Managing Common Infections

Consultation on draft guideline – Otitis media (acute): antimicrobial prescribing

Stakeholder comments table

22/09/2017 – 19/10/2017

ORGANISATION NAME	DOCUMENT	PAGE NO.	LINE NO.	COMMENTS	DEVELOPER'S RESPONSE
Barking and Dagenham, Havering & Redbridge CCGs - London Antimicrobial Resistance Strat Group	Visual summary			My only comment would be that more reference could be made to patient (parent) information leaflets provided in the TARGET toolkit. There is one called "treating my infection" which is focused on self-care, and another called "when should I worry" providing info on signs of deterioration which should lead to medical review. These resources will also save time in the surgery.	Thank you for your comment. NICE can only refer to resources produced by external organisations that have been through the NICE Endorsement Programme. The TARGET toolkit resource leaflets for 'managing your infection' and 'treating your infection – respiratory tract infection' have now been endorsed..
British Association of Audiovestibular Physicians (BAAP)	Guideline	14	General	As most cases of Acute Otitis Media (AOM) will present to the GP, in practice implementing back up prescribing in 3 days may be difficult to achieve or monitor as parents may view any discomfort of the child as worsening symptoms and start the antibiotics earlier if given the prescription. If not given the prescription, in practice may be difficult to get to see the GP in 3 days. This may have to acknowledged in the guidelines	Thank you for your comment. The committee agreed that the recommendation reflects good practice. There are several different approaches to implementing a 'back-up' (delayed) prescription which allows prescribers flexibility in their approach. A definition of back-up (delayed prescribing) is included in the NICE glossary. NICE is also exploring the development of an additional tool to explain the different approaches that can be taken when implementing a delayed prescribing approach.
British Association of Audiovestibular Physicians (BAAP)	General			No changes suggested for other parts of the guidelines	Thank you for your comment.
British Association of Audiovestibular Physicians (BAAP)	Guideline	4	1,2	I am concerned that your recommendation here is going to result in unnecessary antibiotic treatment. The natural course of acute otitis media caused by bacteria is for pus to accumulate in the middle ear and form an abscess which drains through a perforation in the tympanic membrane. This signifies resolution of the infection for the majority and is a useful and reassuring sign. Antibiotics should not be given at this stage of the infection. There is just no indication for treatment at this point unless the child is systemically unwell or if the discharge persists for more than 24 hours.	Thank you for your comment. The committee discussed the groups of children who may be more likely to benefit from an antibiotic. The committee agreed that the individual patient data meta-analysis (Rovers et al. 2006) that was also included in the Cochrane review (Venekamp et al. 2015) shows a large absolute risk reduction in symptom resolution in children with otorrhoea, with antibiotics compared with placebo. The committee recognised that the presence of otorrhoea signifies that the infection is starting to resolve. However, most children with acute otitis media in the studies did not have otorrhoea and the committee agreed that this may indicate that the child has a more severe infection. The committee recognised the limitations of the evidence (the literature search was not designed specifically to identify prognostic evidence), the self-limiting nature of the infection and the need

					to take account of antimicrobial resistance. Consequently, specialist advice was sought. Having reviewed the evidence identified and the advice received, the recommendation has been amended to also include the option of 'no antibiotic', in addition to the options of back-up antibiotics and immediate antibiotics, for children with acute otitis media with otorrhoea.
British Association of Audiovestibular Physicians (BAAP)	Guideline	6	12 onwards	This reads as if tugging or pulling at the ear could be a valid sign of AOM. Combined with some of your clinical signs I would say that you are putting all manner of problems of childhood down to an acute ear infection. The child with AOM above all else is miserable and unwell. That should be made clear. I get a lot of children in clinic where the parents have said that tugging at an ear has been diagnosed as an infection by a GP and they want an operation – it makes life extremely difficult because I cannot take this as evidence of infection when weighing up surgery as a treatment option. The way this is written makes one much less inclined to believe GPs when they say a child has acute OM because your description could cover any one of a number of problems.	Thank you for your comment. The committee has considered your comments. The 'Common symptoms and signs' section has been removed from the guideline to avoid confusion. The guideline assumes that a diagnosis of acute otitis media has already been made. . The preceding recommendations outline the self-limiting nature of most cases of acute otitis media, providing advice on self-care and advice on the effect of antibiotics. This guideline did not consider surgery for acute otitis media as this is outside of scope.
British Association of Audiovestibular Physicians (BAAP)	Guideline	6	20	From my point of view the ear drum in AOM is red and inflamed. Yellow and opaque ear drums predominantly indicate otitis media with effusion and this is not an acute infection at all. I think you would be hard pushed to see a fluid level in acute OM because the ear drum is oedematous and difficult to see through. Indeed if you see a fluid level clearly the drum cannot be inflamed enough to call this acute OM. You have omitted the signs of pointing – a red ear drum with a bulging yellow centre which precedes perforation and otorrhoea.	Thank you for your comment. This guideline focusses on acute otitis media. In response to your comment the 'Common symptoms and signs' section has been removed from the guideline to avoid confusion. The guideline assumes that a diagnosis of acute otitis media has already been made.
British Association of Audiovestibular Physicians (BAAP)	Guideline	6	20	A perforation of an ear drum with discharge can only be called acute OM in the context of a sudden onset of pain and fever in a child, otherwise why is this not an otitis media et externa or an infected grommet needing topical antibiotic ear drops and not oral antibiotics? This has to be written so that the symptoms of acute infection tally with the findings of acute infection. I am really concerned that a huge number of other conditions are being lumped in with acute OM. It is so important to make an accurate diagnosis not just because you are considering antibiotics for this episode but because the full management of the child needs to be considered as well. Over diagnosing acute OM means more grommets because one of the criteria is frequent acute otitis media. We really must aim to be accurate in diagnosis.	Thank you for your comment. In response to this the 'Common symptoms and signs' section has been removed from the guideline to avoid confusion. The guideline assumes that a diagnosis of acute otitis media has already been made.
British Association of Audiovestibular Physicians (BAAP)	Guideline	7	5	I disagree that all children with acute otitis media and otorrhoea should have antibiotics – the pus is coming out and the condition is generally resolving at this point. I can understand that you would wish to give antibiotics if at the acute presentation there was otorrhoea, but would you really wish to do that when the whole is resolving? Yet you are advocating delayed antibiotics and assume there should be given if there is otorrhoea even if the child is getting better clinically and the condition settling. I really think this needs more clarity.	Thank you for your comment. The committee discussed the groups of children who may be more likely to benefit from an antibiotic. The committee agreed that the individual patient data meta-analysis (Rovers et al. 2006) that was also included in the Cochrane review (Venekamp et al. 2015) shows a large absolute risk reduction in symptom resolution in children with otorrhoea, with antibiotics compared with placebo. The committee recognised that the presence of otorrhoea signifies that the infection is starting to resolve. However, most children with acute otitis media in the studies did not have otorrhoea and the committee agreed that this may indicate that the child has a more severe infection. The committee recognised the limitations of the

