Pneumonia in adults: diagnosis and management

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Stakeholder	Page no.	Line no.	Comments	Developer's response
British Thoracic Society	General	General	Q2: Are there any aspects of diagnosing Community Acquired Pneumonia and Hospital Acquired Pneumonia for which guidance is needed (beyond microbiological tests to determine causal agents)? The differentiation between CAP and HAP, in terms of duration in hospital / time from previous admission or institution Infection Prevention and Control measures – although this guideline focuses on bacterial pneumonia rather than viral pneumonitis, there is a period of time when micro results are pending and differentiation between these not clear – esp in ED setting. Guidance on where/how to manage patients in this period may be helpful, although not sure this sits within this guideline?	Thank you for your response to this question. The planned piece of work will include the diagnosis of Community Acquired Pneumonia (CAP) and Hospital Acquired Pneumonia (HAP). Although the review questions do not specifically focus on the issue you raised the committee are aware of it and will try to provide guidance if they can. As you note, the current guideline on pneumonia in adults: diagnosis and management (CG191) does have a focus on bacterial pneumonia and this is continued in the pneumonia (community-acquired): antimicrobial prescribing (NG138) and pneumonia (hospital-acquired): antimicrobial prescribing (NG139) guidance. However, the planned work is not limited to bacterial pneumonia but will cover diagnosis and management of SARS-CoV-2 negative viral pneumonia as well. SARS-CoV-2 pneumonia is covered in the NICE COVID-19 rapid guideline: managing COVID-19 and will be cross referred to at relevant points in the updated CG191 guidance. The draft scope questions cover the use of point of care microbiological and biomarker tests to help with diagnosis and treatment decisions. We envisage that these may provide some information about what approach to take while waiting for the results of more specific microbiological tests.

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British Thoracic Society	General	General	Feels like there has been a change in how patients with pneumonia and T1RF are managed following Covid, with lower thresholds for keeping these patients on the ward with eg. HiFlow, rather than escalating care – esp amongst juniors. Helpful if the issue of whether/where CPAP or Hiflow should be used in patients with pneumonia and T1RF who are for full escalation could be addressed within the non-invasive respiratory support section.	Thank you for your comments. We agree that the issue of whether CPAP or Hiflow is effective in patients with pneumonia and T1RF who could make a full recovery could be addressed as part of the review question about non-invasive respiratory support. We will discuss including these people as a subgroup of interest and stratifying the data by setting when we develop the review protocol with the committee.
British Thoracic Society	General	General	Point 6.2 states that there will be a comparison between non-invasive respiratory support and other non-invasive respiratory support – perhaps a typo?	Thank you for your comments. The question was intended to represent the comparisons of individual types of non-invasive respiratory support (high-flow nasal oxygen, continuous positive airway pressure, and bilevel positive airway pressure) compared to other type of non-invasive respiratory support or usual care. For example, high-flow nasal oxygen compared to continuous positive airway pressure. We have reworded the draft question to make this clearer.
British Thoracic Society	General	General	The guideline explicitly states that it will not address nutrition or vaccination – helpful to clarify re. HIV testing, smoking cessation support (including use of nicotine patches). Both perhaps core to CAP care.	Thank you for your comments. The guideline starts at the point of diagnosis and prevention of pneumonia is outside of the scope of this work. It also does not currently cover the prevention of recurrence of pneumonia. Factors that increase the risk of having pneumonia, such as smoking, may be covered under pneumonia diagnosis and we will cross refer to other relevant NICE content where appropriate (for example,

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				the guideline on Tobacco: preventing uptake, promoting quitting and treating dependence [NG209]). People who are severely immune-compromised (have a primary immune deficiency or secondary immune deficiency related to HIV infection) are not covered by this guideline.
British Thoracic Society	011	009	On page 11, line 9, point 6.2: the term "non-invasive respiratory support" is quite vague. Could it include the exact type of support instead, such as CPAP or NIV?	Thank you for your comments. As requested, we have included examples of the type of support in the draft review question. The limitations of space do not allow for an exhaustive list of the exact types of support to be outlined in the review question. The final research protocol will outline specific search terms and a more exhaustive list of the types of non-invasive respiratory support that will be considered.
DiaSorin UK Ltd	004	012 - 013	The draft scope does not currently define whether microbiological tests that are used prior to a pneumonia diagnosis (such as when a patient initially presents) will be included in this consideration. NICE Guidance NG138 states that recent microbiological results should be taken into account when choosing an antibiotic, but does not specifically consider tests which may help distinguish between bacterial and viral causes of infection at presentation. Clinical Guidance CG191 currently recommends blood and sputum culture for moderate/high-severity community-acquired pneumonia, which has a significant time delay of 24-48 hours. The new guideline may give the opportunity to consider measurement of more timely assessment options.	Thank you for your comments. We have taken them into account and changed the wording of the relevant draft questions to refer to people with suspected pneumonia to allow us to examine the the use of microbiological and biomarker tests as part of the process of diagnosis and to help inform initial treatment decisions.

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DiaSorin UK Ltd	004	014 - 015	Importantly, the draft scope acknowledges the role of the 'other biomarker' group. However, it would be of value to specifically consider biomarker combinations which offer greater ability (versus C-reactive protein or procalcitonin alone) to distinguish between bacterial/co-infection and viral infections, such as a combined C-reactive protein, TRAIL, IP-10 signature assay (Oved et al, PLoS One, 10(3):e0120012. doi:10.1371/journal.pone.0120012; Van Houten et al, Lancet Infect Dis, 17(4):431-440; Srugo et al, Paediatrics, 140(4):e20163453).	Thank you for your comments. We have taken them into account and expanded both biomarker draft questions to include combinations of biomarkers as well as individual biomarkers. We have not specified what these combinations are or what individual biomarkers will be included, other than CRP and procalcitonin, as this is too much detail for the draft question and will be covered in the review protocol instead. We will discuss including the biomarkers you suggest with the committee at this time.
DiaSorin UK Ltd	004	016 - 017	Whilst the draft scope considers the use of C-reactive protein and procalcitonin to stop or change treatment, no consideration has yet been given to the commencement of treatment in a hospital setting. Biomarker combinations such as a combined C-reactive protein, TRAIL, IP-10 signature assay would help support the initial decision to prescribe or withhold antibiotic therapy (Ashkenazi-Hoffnung et al, Eur J Clin Microbiol Infect Dis, 37(7):1361-1371; Papan et al, Clin Microbiol Infect, 28(5):723-730). Therefore consideration of such combinations may be of significant value to help ensure antimicrobial stewardship. Furthermore, C-reactive protein and procalcitonin may not be particularly effective with regards to viral pneumonia severity, or in patients treated with oral corticosteroids. The long induction time, lack of specificity for clinically relevant bacterial infection, and corticosteroid-presence suppression of C-reactive protein may reduce its relevance to life-saving decision making (Morgenthaler et al,	Thank you for your comments. We have taken them into account and amended the question about initial treatment decisions so that it now covers the commencement of treatment for suspected pneumonia without reference to setting. This question also includes biomarker combinations, as requested, as well as individual biomarkers. We have not specified what these combinations are or what individual biomarkers will be included, other than CRP and procalcitonin, as this is too much detail for the draft question and will be covered in the review protocol instead. We will discuss including the biomarkers you suggest with the committee at this time.

