National Institute for Health and Clinical Excellence

Pneumonia
Scope Consultation Table
11 July – 22nd August 2012

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	ARNS	1	general	I have read through the paperwork and cannot add any additional comment to this document at this stage.	Thank you for your feedback.
SH	Basilea Pharmaceutica International Ltd	1	3.2 g	In addition to the fact that pneumonia represents a significant burden of illness, it is important to add that the economic and clinical outcomes of the bacterial infection depend on: • the pathogens causing the infection • the general condition of the patient. This has been recognised by several publications, for example: Torres A, Ewig S, Lode H, Carlet J; European HAP working group. Defining, treating and preventing hospital acquired pneumonia: European perspective. Intensive Care Med. 2009 Jan;35(1):9-29 American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults	Thank you for this information. We believe that these considerations will be taken into account in determining evidence-based, cost-effective best practice, but we do not wish to pre-empt the evidence that will be comprehensively reviewed during guideline development.

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				with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am J Respir Crit Care Med. 2005 Feb 15;171(4):388-416.	
SH	Basilea Pharmaceutica International Ltd	2	4.1.2 a	Our comment is in reference to the exclusion of patients in ICUs. We recommend including this important patient group, as they represent the more severe cases. Furthermore, to our knowledge many clinical studies in HAP include both patients treated in and outside ICUs and publications often do not present the respective data separately. Furthermore, ICU admission algorithms may vary by geographic region and hospital/healthcare setting.	Thank you for your comment. We agree that this is an important patient group but alternative guidelines exist for the management of patients within an ICU setting. ICU patients also differ from patients with community acquired and hospital acquired pneumonia in the following aspects • The presence of co-morbidities severe enough to require treatment in ICU +/- ventilatory support, will affect outcomes • Pathogens are different We are aware that many HAP studies include both patient populations and the appointed GDG will agree the most appropriate way to review this data during the development process. The scope does however include severity assessment, and ICU admission algorithms will be considered.
SH	Basilea Pharmaceutica International Ltd	3	4.1.2 a	In order to enhance the comprehensibility, please consider to mention alongside to "pneumonia acquired while intubated" also the term "ventilator-associated pneumonia" which is often used in the literature.	Thank you for your comment. The scope now includes your suggested text.

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SH	Basilea Pharmaceutica International Ltd	4	4.3	One key issue in clinical management is the heterogeneity of the patient population. Literature shows that the outcomes can vary depending on the characteristics of patient subpopulations (e.g. age, co-morbidities, pneumonia severity, and HCAP*), the pathogens involved and specific situations (e.g. flu epidemics). We recommend addressing this also in the clinical guideline when describing antibiotic therapy. *Health care-associated pneumonia (Chalmers JD, Taylor JK, Singanayagam A, Fleming GB, Akram AR, et al. Epidemiology, antibiotic therapy, and clinical outcomes in health care-associated pneumonia: a UK cohort study. Clin Infect Dis. 2011 Jul 15;53(2):107-13.)	Thank you for your comment. The GDG will determine whether to include all of these factors as either subgroups in which to explore heterogeneity or as subgroups for which the data will be stratified up-front.
SH	Basilea Pharmaceutica International Ltd	5	4.3.1 d	An additional important aspect in daily practice is the decision to escalate or de-escalate anti-infective treatment depending on clinical and microbiological results. We would recommend adding this aspect to the scope of the clinical guideline.	Thank you for your comment. Section 4.3.1 f) covers escalation and de-escalation of anti-infective treatment based on biochemical indicators of inflammation or sepsis. Clinical recognition of recovery or deterioration is a matter of training and clinical skill. Changing therapy in response to microbiological results was not considered to be an issue of uncertainty, poor or variable practice. These areas therefore remain outside the scope for this guidance.
SH	Basilea	6	4.4	Assessment of clinical cure is the	Thank you for your comment. Clinical cure and