					evidence (the literature search was not designed specifically to identify prognostic evidence), the self-limiting nature of the infection and the need to take account of antimicrobial resistance. Consequently, specialist advice was sought. Having reviewed the evidence identified and the advice received, the recommendation has been amended to also include the option of 'no antibiotic', in addition to the options of back-up antibiotics and immediate antibiotics, for children with acute otitis media with otorrhoea.
British Association of Audiovestibular Physicians (BAAP)	Guideline	General		In general the document is fine but I think more clarity is needed on the question of otorrhoea as a sign of resolution	Thank you for your comment. The committee discussed the groups of children who may be more likely to benefit from an antibiotic. The committee agreed that the individual patient data meta-analysis (Rovers et al. 2006) that was also included in the Cochrane review (Venekamp et al. 2015) shows a large absolute risk reduction in symptom resolution in children with otorrhoea, with antibiotics compared with placebo. The committee recognised that the presence of otorrhoea signifies that the infection is starting to resolve. However, most children with acute otitis media in the studies did not have otorrhoea and the committee agreed that this may indicate that the child has a more severe infection. The committee recognised the limitations of the evidence (the literature search was not designed specifically to identify prognostic evidence), the self-limiting nature of the infection and the need to take account of antimicrobial resistance. Consequently, specialist advice was sought. Having reviewed the evidence identified and the advice received, the recommendation has been amended to also include the option of 'no antibiotic', in addition to the options of back-up antibiotics and immediate antibiotics, for children with acute otitis media with otorrhoea.
British Infection Association	General			The title of the guideline does not make it clear it is only for children.	Thank you for your comment. This is NICE style and has been agreed with the committee. The review of the evidence did not restrict its searches by age. The evidence that was identified focused on those aged 18 years and under. This is stated in the guideline above the summary of evidence section.
British Society for Antimicrobial Chemotherapy (BSAC)	Visual summary	2	Antibiotic duration	We are surprised that the committee has gone for 7 days for this guidance, and 5 days for sinusitis. Consistency in length of treatment for most upper RTIs would be helpful. The detailed evidence you present does indeed show less than 48 hours duration has poor outcome, but is there any evidence that 5 days is any worse than 7 days?	Thank you for your comments. The committee has discussed your comments. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al. 2010). No comparisons were identified for 5 day versus 7 days of treatment.

					In comparison of short (more than 48 hours but less than 7 days) versus longer (7 days or longer) courses, shorter courses had greater odds of treatment failure at various time points compared with longer courses. However, the absolute differences between short and longer courses of treatment were small, with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection.
British Society for Antimicrobial Chemotherapy (BSAC)	Visual summary	2	Antibiotic duration	It will be more difficult to implement 7 days treatment when GPs are currently prescribing for 5 days, and ESPAUR, BSAC and the BMJ are suggesting using shorter courses. Please can you look at 5 versus 7 days and what length of course was used in recent trials in the UK?	Thank you for your comment. The current recommendations are based on the best available evidence and committee discussion. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al 2010). No comparisons were identified for 5 day versus 7 days of treatment. In comparison of short (more than 48 hours but less than 7 days) versus longer (7 days or longer) courses, shorter courses had greater odds of treatment failure at various time points compared with longer courses. The absolute differences between short and longer courses of treatment were small, with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day