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			Clin Lab, 1;48(5-6):263-70; Escadafal et al, BMJ Global Health, 5:e002396). Accordingly, a biomarker such as mid-regional proadrenomedullin (MR-proADM) may provide a more accurate indication of patient disposition across both bacterial and viral pneumonia (Bello et al, Eur Respir J, 39(5):1144-55, Gordo-Remartinez et al, PLoS One, 10(6):e0125212), so should form part of the consideration.	
DiaSorin UK Ltd	010	005 - 008	For this question, it would be valuable to consider the accuracy merits of a combined C-reactive protein, TRAIL, IP-10 signature assay that has previously been shown to outperform both C-reactive protein and procalcitonin alone at distinguishing between acute bacterial and viral infections (Oved et al, PLoS One, 10(3):e0120012. doi:10.1371/journal.pone.0120012; Van Houten et al, Lancet Infect Dis, 17(4):431-440; Srugo et al, Paediatrics, 140(4):e20163453). Furthermore, this greater degree of accuracy will likely result in more appropriate initial treatment pathways, potentially improving patient outcomes including readmission rate.	Thank you for your comments. We have taken them into account and expanded both biomarker draft questions to include combinations of biomarkers as well as individual biomarkers. We have not specified what these combinations are or what individual biomarkers will be included, other than CRP and procalcitonin, as this is too much detail for the draft question and will be covered in the review protocol instead. We will discuss including the biomarkers you suggest with the committee at this time.
DiaSorin UK Ltd	010	023 - 028	Whilst the draft scope considers the use of C-reactive protein and procalcitonin to stop or change treatment, biomarker combinations such as a combined C-reactive protein, TRAIL, IP-10 signature assay would help support the decision to de-escalate or change antibiotic therapy (Ashkenazi-Hoffnung et al, Eur J Clin Microbiol Infect Dis, 37(7):1361-1371; Papan et al, Clin Microbiol Infect, 28(5):723-730). Therefore consideration of such combinations may be of significant	Thank you for your comments. We have taken them into account and expanded both biomarker draft questions to include combinations of biomarkers as well as individual biomarkers. We have not specified what these combinations are or what individual biomarkers will be included, other than CRP and procalcitonin, as this is too much detail for the draft question and will be covered in the review protocol instead.

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			value to appropriately manage patients. It would also be important to include the biomarker mid-regional proadrenomedullin (MR-proADM). The MR-proADM assay is designed to guide clinical decision-making around discharge or admission into ICU, and so therefore it is important that this is considered to add value to the existing standard of care (Saeed et al, Critical Care, 23(1):40; Renaud et al, Chest, 142(6):1447-1454; Lenihan et al, Pediatr Crit Care Med, 2022 Oct 14. doi: 10.1097/PCC.0000000000003075).	We will discuss including the biomarkers you suggest with the committee at this time.
MAST Group	General	General	Point 1.1.1 The draft scope covers the use of CRP to aid in the diagnose patients with lower respiratory tract infection in primary care. No problem with this. Since the context of this use of CRP is to help confirm a diagnosis and to guide antibiotic usage, would it not be appropriate to also include other point of care tests for procalcitonin (being more indicative of bacterial infection than a more generic CRP inflammatory marker) and a point of care lactate test as a marker of severity? This would offer a better diagnosis of lower respiratory tract infection, the necessity for antibiotic prescribing and potentially the need to transfer care to a hospital setting (if tested in the community of course). These assays are now available as individual or as multiplex Point of Care tests for a more complete picture to improve management, antibiotic stewardship and patient outcome.	Thank you for your comments. As you note, the scope of this work covers the use of CRP to help with diagnosis and to guide treatment decisions. However, although we have included people with suspected lower respiratory tract infection (LRTI) as a population of interest in some of the review questions please note that the focus of this guideline is the diagnosis and treatment of pneumonia, rather than LRTI, and this is only included while some uncertainty around the diagnosis of pneumonia remains. The draft scope questions also include procalcitonin and other biomarkers (now amended to include combinations of biomarkers). We have not specified what these combinations are or what individual biomarkers will be included, other than CRP and procalcitonin, as this is too much detail for the draft question and will be covered in the review protocol instead.

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				We have taken a similar approach for the microbiological test draft questions. We will discuss your suggestions and those from other stakeholders with the committee as we develop these review protocols.
NHS England	General	General	No additional areas that need to be included and agree with the scope from a primary care perspective and we think this is highly relevant to primary care.	Thank you for your comment and support for the draft scope.
NHS England	General	General	We strongly suggest the scope should be widened to consider specifically the needs of people with a learning disability within the guidelines. We know from LeDeR national reports that people with a learning disability are significantly more likely to die an avoidable death from pneumonia than the general population. Therefore, the specific needs of people with a learning disability should be considered when writing the new guidance. Our evidence would suggest the guidelines should cover: The different way in which people with a learning disability may present as unwell The importance of providing person centred care and reasonable adjustments when assessing and treating a person with a learning disability	Thank you for your comments. The planned work on our guideline for pneumonia consists of a large number of review questions and is expected to take a long time to complete. It is therefore not possible to expand this work by having dedicated review questions that focus specifically on a single group of people. However, as mentioned above we have included people with learning difficulties in the equalities impact assessment that accompanies this work, and we will discuss with the committee how we will address this when we develop the review protocols. NICE has a number of guidelines that focus on people with learning disabilities including: Learning disabilities and behaviour that challenges: service design and delivery (NG93); Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges (NG11); and Care

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			Consideration of comorbidities The risks of diagnostic overshadowing	and support of people growing older with learning disabilities (NG 96). In particular, NG96 has recommendations for Before and during a hospital stay, which covers reasonable adjustments, ensuring person centred care and that information is accessible. In addition, the NICE guideline on Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (CG138) also covers patient centred care. We will cross refer to them as appropriate during the current work. However, the learning disability guidelines do not cover general principles for assessing, diagnosing, admitting and treating people with a learning disability. We will flag this issue to the surveillance team as a gap in the portfolio that is wider than just pneumonia.
NHS England	General	General	Date of publication – would be helpful to have this joined up with the publications of the RightCare work and BTS work (publication TBC)	Thank you for your comment. We will investigate whether this is possible and try to link up with/ refer to other relevant pieces of work such as the ones you mention.
NHS England	002	020 - 022	Strongly suggest mention learning disability and autism specifically	Thank you for your comment. This section of the scope is only intended to give a very high-level overview of the identified equalities issues. NICE undertakes an equality impact assessment (EIA) which seeks to support NICE's compliance with the Equality Act 2010 and the Human Rights Act 1998; and seeks to eliminate unlawful discrimination, advance equality of opportunity and foster good relations between particular population groups. In the draft EIA, which was available for comment during consultation, it was acknowledged that "people with learning disabilities are more

