their risk of complications, and previous sputum culture results.
38	NHS England		Table 1		Ciprofloxacin in patients with known pseudomonas colonisation?(CLR)	Thank you for your comment. The committee discussed this further and has not highlighted pathogen specific antibiotic choices. Sputum culture is not recommended routinely in people with an acute exacerbation of COPD, therefore in most cases empirical treatment will be required. However, the prescribing table has been amended to give more clarity on when a broader spectrum antibiotic, or an antibiotic with specific activity against a pathogen such as pseudomonas aeruginosa may be required, guided by

ID	ORGANISATION NAME	DOCUMENT	PAGE NO.	LINE NO.	COMMENTS Please insert each new comment in a new row	DEVELOPER'S RESPONSE Please respond to each comment
						susceptibilities when available. The committee agreed that levofloxacin was the appropriate choice of quinolone for people with an acute exacerbation of COPD, based on the evidence identified. Moxifloxacin has been removed from the prescribing table to take account of EMEA advice.
39					Laevofloxacin has previously been avoided because of the risk of tendonitis. Is this no longer a problem? (CLR)	Thank you for your comment. The choice of antibiotics takes account of the balance between risks and benefits and the committee agreed that quinolones are an appropriate alternative choice in specific circumstances for people with an acute exacerbation of COPD. This has been clarified in the prescribing table. The committee agreed that levofloxacin was the appropriate choice of quinolone, based on the evidence identified. A statement about tendon damage (including rupture) has been added to the safety of antibiotics section in the guideline. However, the guideline states 'See the summaries of product characteristics for information on contraindications, cautions and adverse effects of individual medicines.