					courses for those with a clinical assessment of more severe or recurrent infection.
British Society for Antimicrobial Chemotherapy (BSAC)	Visual summary	2	Choice of antibiotic	It would be useful to have the numbers needed to treat in each of the boxes, and if no ottorhoea overall (Venekamp): <2 years and bilateral AOM (NNT4); all ages with ottorhoea (NNT3). See evidence from Rovers et al (Lancet; 2006), and Rovers et al (Paediatrics; 2007).	Thank you for your comment. This is NICE style and NNTs are not included in the recommendations or in the visual summary. Information on NNTs is outlined in the 'summary of the evidence' section of the guideline.
British Society for Antimicrobial Chemotherapy (BSAC)	Visual summary	2	Choice of antibiotic	Is erythromycin as a choice in pregnancy applicable from age 8?	Thank you for your comment. Erythromycin is the macrolide of choice in pregnant young women under 18 years. BNF age bands have been used, and the only age band in the BNF that covers young women is the 8 to 17 year age band.
British Society for Antimicrobial Chemotherapy (BSAC)	Guideline	7 (lines 3-6)	Children who may benefit from antibiotics	Unlike the other areas of the guidance, there is no actual reference cited here. Hobermann et al (2011) showed that higher symptom scores at entry were associated with less favourable results at 10-12 days (p=0.004). The has a helpful scoring system rather than just saying those with "symptoms or signs of serious illness", as this is very non-specific.	Thank you for your comment. The 'Common symptoms and signs section has been removed from the guideline to avoid confusion. The guideline assumes that a diagnosis of acute otitis media has already been made. The literature search is designed to identify evidence from systematic reviews and RCTs for the effectiveness and safety of interventions. The best available evidence is prioritised and included in the evidence review. Prognostic evidence and evidence or scoring tools is outside the scope of this guideline.
British Society for Antimicrobial Chemotherapy (BSAC)	Guideline	7 (lines 3-6)	Children who may benefit from antibiotics	Hobermann et al (2011) suggest antibiotics for those under 2 years and symptom score >3 for: fever, tugging ears, crying, irritability, difficulty sleeping, less playful, eating less (0 = no symptoms; 1 = a little; 2 = a lot). They also say for under 2 years of age and bulging membrane	Thank you for your comment. The 'Common symptoms and signs' section has been removed from the guideline to avoid confusion. The guideline assumes that a diagnosis of acute otitis media has already been made. The literature search is designed to identify evidence from systematic reviews and RCTs for the effectiveness and safety of interventions. The best available evidence is prioritised and included in the evidence review. Prognostic evidence and evidence or scoring tools is outside the scope of this guideline.
Department of Health	General			No comment	Thank you.
ENT UK	Guideline	2		We cannot understand why the under 2 year old children need to have infection in both ears. Surely a single infection is sufficient if child is clinically unwell.	Thank you for your comment. The committee discussed your comment. The first recommendation and the summary of the evidence section outline the self-limiting nature of acute otitis media and the efficacy of antibiotics. The committee agreed that no antibiotic or a back-up antibiotic prescription is appropriate for this group of children. For any child or young person who is systemically very unwell, the recommendation is to offer an immediate antibiotic.

ENT UK	Guideline	General		An excellent and well overdue document. No attempt has been made to address recurrent acute otitis media and the role of prophylactic antibiotics and surgery which is a common presenting complaint in ENT.	Thank you for your comment. This guideline is for managing uncomplicated acute otitis media. Recurrent otitis media was not a specific inclusion or exclusion criteria in most of the studies. Most studies excluded children who had received antibiotics within the past few days or weeks, so would have excluded children with persistent acute otitis media. However, children may or may not have been included if they had an acute episode of recurrent acute otitis media separated by a period of time.
MSD	General			No comment	Thank you.
Neonatal and Paediatric Pharmacists Group (NPPG)	Visual summary	General	General	We welcome the format of this easy to understand and easily accessible summary.	Thank you for your comment.
Neonatal and Paediatric Pharmacists Group (NPPG)	Guideline	General	General	NPPG welcomes the development of this guideline.	Thank you for your comment.
Neonatal and Paediatric Pharmacists Group (NPPG)	Guideline	15-17	2-1	The rationale behind the choice of antibiotic is sound and appropriate.	Thank you for your comment.
Neonatal and Paediatric Pharmacists Group (NPPG)	Guideline	19	1	NPPG supports the decision to recommend three times a day dosing for both amoxicillin and co-amoxiclav, as per standard BNFC doses.	Thank you for your comment.
NHS Sheffield CCG	Guideline	4, 5, 17 & 18	Tables 5 & 14 Table	The current consultation promotes the use of antibiotics, suggesting prescribing **a 7 day course.** The latest versions of the both NICE Clinical Knowledge Summaries and the Public Health England Management and Treatment of Common Infections guidance (September 2017) promote a **5 day course.** It would not make any sense for there to be any lack of consistency between these national sets of guidance.	Thank you for your comment. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al 2010). No comparisons were identified for 5 day versus 7 days of treatment. In comparison of short (more than 48 hours but less than 7 days) versus longer (7 days or more) courses, shorter courses of treatment had greater odds of treatment failure at various time points compared with longer courses. The absolute differences between short and longer courses of treatment were small with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection.

					NICE is working closely with Public Health England and CKS to provide consistent prescribing guidance for managing common infections.
NHS Tameside and Glossop CCG	Guideline	4-5	23	Duration of treatment seems excessive and not in line with PHE antibiotic guidance	Thank you for your comment. The committee discussed your comment. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al 2010). No comparisons were identified for 5 day versus 7 days of treatment. In comparison of short (more than 48 hours but less than 7 days) versus longer (7 days or more) course, shorter courses of treatment had greater odds of treatment failure at various time points compared with longer courses. The absolute differences between short and longer courses of treatment were small with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection. NICE is working closely with Public Health England and CKS to provide consistent prescribing guidance for managing common infections.
Royal College of Nursing	Guideline	General	General	The biggest impact will be prescribing and how to safety net this. This would mainly be in primary care, especially out-of-hours and walk-in centres	Thank you for your comment. Safety netting advice is given in the guideline and visual summary.
Royal College of Nursing	Guideline	General	General	Education would have cost implications, however this could be made more cost-effective by utilising e-learning.	Thank you for your comment. Any tools and resources that support implementation of the guideline and are endorsed by NICE will be added to the guideline homepage, tools are resources tab.
Royal College of Nursing	Guideline	General	General	We feel users would overcome challenges by making use of e-learning resources and CPD papers in journals.	Thank you for your comment. Any tools and resources that support implementation of the guideline and are endorsed by NICE will be