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				susceptible to respiratory illnesses like pneumonia. They also have poorer outcomes if admitted to hospital with pneumonia. This may be due to discrimination at point of care, not being listened to, or they may have trouble with accessing healthcare". We have updated the EIA based on your comments here and below. Please see our response to your other comments on this topic for more information. We have not added the requested information to the scope as this is covered in the EIA and no other detailed examples are included in the scope itself. The EIA document is published alongside the guideline document and a hyperlink will be added to the scope at publication to facilitate reference. During development consideration will be given to this group of people and other groups with specific needs as identified in the EIA. They may be included as subgroups of interest in the review protocols and/or covered as part of committee discussions.
NHS England	006 - 007	General	Strongly suggest specific mention of ensuring that 'information for patients, their families and carers' is made accessible through plain English (or other languages)	Thank you for your comments. The scope document sets out the parameters of the guideline and the areas to be updated. NICE undertakes a separate equality impact assessment (EIA) to support NICE's compliance with the Equality Act 2010 and the Human Rights Act 1998; and to help eliminate unlawful discrimination, advance equality of opportunity and foster good relations between particular population groups. The EIA document is referred to in the scope and contains

				details of the equality issues we have identified relating to this work. These will be considered by the committee as we develop the review questions, examine the evidence and make recommendations. The draft EIA that accompanies this scope mentions people with low levels of literacy/health literacy who may be unable to understand information leaflets relating to their care if they develop pneumonia. We have added a comment that these patients may need information to be provided in plain English or in a simplified form. We also mention that people who do not speak English may have barriers to accessing care, following information provided verbally or in writing and being involved in shared decision making regarding their care. In response to your comment, we have added that they may need information to be provided in another language. NICE has a separate guideline on Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (CG138), which has a section on Enabling patients to actively participate in their care (section 1.5) that covers communication and information. Recommendation 1.5.13 addresses the issue you mention: 'Give the patient information in an accessible format, at the first and subsequent visits. Possible formats include using written information, pictures, symbols, large print, Braille and different languages.' We will not include additional recommendations on the topics covered by this guideline and those in the guideline on Shared decision making (NG197) unless there are specific issues related to pneumonia. Instead

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				readers will be referred to these guidelines and any other relevant core guidelines (including Medicines optimisation (NG5) and Medicines adherence (CG76) at appropriate places in the pneumonia guideline.
NHS England	011, 013	General	7.1 Should be made available in an accessible format for people with a learning disability	Thank you for your comments. Please see our response to your comment above. The equality impact assessment already includes people with learning disabilities and, in response to your comment, we have added that they may need information to be provided in a different format that is more accessible for them (for example, in Easy Read style). NICE has a number of guidelines that focus on people with learning disabilities and we will cross refer to them as appropriate.
NHS England - Antimicrobial Prescribing and Medicines Optimisation Team	General	General	There is significant overlap in the clinical spectrum of pneumonia presenting to primary and secondary care. For example, patients in large urban centres with poor access to GPs and easy access to emergency departments may be more likely to present to secondary care for more minor infections. Therefore, it may be more helpful to discuss management pathways based on clinical condition rather than place of presentation.	Thank you for your comments. We will take this information into account when we are developing the review protocols and recommendations and structuring the resulting guideline.
NHS England - Antimicrobial Prescribing and Medicines Optimisation Team	General	General	Are there any aspects of diagnosing Community Acquired Pneumonia and Hospital Acquired Pneumonia for which guidance is needed (beyond microbiological tests to determine causal agents)? Current advice in CG191 "consider pneumococcal and legionella antigen tests" is unhelpful in practice could you	Thank you for your response to this question. The points you raise should be addressed by the draft review questions on the use of microbiological tests and biomarkers, including CRP and PCT, in primary and secondary care. These will include POCT where relevant. Where the information identified/ committee expertise allows we will try to make more specific recommendations regarding pneumococcal and

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			make more specific recommendations, for example when it might be useful in more specific patient groups POCT – viral panels to reduce uncertainty around antibiotic use Use of CRP in primary care Use of PCT in primary and secondary care	legionella antigen and other tests, for example for the groups of people highlighted in the equalities impact assessment or as subgroups of interest in the review protocols.
NHS England - Antimicrobial Prescribing and Medicines Optimisation Team	003	023	Aspiration pneumonia should be included because there is a clear need for strong evidence-based guidance around diagnosis and management of this condition. Aspiration pneumonia is a common indication for antimicrobial prescribing in secondary care, with increasing populations of patients at risk. There is currently significant variation in practice within the UK in guidance for this infection in the advice on spectrum, route, and duration of antibiotic therapy.	Thank you for your comments. Aspiration pneumonia has been excluded from this piece of work because it has a different causal mechanism, may have different causal agents and often has different treatments to non-aspiration pneumonia. This decision is not related to the prevalence and importance of this topic but specifically because the current planned update will be a large, time consuming piece of work and we will be unable to expand the scope of it to cover aspiration pneumonia. However, we will pass your comments onto the surveillance team at NICE to alert them to a potential gap in our portfolio and the impact this is having on practice and antibiotic prescribing.
NHS England - Antimicrobial Prescribing and Medicines Optimisation Team	004	011	Pulse oximetry is routinely used in assessment of pneumonia in both primary and secondary care but is not included in the guidelines or draft scope. Suggest increasing the scope to consider how pulse oximetry should support appropriate initial severity assessment and monitoring response to treatment. With a particular focus on the evidence around how traditional	Thank you for your comments. In response we have expanded the draft review question about risk prediction tools for use in emergency care settings to include use with or

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			pulse oximetry underestimates severity in patients with darker skin.	without oxygen saturation monitoring. However, we will not be looking at the use of pulse oximetry separately. We are aware of the issues around using pulse oximetry in people with darker skin and have noted this specifically in the equality impact assessment that accompanies the scope. We will take this into consideration when the committee discuss the evidence.
NHS England - Antimicrobial Prescribing and Medicines Optimisation Team	004	014	As discussed above, some patients seen in secondary care may be of similar population to those seen in primary care. Therefore, it would be helpful not to restrict decisions around using CRP, PCT and other biomarkers to inform decisions to primary care only.	Thank you for your comments. We have taken them into account and amended the question you refer to so that it now covers the commencement of treatment for community acquired pneumonia without reference to setting.
NHS Surrey Heartlands Integrated Care Board	006		Antibiotic Treatment – include a review of the use of higher doses of antibiotics where a partial sensitivity result is received from a microbiological culture susceptibility test. See EUCAST guidance. see eucast: Clinical breakpoints and dosing of antibiotics and Dosages_v_12.0_Breakpoint_Tables.pdf (eucast.org)	Thank you for your comments. There is ongoing work around EUCAST and antibiotic doses led by NHSE and APHRAI. We will update our guidelines as needed in line with any resulting changes that are made to the BNF.
Royal college of Emergency Medicine (RCEM)	003	011	Comment: This will likely have the effect of mandating COVID testing on all pneumonias, which is currently not unreasonable.	Thank you for your comment. NICE guidelines provide guidance to cover most people with a specific condition or need, and people in particular circumstances or settings. The recommendations are intended to guide treatment decisions and are not mandatory unless they refer to a specific legal requirement to do something. However, you are correct that the division of pneumonia into COVID pneumonia, covered by