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	Pharmaceutica International Ltd			primary objective of antimicrobial therapy in many pneumonia studies which is supported by recent guidance documents published by the European Medicines Agency*. In addition, microbiological outcome is an important outcome measure for pneumonia infections. We therefore recommend adding these outcome measures and analysing these endpoints in the overall by study population and by pathogen (e.g. clinical cure and microbiological outcomes in patients with pneumonia caused by Staphylococcus aureus, penicillin- and ceftriaxone resistant pneumococci etc.). *European Medicines Agency. Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 REV 2) to address indication-specific clinical data (draft). London, 21 June 2012 (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/07/WC500129443.pdf)	microbiological outcome will be considered where the GDG considers them relevant. The list of outcomes in the scope is not exhaustive.
SH	Basilea Pharmaceutica International Ltd	7	4.4	We recommend to also review and include current epidemiology and susceptibility patterns of clinically	Thank you for your comment. We are providing recommendations for the empirical treatment of patients when the pathogen is not known which is the case

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				relevant pathogens to antibacterials used in England & Wales. The latter may provide useful information in addition to randomised clinical trials, as susceptibility patterns may change over time and antibacterial surveillance studies may provide more updated information regarding susceptibility/resistance to certain antibiotics.	when patients first present to the medical interface.
SH	Basilea Pharmaceutica International Ltd	8	4.4 b	Number of days in hospital is an important outcome. However, in patients with HAP, the length of stay may depend not only on the bacterial infection, but may be largely influenced by other (non-pneumonia-related) underlying disease conditions. Therefore the duration of antibiotic treatment should be considered as an additional parameter to evaluate the resource use implications of different treatment regimens.	Thank you for your comment. Patient characteristics in well conducted RCTs should be balanced across population groups. Duration of antibiotic treatment will be considered as an outcome where relevant and should the GDG deem this to be appropriate.
SH	BOARD OF COMMUNITY HEALTH COUNCILS IN WALES	1	general	There appears to be insufficient responsibility on GP,s to try and successfully treat pneumonia in the home setting. Are they reluctant to treat and test at the same time because of the cost to themselves? What is happening is a 5 day course of	Thank you for your comment. We believe that the current scope will facilitate review of the necessary evidence to determine recommendations for appropriate management in primary care. The aim of the guideline is to present the evidence supporting appropriate care in an appropriate setting and this is covered in the scope of the guideline.

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				antibiotics is given, no tests taken, patient slow to respond ,course ends ,patient becomes worse ends up in hospital setting ,if lucky given I'V antibiotics if not then intensive care . The chances of the patient surviving dramatically reduces once they are hospitalized ,this could have been prevented by a GP testing along with treatment and re evaluating continued treatment after seeing test results. Something therefore needs to be in place in NICE guidelines to encourage GP,s to treat at home.	
SH	BOARD OF COMMUNITY HEALTH COUNCILS IN WALES	2	general	The guidelines for under 18s should be reduced to under 16 years of age as they are really adults at 16 these days	Thank you for your comment. For the purposes of clarity and consistency, NICE usually defines adults as people over 18. However it is within the discretion of the clinician to apply this guidance to young people below this age depending upon individual clinical circumstances.
SH	BRAHMS UK Ltd ThermoFisher Scientific	1	3.2 b c	Early PCT(Procalcitonin) assay can be used to discriminate between clinical cases which require urgent admission for specialist care from Primary care for unrecognised sepsis due to pneumonia.	Thank you for your comment. PCT will be considered in this context only if it is part of one of the severity assessment scores that we will evaluate for use in determining admission.