					added to the guideline homepage, tools are resources tab.
Royal College of Nursing	Guideline	General	General	A visual summary of recommendations would be very useful – dissemination will be key and nurse prescribing would also benefit from and require this information.	Thank you for your comment. The visual summary provides an overview of the guideline with a link provided to the full guideline where additional detail is provided.
Royal College of Nursing	Guideline	General	General	We feel that the key issues for learning points for professional groups is prescribing guidance	Thank you for your comment.
Royal College of Paediatrics and Child Health	General			No comment	Thank you.
Royal College of Physicians and Surgeons of Glasgow	General			The Royal College of Physicians and Surgeons of Glasgow welcomes this review. Although the College is based in Scotland, its fellows and members practice throughout the United Kingdom. Its expert reviewer has an expertise otitis media in children. The College welcomes this guidance in a difficult area of management for general Practitioners, paediatricians and ENT Surgeons. Antibiotics should only be used when clinically indicated. Our reviewer made the following comments.	Thank you for your comments.
Royal College of Physicians and Surgeons of Glasgow	Guideline	2	11	This is a confusing sentence because of the qualifiers. It should be broken up to make clearer.	Thank you for your comment. The wording of the recommendation has been amended to make this clearer.
Royal College of Physicians and Surgeons of Glasgow	Guideline	2	15	The use of the word “consider” allows the prescriber to ignore the recommendations. Was this the intention?	Thank you for your comment. The use of the word ‘consider’ reflects the strength of the evidence used to underpin the recommendation in line with NICE methods and process guide as outlined in Developing NICE guidelines: the manual.
Royal College of Physicians and Surgeons of Glasgow	Guideline	3	1	There is no definition of “symptoms deteriorating rapidly or significantly/	Thank you for your comment. The committee discussed your comment and agreed that clinicians should be able to use their clinical judgement.
Royal College of Physicians and Surgeons of Glasgow	Guideline	4	3	The appears to be no rationale for including otitis media in both ears? Our reviewer could not find the evidence in the Cochrane review for this.	Thank you for your comment. The Venekamp et al (2015) Cochrane review makes reference to an individual patient data meta-analysis of 6 RCTs (Rovers et al. 2006). This study has now been included in the guideline and the rationale is described in the ‘Summary of evidence’ section for antibiotics.
Royal College of Physicians and Surgeons of Glasgow	Guideline	4	4	There no mention or discussion of topical antibiotic / antibiotic and steroid ear drops in the management of a discharging ear?	Thank you for your comment. No evidence was found for the effectiveness of topical antibiotics or topical antibiotic/steroid ear drops for acute otitis media, therefore the committee was unable to develop any recommendations. The guideline now states that no systematic reviews or RCTs of topical antibiotics were identified.
Royal College of Physicians and Surgeons of Glasgow	Guideline	5	12	If the child is in distress which cannot be alleviated then rather than change agent they should consider ENT referral to exclude complications.	Thank you for your comment. The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.
Royal College of Physicians and Surgeons of Glasgow	Guideline	6	1	There is no rationale presented for not advising co prescription of Paracetamol and ibuprofen.	Thank you for your comment. The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.

Royal College of Physicians and Surgeons of Glasgow	Guideline	6	5	Is there any value to mentioning anaesthetic ear drops in the main recommendation section if they are not licensed in the UK? (Also quoted on recommendations box Page 9)	Thank you for your comment. This recommendation has now been removed.
Royal College of Physicians and Surgeons of Glasgow	Guideline	6	24	Our expert reviewer disagree that otoscopy is more difficult in babies.	Thank you for your comment. The 'Common symptoms and signs' section of the guideline has now been removed.
Royal College of Physicians and Surgeons of Glasgow	Guideline	7	4	There is no rationale for the statement regarding both ears and under 2 years. It should be a clinical judgement on the severity of infection rather than laterality or age.	Thank you for your comment. The committee discussed the groups of children who may be more likely to benefit from an antibiotic. The committee agreed that the individual patient data meta-analysis (Rovers et al. 2006) that was also included in the Cochrane review (Venekamp et al. 2015) shows a large absolute risk reduction in symptom resolution in children under 2 years with bilateral acute otitis media, with antibiotics compared with placebo. The committee recognised that the presence of otorrhoea signifies that the infection is starting to resolve. However, most children with acute otitis media in the studies did not have otorrhoea and the committee agreed that this may indicate that the child has a more severe infection. The committee recognised the limitations of the evidence (the literature search was not designed specifically to identify prognostic evidence), the self-limiting nature of the infection and the need to take account of antimicrobial resistance. Consequently, specialist advice was sought. Having reviewed the evidence identified and the advice received, the recommendation has been amended to also include the option of 'no antibiotic', in addition to the options of back-up antibiotics and immediate antibiotics, for children with acute otitis media with otorrhoea. The rationale is described in the 'Summary of evidence' section for antibiotics.
Royal College of Physicians and Surgeons of Glasgow	Guideline	8	5	There is no mention of the use of topical drops for discharging ears	Thank you for your comment. No evidence was found for the effectiveness of topical antibiotics or topical antibiotic/steroid ear drops for acute otitis media therefore the committee was unable to develop any recommendations. The guideline now states that no systematic reviews or RCTs of topical antibiotics were identified.
Royal College of Physicians and Surgeons of Glasgow	Guideline	10	6	This statement cannot be substantiated.	Thank you for your comment. The sentence is based on the background section of the evidence review which gives further detail.
Royal College of Physicians and Surgeons of Glasgow	Guideline	11	4	Tympanometry measures middle ear impedance NOT hearing. No explanation is given on what they are attempting to look for on tympanography. This is not a replacement for a hearing test.	Thank you for your comment. The committee discussed and agreed that tympanometry is a surrogate measure for hearing problems caused by middle-ear fluid and it does not replace a hearing test. In the evidence reviewed tympanometry was used as a surrogate measure