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				the NICE COVID-19 rapid guideline: managing COVID-19 guideline (NG191) and non-COVID pneumonia, covered by this guideline on pneumonia in adults: diagnosis and management (CG191) is likely to necessitate COVID testing to ensure patients are treated with reference to the correct guidance.
Royal college of Emergency Medicine (RCEM)	005		The following does not appear to have been included in the scope and we wonder whether it would be worth including: The role of Exercise Testing eg. 40 step test in risk stratification for hospital admission	Thank you for your comments. As you note the draft review questions do not specifically mention the use of Exercise Testing in risk stratification for hospital admission. However, if this is included as part of a risk prediction tool or as standalone risk prediction tool then it will be included in our review question on this topic.
Royal college of Emergency Medicine (RCEM)	005		The following does not appear to have been included in the scope and we wonder whether it would be worth including: The role of arterial blood gas sampling and the diagnosis of hypoxaemia in risk stratification for hospital admission	Thank you for your comments. Using arterial blood gas sampling and the diagnosis of hypoxaemia in risk stratification are not covered separately in the review questions but these tests will be included if they are part of a risk stratification tool for hospital admission.
Royal College of Nursing	003	General	2.1 In babies, children, and young people presenting with suspected or 2 confirmed community-acquired pneumonia in primary care, what is the 3 most accurate and cost-effective outcome prediction tool to identify under 4 18s whose outcome will be improved by referral to hospital? What role does Inhaled Salbutamol role in supporting this this group of patients? Should it part of standardised treatment? Does its value only lie in symptom relief?	Thank you for your comments. NICE's understanding is that salbutamol is most commonly used as an 'as needed inhaler' for shortness of breath in asthma and COPD, and can also be used as for viral induced wheeze in children to relieve small airway obstruction. Whilst a wheeze could be a possible symptom of pneumonia in children, salbutamol would be used for the treatment of wheeze rather than treating the underlying infection, and the

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			Safe discharge from hospital: No review of evidence. This is because no substantive new evidence in this area was identified. No evidence was identified last time, and no recommendations made. We belief a follow-up of this group of patients is so important. Some of these patients have known vulnerabilities such as homelessness, mental health issues and addictions. A more caring and supportive offer should be given to these patients who self-discharge. Medications to take home, possible Same day emergency care follow call and facilitating the 6 weeks Xray check. The risk of sepsis, readmission and needing ventilation is so high if treatment is not completed. As part of a holistic approach, the importance of housing/living conditions e.g., damp, mould, crowded homes should be included in the information given to patients and their families. Clinicians must ask those important questions as recurrent community acquired pneumonia can be due to poor housing and socioeconomic challenges (no heating, lack of food and nutrition). That could be a point to offer support to	treatment of symptoms that might be associated with pneumonia is not in the scope of this update. NICE agrees that safe discharge from hospital is important and the current NICE guideline CG191 (pneumonia in adults: diagnosis and management), already has recommendations relating to signs that could prevent discharge from hospital for people with community acquired pneumonia. No substantive new evidence relating to these signs was identified during the scoping process and this area will therefore not be prioritised for update. The issue of follow up of vulnerable patients is not unique to this guideline. NICE has other guidance that relates to this topic: Transition between inpatient hospital settings and community or care home settings for adults with social care needs (NG27), however, this does not cover same day discharge. During guideline development we will endeavour to cross refer to this and any other relevant guidance, such as the NICE guideline Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence (CG76) at appropriate points in the guideline. NICE undertakes an equality impact assessment (EIA) which seeks to support NICE's compliance with the Equality Act 2010 and the Human Rights Act 1998; and seeks to eliminate unlawful discrimination, advance equality of opportunity and foster good relations between particular population groups. In

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			patients and their families e.g., social services, local authorities.	the draft EIA, which was available for comment during consultation, we mention people experiencing homelessness, and people from deprived areas/ of low socioeconomic status as groups who may need additional consideration when recommendations are being made. We have added some text about the possible need for additional support to adhere to prescribed medications on discharge and attend any follow up appointments to the sections on these vulnerable groups and now include people with mental health issues and substance misuse issues in the section on disabilities. The current guideline does not cover the prevention of pneumonia as it starts at the point of diagnosis. It also does not cover the prevention of pneumonia recurrence currently. The review question about information for patients is focused on information about symptom duration after discharge and when the person should seek help from a GP. However, in the draft equality impact assessment (EIA) we mention poor housing, fuel poverty and poor diet) and we will discuss the impact of these issues with the committee when we develop recommendations for this part of the guideline. In response to your comment we have added to the EIA that poor housing, in particular if it is damp and mould infested, may increase the risk of developing pneumonia.
Royal College of Nursing	004	001	Also - 3.1 This is a very important matter for consideration as early diagnosis and access to treatment in the community is essential and often not consistently commissioned or considered. There needs to be consideration of referral	Thank you for your comments and support for draft question 3.1. The draft scope also contains review questions about diagnosis of pneumonia and the use of prediction tools to inform whether someone should be referred for further

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			pathways and how this links in with 111 assessment and provision.	assessment or, if they present to a hospital setting initially, where they should be treated if diagnosed with pneumonia. We will raise the issues in your comment for consideration by the committee when we present the results of these reviews and draft recommendations. As part of this we will also consider whether any prediction tools are suitable for use to remotely assess whether someone has pneumonia or whether they should be referred for further examination. However, decisions about the commissioning of services and local health system configurations are outside of NICE's remit.
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. e would like to endorse the response submitted by the British Thoracic Society (BTS).	Thank you for your comment and this information.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	General	General	The FPM is concerned by the proposed revisions and the rationale provided for the work required. Whilst it is common in other guidance such as CDC (US) and ERS to group pneumonias with a single-entry portal from an epidemiological point of view, the definition of acute lower respiratory infections which may be part of the differential diagnosis of bacterial pneumonia include acute bronchitis and bronchiolitis, which may be a result of various virus infections. Thus, the rationale seems inappropriate to limit to differences between SARS-CoV-2 infection and later pneumonitis, and	Thank you for your comments. NICE has produced guidelines that cover other respiratory conditions including cough (acute): antimicrobial prescribing (NG120) which sets out antimicrobial prescribing strategy for acute cough associated with an upper respiratory tract infection or acute bronchitis in adults, young people and children; and COVID-19 rapid guideline: managing COVID-19 which has recommendations on identifying and managing co-infections. Where appropriate this proposed update will cross-reference to these other guidelines.