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				This should be evaluated. This is particularly relevant to minimise discrimination between socio-economic groups and patients of advancing age, who may not volunteer/ demonstrate the signs or history of advanced sepsis.	The section of the scope to which you refer represents current practice and is a necessarily brief overview.
SH	BRAHMS UK Ltd ThermoFisher Scientific	2	4.1.2 b	I can understand the reasons for not explicitly including immune-compromised patients but to avoid discrimination of such an important minority it would be useful to have instructions for guidance that PCT assay might also be useful for early recognition of sepsis secondary to Pneumonia, in this subset of patients who will not display the characteristic signs and symptoms of disease.	Thank you for your comment. It is not possible to include a particular population selectively for certain specific questions.
SH	BRAHMS UK Ltd ThermoFisher Scientific	3	4.3.1 a	The heightened specificity and sensitivity of PCT for sepsis (as distinct from inflammatory reaction) when combined with CRP assay should be recognised in the guideline.	Thank you for your comment. The combination of CRP and PCT will be reviewed if there is appropriate evidence.
SH	BRAHMS UK Ltd ThermoFisher Scientific	4	4.3.1 d	It is very useful to collate the evidence the PCT has on the effect of reducing (unnecessary risks and costs) the appropriate and responsible use of antibiotics in the Emergency room and Intensive Care settings.	Thank you for your comment. The GDG reviews all topics considered to have a potential health economic impact and prioritises a limited number for original health economic modelling. Depending on its importance relative to other issues, the effect of PCT on reducing antibiotic prescribing in ICU and A&E may be prioritised by the GDG for health economic evaluation.

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SH	BRAHMS UK Ltd ThermoFisher Scientific	5	4.3.1 f	Care should be used in the guidelines, as PCT is not there as an assay for Inflammatory response per se....but as a specific biomarker for Sepsis.	Thank you for your comment. We will examine whether PCT assists clinical decision making.
SH	British Lung Foundation	1	4.3.1	The British Lung Foundation is very pleased that patient information, support and communication needs are included in the draft scope of the guidelines. Patients have particular needs relating to information about their condition, and can often be helped to manage their condition and to stay well again after an episode of ill health if they are supported to do so with timely, relevant, accurate and appropriate information about their condition. We further welcome the inclusion of carers and patients' families in the context of information, communication and support needs. Carers and family members can play a critical role in supporting pneumonia patients, both during and after illness and into recovery. In order for patients to be supported throughout their illness, and to increase the chances of patient recovery, it is important that the information and communication needs or	Thank you for your feedback.

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				carers and families are met.	
SH	British Thoracic Society	1	4.1.2 b	Exclusion of HIV patients is a standard statement BUT in reality perhaps only HIV patients with severe levels of immunocompromise (eg CD4 counts < 200) should be excluded; HIV positive subjects with normal CD4 counts are managed the same as non-HIV positive individuals and therefore should be covered by 'normal' CAP guidelines?	Thank you for your comment. This guideline may be applied to the management of pneumonia in patients with any comorbidities at the discretion of clinicians.
SH	British Thoracic Society	2	4.1.2	Given that 'pneumonia associated with bronchiectasis' is a clinical area that will not be covered (4.3.2), it should be mentioned as an exclusion group in section 4.1.2	Thank you for your comment. The scope has been amended to include the words "pneumonia complicating bronchiectasis".
SH	British Thoracic Society	3	4.3.1 b	Need to consider adding in whether HIV test is necessary in some patients presenting with CAP	Thank you for your comment. This was discussed at length **and**, although it was acknowledged that this is an important issue, it was agreed that HIV testing is not specific to a clinical guideline on pneumonia.
SH	British Thoracic Society	4	4.3.1 f and g	Although it is probably implicit in these two sections, should the guidelines explicitly include recognition of complications (although not the management)? Important perhaps for affecting outcomes in a positive way.	Thank you. We intend to record specific complications as outcome data for the relevant questions. The recognition of complications was not prioritised for review within this guideline – this is a matter of clinical skill and outside the scope of a guideline.
SH	British Thoracic Society	5	4.3.2	The list of clinical issues that will not be covered is surprising as we would	Thank you for your comment. We agree that these are important topics. However given the defined timescale