					for hearing loss which is why this wording is used in the guideline.
Royal College of Physicians and Surgeons of Glasgow	Guideline	13	6	Again tympanometry is not a hearing test	Thank you for your comment. The committee discussed and agreed that tympanometry is a surrogate measure for hearing problems caused by middle-ear fluid and it does not replace a hearing test. In the evidence reviewed tympanometry was used as a surrogate measure for hearing loss which is why this wording is used in the guideline.
Royal College of Physicians and Surgeons of Glasgow		General		Our reviewer recommends the use of the term tympanic membrane rather than ear drum. All the other definitions are in medical English e.g. otorrhoea, tympanography, mastoiditis. This is a document for health professionals.	Thank you for your comment. The term ear drum has been used to support the use of plain English. Where possible NICE try to use plain language and avoid medical terminology where such changes do not change the meaning or intent of what is being said, to make guidance accessible to all.
Royal College of Physicians				Endorse BAAP's comments	Thank you.
Scottish Antimicrobial Prescribing Group	Q1			Reducing prescribing for AOM as prescribers often pressurised by parents.	Thank you for your comment.
Scottish Antimicrobial Prescribing Group	Q2			A reduction in number of prescriptions may generate cost savings but could result in an increase in repeat consultations.	Thank you for your comment
Scottish Antimicrobial Prescribing Group	Q3			Providing evidence to support not prescribing an antibiotic being safe is crucial as well as low potential for development of complications. TARGET resources from RCGP and ScRAP resources from NHS Education for Scotland may help to educate prescribers and parents.	Thank you for your comment. NICE can only refer to resources produced by external organisations that have been through the NICE Endorsement Programme. The TARGET toolkit resource leaflets for 'managing your infection' and 'treating your infection – respiratory tract infection' have now been endorsed and will be included on the tools and resources tab on the guideline home page.
Scottish Antimicrobial Prescribing Group	Q4			Visual summary is helpful but suggest some changes to improve clarity. I think would be helpful to make it clearer that otorrhoea **or** under 2 years with bilateral symptoms are criteria for considering an antibiotic.	Thank you for your comment. The visual summary outlines otorrhoea or under 2 years with bilateral symptoms.
Scottish Antimicrobial Prescribing Group	Q4			May also be helpful to include ages for young people – not aware that older children often get AOM so do we mean up to 12y, 16y?	Thank you for your comment. The committee discussed your comment and a sentence has been added in the 'Summary of evidence' section in the guideline to clarify the population covered based on the evidence identified.
Scottish Antimicrobial Prescribing Group	Q4			Where patient does not have otorrhoea or are >2yrs with bilateral infection should it not just have the first line of analgesia if required and reassurance? i.e. don't include 'consider back up/ delayed' I appreciate there is evidence for using delayed but this is just in the few where there is uncertainty over likelihood of worsening, but this reads like it can really be used in all patients. It might help prescribers if there were not too may treatment 'options' and more quantification of risk e.g. using NNT for mastoiditis etc.	Thank you for your comment. The recommendations are based on committee discussions of the best available evidence and outline that **all children** with acute otitis media should be offered paracetamol or ibuprofen. The committee discussed that a back-up antibiotic prescription may be preferred over no antibiotic for some children but that prescribers need to weigh up the small clinical benefits from antibiotics against their potential to cause adverse effects.
Scottish Antimicrobial Prescribing Group	Q4			In Delayed prescription advice 'return if symptoms significantly worsen or the antibiotic is stopped' – not sure what 'the antibiotic is stopped' refers to. Prescription started but then	Thank you for your comment. The reference to "antibiotic being stopped" was summarised in the