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			not including the contribution of several other respiratory virus families that are now resurging as the SARS-CoV-2 disease profile is changing. The preamble incorrectly states that bacteria are the most common cause of pneumonia. In fact, multiple studies have demonstrated that viral pneumonia is at least as frequent, but that it is not appropriately diagnosed and treated. This contributes to the inappropriate prescription of antibiotics, which do not relieve viral pneumonia unless it has bacterial superinfection, contributing to extending antimicrobial resistance. Whilst immunocompromised patients are excluded from the guidance, consideration might be given to pneumonia caused by fungal infections or opportunistic infections which are increasingly common among individuals living in poor quality, mould infested housing. FPM urges NICE to adapt this scope of work and consider working on guidance for the diagnosis and management of lower respiratory tract infection and pneumonia in different populations, working with expert societies and practitioners to define the appropriate prevention, diagnosis and management strategies required in various patient types: a good example of the outputs that such an approach can result in can be found here: https://www.cdc.gov/pneumonia/management-prevention-	The current update of the guideline on pneumonia in adults: diagnosis and management (CG191) does not cover SARS-CoV-2 pneumonia because that is covered in the NICE COVID-19 rapid guideline: managing COVID-19 and will be cross referred to at relevant points in the updated CG191 guidance. However, viral pneumonia that is not caused by SARS-CoV-2 is within the scope of this work. The draft introductory text states that 'Most cases of community-acquired pneumonia in adults were **thought** to be bacterial…' not that they were bacterial in origin. To reduce the potential for confusion we have removed this sentence. Fungal pneumonia is included in the scope of this work and the accompanying equality impact assessment mentions poor housing as a factor linked to higher levels of pneumonia in people from lower socioeconomic groups. We have added a specific reference to mould infestation in light of your comment. Taking your comment into account with committee feedback we have expanded the populations included in some of the draft review questions to cover people with a lower respiratory tract infection as well as suspected pneumonia but the focus of this work will remain the diagnosis and management of pneumonia. This is already a large piece of work that will take a substantial amount of time to deliver an expanding it further would make it unmanageable.

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			guidelines.html. Indeed, the majority of this guidance would be equally applicable to practice in the UK.	NICE's process of guideline development makes extensive use of practitioners who are recruited to be expert committee members (see Developing NICE guidelines: the manual and section 3 Decision-making committees for more information). We also consult with the wider community of stakeholders at the scoping stage and prior to publication of the work (see section 10 The validation process for draft guidelines, and dealing with stakeholder comments for more details).
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	003	002	Section 3.1 Groups that will be covered The proposal to produce one guideline across individuals of all ages is almost impossible unless it is clearly sectioned, as the pattern of disease and organisms causing pneumonia in children differ from those in adults. Whilst the existing the three guidances proposed to be merged are separated for hospital acquired pneumonia, community acquired pneumonia and paediatric pneumonia, it is not clear that this document will be sectioned in this way. HAP is more likely to be caused by multidrug resistant organisms and the preponderance of the latter differs markedly between institutions, which requires local advice on the extent and nature of the MDDR organisms prevalent within the particular institution with relevant local antibiotic policies informed by expert infectious disease consultation.	Thank you for your comment. This is the draft scope document which set out the proposed parameters for the guideline. Until the evidence has been reviewed and discussed it is not possible to predict what the content of recommendations will be or the format the guideline will take with any accuracy. It is likely that the division of community acquired and hospital acquired pneumonia as seen in the current version of the guideline on pneumonia in adults: diagnosis and management (CG191) will remain. However, the structure of the guideline will be agreed with the committee during development bearing in mind user needs and we will also take your comments into account at this time. There will be an opportunity for stakeholders to comment on the recommendations and structure of the guideline when the draft guideline is out for consultation. The current update will cover microbiological tests to inform treatment decisions for people with suspected HAP. These tests are expected to provide information about causal agents

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				to allow appropriate treatments to be prescribed. However, as you correctly point out, the causal organisms are likely to differ between institutions and although the NICE guideline is expected to provide information to underpin local process and guidance the extent and nature of the MDDR organisms prevalent within the particular institution will need to be taken into account.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	004	005, 007 and 010	Diagnosis and severity are important and where to treat people in hospital. Can there be consideration of remote consultations (which may take place with older patients or patients with comorbidity)? It is difficult to apply PSI and even CURB 65. CRP and PCT should be in context with clinical judgement. Neither works well in young adults who are increasingly hospitalised with influenza.	Thank you for your comments. The draft scope contains review questions about diagnosis of pneumonia (including the use of biomarkers) and the use of prediction tools to inform whether someone should be referred for further assessment or, if they present to a hospital setting initially, where they should be treated if diagnosed with pneumonia. We will raise the issues in your comment for consideration by the committee when we present the results of these reviews and draft recommendations. In particular, we will discuss whether any prediction tools are suitable for use to remotely assess whether someone has pneumonia or whether they should be referred for further examination. We recognise the importance of using clinical judgement, including when acting on the results of biomarker tests and outcome prediction tools, and expect that clinicians will continue to do so taking into account the individual patient's history, symptoms/signs and other relevant contextual factors.
The Faculty of Pharmaceutical Medicine of the Royal Colleges	004	005, 007, 010	Can there be some comments or referrals to determine the difference between asthma and COPD exacerbations and CAP. Some patients will have both, with exacerbation	Thank you for your comments. The focus of this guideline is people with suspected or diagnosed community-acquired or hospital-acquired pneumonia. We have therefore excluded people with non-pneumonic infective exacerbations of chronic

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of Physicians of the UK (FPM)			triggered by viral CAP. Some will have a bacterial element to exacerbations.	obstructive pulmonary disease and non-pneumonic infective exacerbations of bronchiectasis. NICE has produced antimicrobial prescribing guidance for both conditions: Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing (NG114) and Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing (NG117). There is also a NICE guideline on Asthma: diagnosis, monitoring and chronic asthma management [NG80], which is currently being updated, and a NICE guideline on Bronchiolitis in children: diagnosis and management (NG9). However, we recognise that in the absence of an X-ray to support a diagnosis of pneumonia it may be hard to differentiate asthma, bronchiectasis and COPD exacerbations and community-acquired pneumonia in primary care. Our draft review questions cover the diagnosis of both community and hospital acquired pneumonia. As part of this work we will need to consider how we differentiate between people with pneumonia and people who do not have pneumonia (which will include people with non-pneumonic exacerbations of other respiratory conditions such as asthma and COPD). We will provide what guidance we can on this

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				topic, depending on what the evidence shows and using committee expertise to fill gaps where possible. We recognise that people with asthma or COPD are at increased risk of developing pneumonia, but we will not be specifically addressing the diagnosis or management of non-pneumonic complications of asthma or other illnesses as this is not within the scope of the pneumonia guideline. If, however, a person has a pneumonic exacerbation of an underlying respiratory disease then they are covered by the pneumonia guideline, and we will discuss this scenario with the committee at the appropriate time during development of the guideline.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	004	011	In the CAP section the diagnosis needs to deal with viral only and those that progress to bacterial super infections. Recently, with RSV, flu and COVID these superinfections are becoming more important.	Thank you for your comments. The draft review questions in the scope cover diagnosis and will include diagnosis of both non-COVID-19 and COVID-19 viral pneumonia, with the latter diagnosis directing readers to the COVID-19 rapid guideline: managing COVID-19 (NG191) guideline. People diagnosed with viral pneumonia who also have a bacterial coinfection at presentation or who go on to have bacterial super infections will still be considered in this guideline as long as they do not have COVID-19 first (as this scenario is covered by the COVID-19 guideline instead).
The Faculty of Pharmaceutical Medicine of the Royal Colleges	004	018	CAP antibiotic treatment – something needs to be included regarding failed treatment and how and what to provide if antibiotic treatment is to be switched for immediate failure or failure within 3 days after stopping the course of antibiotics.	Thank you for your comments. The planned update of the NICE guideline on pneumonia in adults: diagnosis and management (CG191) will incorporate the existing guidelines on pneumonia (community-acquired): antimicrobial prescribing (NG138) and pneumonia (hospital-acquired):