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				expect many of these such as 'management strategies' to feature in the guidelines. Items c-f should be covered as these are important topics that healthcare professionals need guidance on.	for development, areas for review need to be prioritised based on known or suspected poor or variable practice, or uncertainty relating to evidence.
SH	British Thoracic Society	6	general	I think including HAP is a positive thing as guidelines in this area are lacking; the amount of extra work may not be too much given the lack of published data….. And exclusion of VAP is correct – too complex a subject, with a large literature database that is more than a little confusing / contentious.	Thank you for your comment.
SH	BSACI	1	4.3.1	No mention is made of history of antibiotic allergy – 10% of the population report allergy to penicillin. Therefore alternative antibiotics will need to be recommended by the guideline and also the patient referred for testing for penicillin allergy either urgently if beta-lactams are the most effective therapy or following recovery by the patient.	Thank you for your comment. Penicillin allergy is not an issue specific to the management of pneumonia. The GDG will agree whether management of pneumonia in the presence of penicillin allergy is prioritised for review. Clinicians may refer to the BNF for alternatives to penicillin-based anti-infectives for treating pneumonia. NICE will be producing guidance on drug allergy in the future (http://guidance.nice.org.uk/CG/Wave0/610). Allergy testing may be more appropriately considered within this context, but the scope for this guidance has yet to be determined.
SH	Department of	1	general	The Department of Health has no	Thank you for your comment.

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	Health			substantive comments to make regarding this consultation.	
SH	Faculty of Intensive Care Medicine	1	General	The Faculty of Intensive Care Medicine (FICM) welcomes the development of up-to-date guidelines for the treatment of community and hospital acquired pneumonia.	Thank you for your comment.
SH	Faculty of Intensive Care Medicine	2	General	The key clinical issues pertaining to intensive care medicine are listed in 4.3.1 c) and 4.3.1 e), given that the scope does not intend to look at evidence for the treatment of ventilator associated pneumonia.	Thank you for your comment.
SH	Faculty of Intensive Care Medicine	3	4.3.1 c	The FICM notes that scoring systems currently in use stratify patients according to risk of mortality – eg CURB65, pneumonia severity index, Infectious Disease Society of America/ American Thoracic Society (IDSA/ATS) prediction rule or SMART-COP. Whilst the scoring systems may be useful at defining those who should be admitted or managed in the community, the simpler scoring systems' ability to predict which patient will need intensive care support is less sensitive – (although more specific) particularly in the younger population and those with variant	Thank you for your comment. The evidence around the sensitivity and specificity of different severity assessment tools will be addressed. Any guideline must be interpreted in the light of clinical experience and individual patient factors.

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				pneumonic pathogens (e.g . Panton-Valentine Leucocidin *Staphylococcus Aureus*). The more complex systems appear to have a high sensitivity but low specificity for predicting intensive care admission. The FICM would suggest that the guideline developers consider inclusion of a statement about the importance of clinical judgment and senior review in cases where predicted mortality is low, but there are adverse features.	
SH	Faculty of Intensive Care Medicine	4	4.3.1 e	Gas exchange management is a key intervention in the management of pneumonia. The FICM would suggest that the pneumonia guideline developers might cross-reference the guidance on oxygen therapy with the British Thoracic Society Emergency Oxygen use in adults (2008).	Thank you for your comment. NICE clinical guidelines do not cross refer to guidelines other than its own in the scope and recommendations because they may not be subject to the same methodology.
SH	Faculty of Intensive Care Medicine	5	4.3.1 e	It is acknowledged that there is an extensive literature base for non-invasive ventilation in acute exacerbations of COPD and a base for continuous positive airways pressure in acute cardiogenic pulmonary oedema. Whilst not wishing to pre-empt the guideline developers, the evidence for the use of NIV or CPAP in CAP or HAP	Thank you for your comment.