				stopped before course complete? I see on p.3 it is if not tolerated so should include in summary too. Suggests that delayed prescribing can only be done by 'giving a ….prescription' but the patient may be asked to reconsult or recontact if worsening. The evidence is it doesn't really matter how delayed prescriptions are done as long as it is explained clearly to the patient.	visual summary from 'antibiotic has been stopped because it was not tolerated' in the full text of the guideline. This wording in the guideline and the visual summary has now been amended.
Scottish Antimicrobial Prescribing Group	Q4			It is important in the decision aid to also know how long the patient has been symptomatic for as this may determine length of delay.	Thank you for your comment. The committee discussed this and the guideline now includes a recommendation for prescribers to be aware that symptoms last for about 3 days, but can last for up to 1 week and that most children and young people get better within 3 days without antibiotics. The recommendations advise to use the back-up prescription if symptoms significantly worsen, or do not improve within 3 days. Clinical judgement should also be used to determine appropriate individualised advice.
Scottish Antimicrobial Prescribing Group	Q4			Suggest link to patient information to support the consultation discussion around delaying and the urgency of need would be helpful within this decision aid (e.g. when should I worry leaflet or target RTI one).	Thank you for your comment. NICE can only refer to resources produced by external organisations that have been through the NICE Endorsement Programme. The TARGET toolkit resource leaflets for 'managing your infection' and 'treating your infection – respiratory tract infection' have now been endorsed and will be included on the tools and resources tab on the guideline home page.
Scottish Antimicrobial Prescribing Group	Q4			**Self-care advice** Suggest rewording to: Paracetamol or ibuprofen need to be given regularly at the right frequency and the right dose for age or weight, using maximum doses for severe pain.	Thank you for your comment. . The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.
Scottish Antimicrobial Prescribing Group	Q4			Anaesthetic ear drops may improve pain but not licensed for use in UK. Not sure of the value of including this information given it's not a treatment option that is available.	Thank you for your comment. This recommendation has been removed.
Scottish Antimicrobial Prescribing Group	Q4			**Evidence for antibiotics** Suggest rewording to: Complications (such as mastoiditis) are rare and can occur whether antibiotics are given or not.	Thank you for your comment. The current wording is in line with NICE style.
Scottish Antimicrobial Prescribing Group	Q5			As in Q1 key change will be not prescribing an antibiotic. There is a misconception that complications are more common than they actually are and that giving antibiotics will prevent complications. GPs need to know the evidence in this area to be able to reassure parents that antibiotics are not the solution. Inclusion of NNT may be useful. General comment – the draft sinusitis and sore throat visual summaries included details of antibiotics that were recommended. For standardisation should AOM one also include this as it would make it more useful to prescribers.	Thank you for your comment. NNTs are included in the summary of the evidence section in the guideline. The visual summary for acute otitis media is in line with the final published version of sinusitis (acute) visual summary and includes details of which antibiotics are recommended on page 2.
Scottish Antimicrobial Prescribing Group	Guideline	2	11-14	From "all children and young people presenting.....with acute otitis media in both ears" - it infers you should always give no prescription or delayed prescription. It does refer to those with systemic illness over on page 3 but I would be concerned that this initial paragraph refers to "all children and young people" when this is actually inaccurate - as we do recommend immediate antibiotics for certain groups.	Thank you for your comment. The wording outlining the population the recommendation is aimed at has been amended in the guideline for clarity.
Scottish Antimicrobial Prescribing Group	Guideline	4	Table	Under "choice of antibiotic" it refers to using macrolides where there is penicillin allergy or intolerance. Should intolerance be used as a reason not to use penicillins without a bit more context as this may encourage overuse of macrolides when penicillins considered the gold standard. There is a considerable issue with mis-labelling of penicillin allergy.	Thank you for your comment. This was discussed further by the committee. Further information on intolerance and allergy is outside the scope of this guideline, but is discussed further in the NICE guideline on drug allergy, which is hyperlinked in the guideline.

Scottish Antimicrobial Prescribing Group	Guideline	5	Table	The wording is unclear about the second choice antibiotics - at the section when 'refer to microbiologist' is stated, it is not clear as to whether this is when the patient has had been tried on two different antibiotics. If the child has not improved after 5-6 days of two different antibiotics perhaps further investigation is merited. Most primary care providers I suspect would be uncomfortable about giving a third antibiotic - and the options would be becoming quite limited at that time.	Thank you for your comment. This was discussed further by the committee and the table has been amended to improve clarity.
Scottish Antimicrobial Prescribing Group	Guideline	6	1-3	Do not give paracetamol and ibuprofen simultaneously. Only consider alternating paracetamol and ibuprofen if the distress persists or recurs before the next dose is due. These two statements appear to contradict each other and it is not clear what is meant by alternating.	Thank you for your comment. . The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.
Scottish Antimicrobial Prescribing Group	Guideline	General		Currently primary care prescribers across the UK follow PHE guidance which recommends symptom scoring to inform whether antibiotics should be considered in patients. Useful if the two documents aligned.	Thank you for your comment. The literature search was designed to identify evidence from systematic reviews and RCTs for the effectiveness and safety of interventions. The best available evidence is prioritised and included in the evidence review. Prognostic evidence and evidence on scoring tools is outside the scope of this guideline.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	There is no dosing listed for children < 1 year of age – is there an expectation that these children be referred to hospital?	Thank you for your comment. All age and weight ranges are as in the BNF for children. Prescribing choices for children aged 1 to 11 months is given in the table.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	Current NICE Clinical Knowledge Summary for AOM recommends a 5 day treatment duration. Current Public Health England 'Management of infection guidance for primary care for consultation and local adaptation' also recommends a 5 day treatment duration. Certainly at Evelina London Children's Hospital we are currently recommending a 5 day treatment course for AOM in children.	Thank you for your comment. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al 2010). In comparison of short (more than 48 hours but less than7 days) versus longer (7 days or more), shorter courses had greater odds of treatment failure at various time points compared to longer courses. The absolute differences between short and longer courses of treatment were small with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection. NICE is working closely with Public Health England and CKS to provide consistent

					prescribing guidance for managing common infections.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	Since co-amoxiclav has a wide therapeutic range in practice it is preferable to use the dose banding rather than the ml/kg dosing in most cases even if children are considered small for their age, this allows for ease of administration and improves adherence. We need to try to avoid unnecessarily complex dosing such as 2.6ml.	Thank you for your comment. Co-amoxiclav dosing is given as in the BNF for children.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	Current Public Health England 'Management of infection guidance for primary care for consultation and local adaptation' recommends usage of scoring to assist prescribers – should this also be included in the NICE guidance?	Thank you for your comment. The literature search was designed to identify evidence from systematic reviews and RCTs for the effectiveness and safety of interventions. The best available evidence is prioritised and included in the evidence review. Prognostic evidence and evidence on scoring tools is outside the scope of this guideline.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	Table states 'Alternative first choices for penicillin allergy or intolerance' – I would avoid using the word intolerance as many parents will claim intolerance and side effects such as gastric irritation or nausea should not be a reason to prescribe a penicillin.	Thank you for your comment. The committee considered this further and no changes were made. Further information on intolerance and allergy is outside the scope of this guideline, but is discussed further in the NICE guideline on drug allergy, which is hyperlinked in the guideline.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	4-5	23	The criteria for 'consult local microbiologist' is slightly unclear – if a patient had failed two different antibacterial agents perhaps referral to secondary care would be indicated?	Thank you for your comment. This was discussed by the committee and the table has been amended for clarity.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	2	11-14	This sentence suggests that all children and young people except those < 2 yrs with AOM in both ears or any child with discharge from the ear should NOT be offered an antibacterial – however the guideline also highlights other groups where an antibacterial may be considered.	Thank you for your comment. The wording outlining the population the recommendation is aimed at has been amended in the guideline for clarity.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Guideline	5-6	12 + 1-3	Advice re paracetamol + ibuprofen could be seen as unclear / could be misinterpreted I appreciate this has been taken from the NICE Fever guidelines – however Does alternating mean giving ibuprofen does in between paracetamol doses Think about re-wording	Thank you for your comment. The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Q1			Reduced prescribing of antimicrobials – although duration now longer	Thank you for your comment
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Q2			Potentially cost saving – reduced prescribing However potentially increased cost – longer duration (although in reality not really due to original pack dispensing)	Thank you for your comment
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Q3			Facts/figures/evidence to support non prescribing	Thank you for your comment
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Q4			Helpful Useful to bullet point criteria for antibacterial Rx For delayed Rx it requests return if antibiotic stopped what is the rationale here	Thank you for your comment. The committee considered this comment but felt the current wording was appropriate.