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of Physicians of the UK (FPM)				antimicrobial prescribing (NG139). In NG138 and NG139 there are recommendations that cover reassessing people with community-acquired or hospital-acquired pneumonia if symptoms or signs do not improve as expected or worsen rapidly or significantly. For community-acquired pneumonia, the recommendations cover reviewing the choice of antibiotic(s) when microbiological test results are available and changing the antibiotics prescribed appropriately or sending samples for testing if this has not already been done. In addition, the recommendations in NG138 go on to cover when to refer people with community-acquired pneumonia to hospital (for example, if their symptoms that are not improving as expected with antibiotics) or to seek specialist advice. NG139 has similar recommendations for hospital-acquired pneumonia cases about seeking specialist advice from a microbiologist if symptoms do not improve as expected with antibiotics. NG138 and NG139 also suggest that as part of the decision making around antibiotic prescribing the clinician takes into account recent microbiology results, previous antibiotic exposure and by the person's clinical stability. We think that together these recommendations address the issues you have raised about treatment failure and we therefore do not plan to revisit this issue in the current update.
The Faculty of Pharmaceutical Medicine of the	004	027, 028	HAP needs more elements of stewardship and needs both more breadth of recommendations for antibiotics and	Thank you for your comments. We agree that antimicrobial stewardship is an important issue. NICE has the following guidelines that cover this in detail: Antimicrobial stewardship:

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Royal Colleges of Physicians of the UK (FPM)			guidance on not just IV oral switch but switch or de-escalation.	systems and processes for effective antimicrobial medicine use (NG15) and Antimicrobial stewardship: changing risk-related behaviours in the general population (NG63).. Both guidelines on pneumonia (community-acquired): antimicrobial prescribing (NG138) and pneumonia (hospital-acquired): antimicrobial prescribing (NG139 also have a strong focus on antimicrobial stewardship and the updated version of the pneumonia in adults: diagnosis and management (CG191) that is covered by this scope is currently expected to have a section covering the principles of antibiotic treatment and reassessment that consists of recommendations brought together from the existing recommendations in NG138. NG139 and CG191. Where related guidelines, for example NG63, add value and are relevant they will be cross referred to. NG139 has prescribing tables that provide a range of treatment options and the recommendations cover having a review after a total of 5 days of antibiotics and consideration of stopping antibiotics if clinically stable. As you note NG139 also allows for an IV oral switch, with reviews at 48hrs and 5 days. There is a separate section on reassessment which allows for reassessment of the choice of antibiotics when microbiological results are available and there can be a change to a narrower-spectrum antibiotic, if appropriate at this time. We hope that reorganising the recommendations as part of the current update will make them easier to find and follow.

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			How to deal with patients who develop HAP who are already on long term prophylaxis for example pip tazo also needs consideration. It also needs guidance for what to do when patients fail treatment.	Patients who develop HAP who are already on long term prophylaxis would fall into the group of patients at higher risk of resistance in NG139 that includes people with a relevant comorbidity (such as severe lung disease or immunosuppression), recent use of broad-spectrum antibiotics, colonisation with multidrug-resistant bacteria, and recent contact with health and social care settings before current admission. The antibiotic prescribing tables provide recommended antibiotic options for these people. However, it should be noted that severely immunosuppressed patients are excluded from the scope of the guideline. Please see our response to your comment above about treatment failure for community acquired pneumonia. This details the approaches that NG138 and NG139 have taken to this topic for both community and hospital acquired pneumonia.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	004	027, 028	More elements of 'Start Smart - Then Focus' should be included in the guideline.	Thank you for your comments. We agree that antimicrobial stewardship and the principles of PHE's (now UKHSA) 'Start Smart -Then Focus' are important. These elements are already reflected in the NICE guidelines on pneumonia (community-acquired): antimicrobial prescribing (NG138) and pneumonia (hospital-acquired): antimicrobial prescribing (NG139) which the current scope will see brought together with the guideline on pneumonia in adults: diagnosis and management (CG191). The resulting guideline covered by this scope is currently expected to have a section covering

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				the principles of antibiotic treatment and reassessment that consists of recommendations brought together from the existing recommendations in NG138. NG139 and CG191. It is hoped that this new section will make these recommendations easier to find and follow.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	007		Microbiological tests The limitation of microbiology when patients are already taking prophylactic antibiotics or are on antibiotics that have failed should be added.	Thank you for your comments. This is more detail than can be included in the draft scope, but we will discuss this point with the committee when we develop the review protocol, discuss the evidence and draft recommendations on the use of microbiological tests.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	007		Microbiological tests The limitations of obtaining specimens in HAP often a challenge due to inability to cough also needs to be recognised.	Thank you for your comments. This is more detail than can be included in the draft scope, but we will discuss this point with the committee when we develop the review protocol, discuss the evidence and draft recommendations on the use of microbiological tests.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	006		HAP antibiotics HAP antibiotics should be reviewed as there are changes in resistance patterns and MDDRs since the guideline was written – the clinical trial evidence for HAP is not the only driver.	Thank you for your comments. We agree that the clinical trial evidence for HAP is not the only important factor when choosing antibiotics. The NICE guideline on pneumonia (hospital-acquired): antimicrobial prescribing (NG139) advises that when choosing an antibiotic a list of factors are taken into account and these include local hospital and ward-based antimicrobial resistance data. This will be more relevant for a particular locality and up to date than national guidance that is updated every few years can be.

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The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	009	021	Make sure that all the different settings are considered including remote consultation. Use IDSA recent guidance form 2019 (CAP) and 2016 (HAP) on CDC web site.	Thank you for your comments. We will refer to the suggested guidelines for possible settings and discuss which of these are applicable to the UK with the committee as we develop the relevant review protocols.
The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM)	012	008	PROs are what clinical trials align to and for CAP treated in the community is the most important thing for patients especially those that have pneumonia more than once such as asthmatics. Can the outcome be carefully split between CAP and HAP and paediatrics?	Thank you for your comments. The list of outcomes in the scope are general across review questions and are not intended to be exhaustive. As we develop the review protocols for each question we will determine which of the listed outcomes are relevant and whether there are any additional ones that are important for that question. When we develop the review protocols we will ensure that it is clear which outcomes apply to CAP and/or HAP and if any of the outcomes are specific for people under 18.
Thermo Fisher Scientific	General	General	Q1 - Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline? Spurred by a call to action from the World Health Organization (WHO), many countries have set up national antibiotic stewardship programs. These programs encourage hospitals to improve patient safety and implement best practices for reducing rates of infection. In conjunction with antibiotic stewardship programs, health authorities are also using surveys to track the quality of care delivered against predefined benchmarks. Moreover, some countries now include quality metrics in their hospital reimbursement criteria.	Thank you for your response to this question and the references. These provide additional support for the draft review questions we have around the use of biomarkers, including procalcitonin, to inform decisions about antibiotic prescribing in primary care and changes in treatment in hospital. Based on stakeholder comments we have removed the setting from the first question about using biomarkers to inform initial treatment decisions to enable it to cover secondary as well as primary care settings. We will carry out a search and review of the economic evidence relating to the review questions mentioned above