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				is limited. Indeed a recent guideline from Canada was unable to make any recommendations for use of either, as the data are not of sufficient quality or quantity. There are data concerning NIV or CPAP use in patients with pneumonia secondary to drug-induced immunosuppression, but this population is excluded from the current guideline frame of reference.	
SH	Faculty of Intensive Care Medicine	6	4.3.1 e	There are now data concerning the use of extra-corporeal membrane oxygenation (ECMO), extra-corporeal carbon dioxide removal and emerging data on oscillatory ventilation as alternatives/ adjuncts to conventional invasive ventilation, in patients with respiratory failure. The FICM wonders whether the guideline development group plans to consider these technologies?	Thank you for your comment. These technologies are only undertaken in a small minority of extremely ill patients. Most stakeholders have prioritised for review considerations common to the majority of presenting patients and it has been decided that this should not be included in the scope for this guideline. NICE has issued Interventional Procedure guidance on Extracorporeal membrane carbon dioxide removal http://guidance.nice.org.uk/IPG428 and Interventional Procedure guidance on Extracorporeal membrane oxygenation for severe acute respiratory failure in adults (IPG391) http://guidance.nice.org.uk/IPG391. PSG002 Technical Patient Safety Solutions for Ventilator Associated Pneumonia may also be relevant http://guidance.nice.org.uk/PSG002. We will therefore be able to cross refer to these pieces of guidance in the NICE pathway (if appropriate).
SH	Primary Care Respiratory	1	3.2 a	We think it is important that this guideline is considered in the context of	Thank you for your comment. We intend to address in the guideline the issue of how to stratify at presentation

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	Society UK		4.3.1	the guideline on self-limiting infections (CG69). In the real world, front line clinicians are presented with a patient with a respiratory infection. They need help differentiating between those with self limiting infections and those who have serious infection and need urgent treatment – some of whom will have pneumonia. Our main feedback on CG69 on antibiotic use in self limiting infections was that clinicians need help differentiating between infections needing antibiotics and those that don't. Whether an infection is self limiting or not may only become clear after lack of treatment is successful or not. In the same way, clinicians need guidance on how to identify pneumonia, and differentiate it from more minor infections.	those with lower respiratory tract infection (LRTI) who need antibiotics and those who don't. We will also be looking at severity scores and the influence they have on admission.
SH	Primary Care Respiratory Society UK	2	3.2 b	If patients are on the caseload of a community nursing team, first presentation may also be to this team, rather than to the GP practice or to A&E.	Thank you for your comment. The scope has been amended accordingly.
SH	Royal College of Nursing	1	general	The RCN has no comments to submit on the draft scope of the above guideline. Thank you for the opportunity to participate.	Thank you for your comment.

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SH	Royal College of Paediatrics and Child Health	1	General	This is a guideline for pneumonia in adults. A similar guideline would be useful in children.	Thank you for your comment.
SH	Royal College of Physicians (RCP)	1	General	The RCP is grateful for the opportunity to respond to the draft scope consultation. In so doing, we have liaised with the British Thoracic Society and would like to endorse their response.	Thank you for your comment.
SH	Royal College of Physicians (RCP)	2	General	The elderly are at particular risk of developing pneumonia (CAP and HAP). This patient group is also at particular risk of developing C Difficile colitis. The indication for antibiotics, agents used and duration of treatment should balance the efficacy versus the pneumonia while at the same time minimising the risk of a pathological C Difficile illness.	Thank you for your comment. We will look to identify subgroups in the evidence, such as older people, and the GDG will include a care of the elderly physician. *C difficile* will be included as an outcome where appropriate.
SH	The Antimicrobial Stewardship Team, York Teaching Hospital NHS Foundation Trust	1	General	No inclusion of discussion on possible aspiration pneumonia, which may be useful,	Thank you for your comment. We will exclude patients with proven recurrent aspiration pneumonia, but patients who *may* have aspiration pneumonia, will be included in the populations reviewed as this reflects the reality of the clinical presentation.
SH	The Antimicrobial	2	General	No inclusion of discussion on early complications – parapneumonic	Thank you for your comment. Complications are included as an outcome, however recognition and

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	Stewardship Team, York Teaching Hospital NHS Foundation Trust			effusion/empyema	management of early complications is a matter of clinical skill and outside the scope of this guidance.