				Reword paracetamol + ibuprofen need to be taken regularly at the right dose	Thank you for your comment. The reference to “antibiotic being stopped” was summarised in the visual summary from ‘antibiotic has been stopped because it was not tolerated’ in the full text of the guideline. This wording in the guideline and the visual summary has now been amended. The committee discussed this and the wording on the use of paracetamol and ibuprofen has been amended.
UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Q5			See Q1	Thank you for your comment
Royal College of General Practitioners	Guideline	General	General	The RCGP welcomes the overall tone of limiting antibiotic treatment. Specific recommendations for variations in the manner of presentation, however, appear unclear. Parents struggle with helping their distressed children and often feel they need to seek urgent GP services. This encourages a culture of parental dependence on health care services, making them more likely to consult for future similar illness episodes, which is expensive for health care providers (consultations and prescriptions) and families (lost time from work and school, travel to primary care centres, purchase of painkilling medicines). Over the counter analgesic eardrops have the potential to improve parent’s access to treatment and improve antimicrobial stewardship. Analgesic eardrops can be administered into the ear every 1 to 2 hours and are available over the counter as a pharmacy medicine in Australia, New Zealand (and other parts of the world, but not in the UK) under the brand name Auralgan. Pain-killing eardrops can, by treating children's ear pain, reduce the inappropriate prescribing of antibiotics for acute otitis media. The drops used contain benzocaine (numbing nerve blocker) and phenazone (pain killer). They are believed to work by directly numbing the eardrum.	Thank you for your comments. The committee discussed your comments and as a result this recommendation has now been removed from the guideline.
Royal College of General Practitioners	Guideline	General	General	The CEDAR study was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (project number 13/88/13), and acknowledges the support of the NIHR Clinical Research Network (CRN). This study was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC Registered Clinical Trials Unit in receipt of NIHR CTU support funding. http://www.bristol.ac.uk/primaryhealthcare/researchthemes/cedar/ Unfortunately the Cedar trial has been stopped in the pilot stage http://www.bristol.ac.uk/primaryhealthcare/researchthemes/cedar/ Urgent action is needed to consider if the trial needs to be restarted or if there is sufficient evidence to make analgesic ear drops available over the counter.	Thank you for your comment. It is not within the NICE remit to determine or advise if this study should be restarted.
Royal College of General Practitioners	Guideline	General	General	Clearly there are interactions with guidance on sepsis and fever in the under-5s. It would be helpful if the guideline appreciated and accommodated other guidelines.	Thank you for your comment. NICE guidelines where relevant have been cross referenced in the guideline and the evidence review.
Royal College of General Practitioners	Guideline	General	General	Although MHRA have come down against topical antibiotics for otorrhoea (they were effective) – it is disappointing that this guideline has avoided this evidential issue.	Thank you for your comment. The search strategy that underpins the evidence review included topical antibiotics. No evidence was found for the effectiveness of topical antibiotics or topical antibiotic/steroid ear drops for acute otitis media therefore the committee was unable to develop any recommendations. The guideline