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			Among these quality metrics are infection rates of pathogens such as *C. diff* and *methicillin-resistant Staphylococcus aureus* (MRSA). Using B·R·A·H·M·S PCT (Procalcitonin), hospitals are better able to lower both their sepsis and readmission rates, and as a result maintain their reimbursement revenue. **Cost-effectiveness literature from across the world:** **Europe:** Steuten L, et al.: Is procalcitonin biomarker-guided antibiotic therapy a cost-effective approach to reduce antibiotic resistant and clostridium difficile infections in hospitalized patients? OMICS. 2018;22 (9), Sep: 616-625 **Asia-Pacific region:** Ito A, et al: Impact of procalcitonin-guided therapy for hospitalized community-acquired pneumonia on reducing antibiotic consumption and costs in Japan. J Infect Chemother. 2017;23 (3), Mar: 142-147 Loo LW, et al: Discontinuation of antibiotic therapy within 24 hours of treatment initiation for patients with no clinical evidence of bacterial infection: A 5- year safety and outcome study from Singapore General Hospital Antimicrobial Stewardship Program. Int J Antimicrob Agents. 2019;53 (5), May: 606-611; Stojanovic I, et al: Economic evaluation of procalcitonin-guided antibiotic therapy in acute respiratory infections: A Chinese hospital system perspective. Clin Chem Lab Med. 2017;55 (4), Mar 1: 561-570) Latin America: Schneider JE, et al: Economic evaluation of procalcitonin guided antibiotic therapy in acute respiratory	during development. This will identify relevant and applicable studies. We will also check the references you have supplied against the review protocols at that time and include any that meet our inclusion criteria. Although antimicrobial stewardship in general is not the focus of this guideline it is an essential consideration that will underpin this work. (There are separate standalone NICE guidelines on Antimicrobial stewardship: changing risk-related behaviours in the general population (NG63) and Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use (NG15) already.) As part of the planned work we will be integrating NICE's guidance on pneumonia (community-acquired): antimicrobial prescribing (NG138) and pneumonia (hospital-acquired): antimicrobial prescribing (NG139) into the pneumonia guideline and this is intended to lead to the establishment of a section covering the principles of antibiotic treatment and reassessment that consists of recommendations from NG138 and NG139. Taking this together with the review questions about the use of biomarkers and microbiological tests to inform treatment decisions the planned work is intended to try to ensure that antibiotics are prescribed appropriately for people with pneumonia. In addition, where related guidelines, for example NG15 or other antimicrobial prescribing guidance from NICE, are relevant they will be cross referred to.

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			infections: A Chile health system perspective. Value Health. 2016;19 (3), May: A306 **U.S.A:** Mewes JC,et al: The cost impact of PCT-aided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis or lower respiratory tract infections in the US: A health economic model analysis. PloS one. 2019 Apr 23;14(4): e0214222 Voermans AM, et al: Cost-effectiveness analysis of a procalcitonin guided decision algorithm for antibiotic stewardship using real-world vs hospital data. OMICS. 2019 Oct 1;23(10):508-15) indicates that adding PCT testing to antibiotic stewardship protocols leads to cost savings for health care systems. Data from U.S. healthcare systems provide an estimate of the economic impact of PCT use. The healthcare impacts were quantified and integrated into a model based analysis using a previously published health economic decision-tree model to compare the costs and effects of procalcitonin-aided care. The analysis considered the societal and hospital perspective with a time horizon covering the length of hospital stay. The main outcomes for comparison were total costs per patient—including treatment costs and productivity losses—the number of patients with antibiotic resistant or *Clostridioides difficile (C. diff)* infections, and costs per antibiotic day avoided (Mewes JC,et al: The cost impact of PCT- aided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis or lower respiratory tract infections in the US: A health economic model analysis. PloS one. 2019 Apr	

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			23;14(4):e0214222). Results from the U.S meta-analysis results demonstrated that PCT-aided antibiotic stewardship versus standard care can lead to significant overall hospital savings: $11,311 per sepsis patient and $2,867 per LRTI patient (Mewes JC,et al: The cost impact of PCT- aided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis or lower respiratory tract infections in the US: A health economic model analysis. PloS one. 2019 Apr 23;14(4): e0214222). Cost and clinical efficacy impact includes antibiotic resistance, decreased *C. diff* rates, decreased average length of stay and decreased antibiotic treatment duration.	
Thermo Fisher Scientific	General	General	Q2 - Are there any aspects of diagnosing Community Acquired Pneumonia and Hospital Acquired Pneumonia for which guidance is needed (beyond microbiological tests to determine causal agents)? There are recommendations from different societies available to use Procalcitonin as an additional aid for the guidance of antibiotic therapy in patients with Hospital Acquired Pneumonia (HAP) or Community Acquired Pneumonia (CAP). The infectious Diseases Society of America (IDSA) suggests in section XXIV titled – 'Should discontinuation of antibiotic therapy be based upon (procalcitonin) PCT levels plus clinical criteria or clinical criteria alone in patients with HAP/VAP?' to use Procalcitonin levels plus clinical criteria to guide the discontinuation of antibiotic therapy, rather than clinical criteria alone.	Thank you for your response to this question which highlights the importance of procalcitonin in guiding antibiotic treatment and provides support for the draft review questions we have around the use of biomarkers, including procalcitonin, to inform decisions about antibiotic prescribing in primary care and hospital, and changes in treatment in hospital.

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			The European Society of Cardiology (ESC) Guidelines on Acute and Chronic Heart Failure recommends the assessment of PCT levels to be considered in patients with acute heart failure with suspected co-existing infection, particularly for the differential diagnosis of pneumonia and to guide antibiotic therapy, if considered.	
Thermo Fisher Scientific	General	General	Q3 - Is it more important to update our guidance on duration of antibiotic treatment for under 18s with Community Acquired Pneumonia or to cover diagnosis of Community Acquired Pneumonia and Hospital Acquired Pneumonia for this age group? According to the World Health Organization (WHO), antibiotic resistance is rising to dangerously high levels in all parts of the world as new resistance mechanisms are emerging and spreading globally. With antibiotics becoming less effective, it has grown increasingly difficult, and in some cases impossible, to treat patients for even common infectious diseases like pneumonia. Patient care is also becoming more costly as first-line antibiotics are being replaced by more expensive medications. A longer duration of illness and treatment, often in hospitals, increases healthcare costs as well as the economic burden on patients and societies (World Health Organization. Antibiotic Resistance, Geneva (CH)) 2020.Yet the true cost of antibiotic resistance is measured in lives and infection rates: inadequate antibiotic therapy can lead to increased mortality and morbidity, as well as a higher rate of infections such as Clostridium difficile (C. diff) (Centers for	Thank you for your response to this question. We agree that antibiotic resistance is a serious risk to world health and that it is essential to reduce unnecessary antibiotic use. Accurate diagnosis of whether pneumonia is bacterial or viral in origin will help target antibiotic use to the people who will benefit from treatment while reducing use in those with viral infections. During the scoping process evidence from the CAP-IT trial was identified that looked at whether 3-day treatment with amoxicillin is noninferior to 7 days. The Pneumonia (community-acquired): antimicrobial prescribing currently recommends that amoxicillin is prescribed for 5 days for under 18s but this could potentially be reduced to 3 days based on the CAP-IT trial. This would also have an impact on antibiotic resistance by reducing the duration of antibiotic use. The question we posed was intended to ascertain whether it was more important from an antimicrobial resistance perspective for us to focus our limited resources on accurate diagnosis and prescribing in the first place or to look at

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			Disease Control and Prevention. Antibiotic resistance threats in the United States, 2019 [Internet]. Atlanta (GA). 2019 Dec). Hospitals can no longer afford to ignore the crisis of antibiotic resistant bacteria. Based on scenarios of rising drug resistance for six pathogens, the review on Antimicrobial Resistance estimates that unless action is taken, the global burden of deaths from antibiotic resistance could balloon to 10 million lives each year by 2050, at a cumulative global economic output cost of $100 trillion USD (Review on antimicrobial resistance. Tackling drug-resistant infections globally: Final report and recommendations [Internet]. London (UK). 2016 May). Therefore, it is critical to limit antibiotic resistance especially in patients under 18s, so that antibiotics remain a potent treatment option against infections. There is proven efficacy that PCT reduces antibiotic exposure in this patient setting with no adverse impact on outcome (Esposito, S., et al., Procalcitonin measurements for guiding antibiotic treatment in pediatric pneumonia. Respir Med, 2011. 105(12): p. 1939-45.; 1; Baer, G., et al., Procalcitonin guidance to reduce antibiotic treatment of lower respiratory tract infection in children and adolescents (ProPAED): a randomized controlled trial. PLoS One, 2013. 8(8): p. e68419.	reducing the duration of antibiotic use in under 18s. We apologise for not making this clearer. We agree that the role of procalcitonin in guiding treatment decisions needs to be assessed and have draft review questions covering this as noted in our earlier responses to your comments.
Thermo Fisher Scientific	045	General	NICE Guideline [NG138] Cause of CAP and Antibiotic prescribing strategies The WHO recognizes that in vitro diagnostics (IVDs) are essential for advancing universal health coverage, addressing	Thank you for your comments and the references/evidence provided. As noted above, procalcitonin is considered within

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			health emergencies, and promoting healthier populations, which are the three strategic priorities of the Thirteenth WHO General Programme of Work, 2019-2023. The organization recommends Procalcitonin to guide antibiotic therapy or discontinuation in sepsis and lower respiratory tract infection (for use only in tertiary care facilities and above) (Second WHO Model List of Essential In Vitro Diagnostics [Internet]. World Health Organization 2020 [cited 2020Dec21]. Evidence background Acute lower respiratory tract infections (LRTIs) including community-acquired pneumonia (CAP), are primarily caused by viral or bacterial pathogens. It is reported that as many as 75% of patients with acute respiratory tract infections are treated with antibiotics even though the cause is mainly viral (Schuetz, P., et al., Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA, 2009. 302(10): p. 1059-66). Procalcitonin (PCT) is a host response biomarker that is sensitive and specific to bacterial infection. In patients with suspected or confirmed LRTI, PCT can help to differentiate bacterial infection from other potential causes and aid in decision-making around the initiation and duration of antibiotic therapy. Schuetz, P., et al., Procalcitonin (PCT)-guided antibiotic stewardship: an international experts consensus on optimized clinical use. Clin Chem Lab Med, 2019. The concept of PCT-guided antibiotic stewardship was first tested	the scope of this guideline under the section on microbiological tests and investigations. We will carry out a search and review of the evidence relating to the review questions on biomarkers during development. This will identify relevant and applicable studies. We will also check the references you have supplied against the review protocols at that time and include any that meet our inclusion criteria.

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			in ED patients with infection of the lower respiratory tract (Christ-Crain, M., et al., Effect of procalcitonin-guided treatment on antibiotic use and outcome in lower respiratory tract infections: cluster-randomised, single-blinded intervention trial. Lancet, 2004. 363(9409): p. 600-7.; Christ-Crain, M., et al., Procalcitonin guidance of antibiotic therapy in community-acquired pneumonia: a randomized trial. Am J Respir Crit Care Med, 2006. 174(1): p. 84-93). Considering that PCT remains low (undetected) in viral infection and increases in bacterial infection, the study algorithm recommended very strongly or strongly against the use of antibiotics if PCT levels were <0.1 µg/L or <0.25 µg/L, respectively. The algorithm also included some overruling criteria, so patients at very high risk would still be treated empirically despite low PCT levels. Accordingly, a two-level recommendation was given also for the initiation of antibiotic treatment for patients with PCT higher than 0.25 µg/L (antibiotic recommended) and PCT higher than 0.5 µg/L (antibiotic strongly recommended). The studies demonstrated significant reduction in antibiotic prescription rates, particularly in patients with bronchitis and COPD exacerbation. Later studies not only investigated PCT for the initiation of empirical antibiotic therapy, but also used PCT to monitor the response to therapy and to decide on discontinuation of antibiotic therapy on an individual basis. In the multicentric, randomized and controlled, interventional ProHosp trial (n=1359), antibiotic duration and antibiotic prescription rates	

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			were significantly reduced in the PCT group in comparison to the standard-of-care group for community-acquired pneumonia (CAP) (n=925), acute exacerbations of COPD (n=228), and bronchitis (n=151), resulting in an overall reduction of antibiotic exposure by 34.8% versus standard-of-care. The drop of PCT below 0.25 µg/L or by at least >80%–90% from the peak was used as stopping rule thresholds. This approach further decreased antibiotic exposure by shortening the duration of therapy, particularly in patients with CAP. (Schuetz, P., et al., Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA, 2009. 302(10): p. 1059-66; The proREAL study further evaluated the effectiveness and safety of PCT-guided antibiotic therapy in LRTIs, but from the perspective of an observational quality surveillance thought to be more reflective of "real life," as compared with RCTs. This study included 1,759 patients, with 53.7 % diagnosed with CAP. Again, PCT guidance significantly shortened antibiotic duration by 1.5 days (5.9 vs. 7.4 days; 95 % CI, -2.04 to 0.98; p<.001) (Scalera, N.M. and T.M. File, Jr., Determining the duration of therapy for patients with community-acquired pneumonia. Curr Infect Dis Rep, 2013. 15(2): p. 191-5; Albrich, W.C., et al., Effectiveness and safety of procalcitonin-guided antibiotic therapy in lower respiratory tract infections in "real life": an international, multicenter poststudy survey (ProREAL). Arch Intern Med, 2012. 172(9): p. 715-22).	

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			A meta-analysis by Schuetz et al. demonstrated similar findings with a reduction in antibiotic exposure by 3.34 days (95 % CI, -3.97 to-2.88; p<.001) in CAP with PCT guidance without an increased risk of mortality or treatment failure. (Schuetz P, Briel M, Christ-Cain M, et al. Procalcitonin to guide initiation and duration of antibiotic treatment in acute respiratory infections: an individual patient data meta-analysis. Clin Infect Dis. 2012;55(5):651–62).	