					now states that no systematic reviews or RCTs of topical antibiotics were identified.
Royal College of General Practitioners	Guideline	General	General	There is no guidance about follow up if otorrhoea is present	Thank you for your comment. Recommendations outline action if otorrhoea is present in children and young people (see p.3 lines 1 to 19). The committee considered this further and no change has been made.
Royal College of General Practitioners	Guideline	General	General	It is unclear why the USA guidelines are different both in using antibiotics, the choice and length of course.	Thank you for your comment. NICE guidelines are based on committee deliberations of the best available evidence, and take account of antimicrobial resistance. The committee has considered your comments further and have not made any changes.
Royal College of General Practitioners	Guideline	2	15	The RCGP broadly agrees with the intended position of antibiotic prescribing here. However, there is a significant difference between no prescription and a delayed prescription yet the guideline gives no steer on which action you would choose – effectively it says 'don't give immediate antibiotics most of the time'. There needs to a clear idea of the circumstances in which an antibiotic is appropriate.	Thank you for your comment. The committee discussed your comments and agreed that the recommendations are based on the best available evidence and committee expertise. There is a recommendation to offer antibiotics to children and young people who are systemically very unwell, have symptoms and signs of a more serious illness or condition, or are at high-risk of complications. The committee recognised that acute otitis media resolves without antibiotic treatment in most children However, they agreed it was appropriate to consider giving a back-up antibiotic to be used only if the child's symptoms do not **start to improve** within 3 days or if they worsen rapidly or significantly at any time.
Royal College of General Practitioners	Guideline	4	1	Please identify the circumstances in which a delayed prescription would be more appropriate than immediate prescription.	Thank you for your comment. The committee discussion box has been amended to add the rationale for this.
Royal College of General Practitioners	Guideline	4 (and 17 line 1)	23	Clarithromycin is not a good choice for children, partly because of the taste. Erythromycin ethylsuccinate syrup (the commonest erythromycin prescription) tastes much better and is well tolerated. HPA guidance acknowledges this problem – and therefore the statement that clarithromycin is currently first choice in children with penicillin allergy is incorrect.	Thank you for your comment. The guideline recommendations are based on the best available evidence. The committee discussed and agreed with your comment. The recommendation has been amended to include erythromycin or clarithromycin as alternative first choices in penicillin allergy.
Royal College of General Practitioners	Guideline	5	20	These signs look like a mixture of acute OM and chronic OM (glue ear). This is confusing.	Thank you for your comment. The committee discussed your comment and as a result the 'Common symptoms and signs' section has been removed from the guideline to avoid confusion.
Royal College of General Practitioners	Guideline	6	1	Can the evidence be referenced that paracetamol and Ibuprofen cannot be used in combination as parents can find it to be useful	Thank you for your comments. The committee discussed this and the wording around the use of paracetamol and ibuprofen has been amended.
Royal College of General Practitioners	Guideline	6	5-7	Although there is world class evidence showing that antibiotics do not help, and the National Institute for Clinical Excellence (NICE) advise against their use, over 85% of UK children with AOM are prescribed an antibiotic – a higher percentage than for any other childhood infection. This level of antibiotic use is inappropriate, unnecessary and contrary to NICE guidelines that recommend antibiotics only for children under two who have the	Thank you for your comment and the additional information you have outlined. The committee discussed your comments and as a result, this recommendation has now been removed from the guideline.

				infection in both ears, and for children with ear discharge. The other 80% of children with AOM are unlikely to benefit from antibiotics. Furthermore, antibiotics are not painkillers and do not treat the worst symptom of ear infections: the child's ear pain. All of this encourages a culture of parental dependence on health care services, making them more likely to consult for future similar illness episodes, which is expensive for health care providers (consultations and prescriptions) and families (lost time from work and school, travel to primary care centres, purchase of painkilling medicines). Even more urgently, the inappropriate use of antibiotics in general practice, to which the current management of otitis media contributes, is responsible for increasing the antibiotic resistance which results in serious hospital infections such as MRSA and C. difficile, as well as undermining the potency of antibiotic medicines to treat common but potentially serious community-acquired infections. Antimicrobial resistance is now recognised by the Department of Health (DoH) and the National Institute for Health Research (NIHR) to be a very severe public health threat. Pain-killing eardrops can, by treating children's ear pain, reduce the inappropriate prescribing of antibiotics for acute otitis media. The drops used contain benzocaine (numbing nerve blocker) and phenazone (pain killer). They are believed to work by directly numbing the eardrum. They can be dropped into the ear every 1 to 2 hours and are available over the counter as a pharmacy medicine in Australia, New Zealand (and other parts of the world, but not in the UK) under the brand name Auralgan. The CEDAR study was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (project number 13/88/13), and acknowledges the support of the NIHR Clinical Research Network (CRN). This study was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC Registered Clinical Trials Unit in receipt of NIHR CTU support funding. http://www.bristol.ac.uk/primaryhealthcare/researchthemes/cedar/ Unfortunately the Cedar trial has been stopped in the pilot stage http://www.bristol.ac.uk/primaryhealthcare/researchthemes/cedar/	
Royal College of General Practitioners	Guideline	11	26	A note linking to the drug allergy guideline would be helpful. ‘10% allergy to penicillin’ is likely to be a major over-estimate of true penicillin allergy. About 10% of people with true allergy to penicillin have cross-reactivity to first generation cephalosporins – but fewer react to later generation – and use of this family of antibiotics is only contraindicated in the small number of people who appear to have severe allergic reactions.	Thank you for your comment. The committee discussed this and a link to the NICE drug allergy guideline has been added to the guideline.
Royal College of General Practitioners	Guideline	18	1	The guidance says, ‘the shortest course’ but then suggests 7 days needed – HPA have stated 5 days for some years, and the speed of resolution of acute OM varies depending on the presence or absence of otorrhoea.	Thank you for your comment. One systematic review was prioritised that informed the recommendations on duration of treatment (Kozyrskyj et al 2010). In comparison of short (more than 48 hours but less than 7 days) versus longer (7 days or more), shorter courses had greater odds of treatment failure at various time points compared to longer courses. The absolute differences between short and longer courses of treatment were small with most children not experiencing treatment failure regardless of the length of antibiotic course. Based on this evidence, their experience and resistance data, the committee agreed that a 5 to 7-day course of all the recommended

					antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. The committee agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection.
Royal College of General Practitioners	Guideline			I remember in the past there occasionally being contention between colleagues – eg paediatricians and ENT specialists about the use of antimicrobial drops in certain cases, for example in the context of acute otitis media with a perforation and discharge. I note there was a recent study looking into this: **Are topical antibiotics an alternative to oral antibiotics for children with acute otitis media and ear discharge? BMJ 2016;352:i308** It may be worth NICE clearly setting out its position on topical antibiotics.	Thank you for your comment and reference. The search strategy that underpins the evidence review included topical antibiotics. No evidence was found for the effectiveness of topical antibiotics or topical antibiotic/steroid ear drops for acute otitis media therefore the committee was unable to develop any recommendations. The guideline now states that no systematic reviews or RCTs of topical antibiotics were identified.