Managing Common Infections

Consultation on draft guideline – Sinusitis (acute): antimicrobial prescribing

Stakeholder comments table

25/05/2017 - 26/06/2017

ID	ORGANISATION NAME	DOCUMENT	PAGE NO.	LINE NO.	COMMENTS	DEVELOPER'S RESPONSE
1	Abertawe Bro Morgannwg University Health Board	Draft Guideline	3-4	26	For all treatment options we have a 5 day course other than for Doxycycline it appears to be a 6 day course (one day 200mg, then 5 extra days 100mg)- unless this has been done intentionally but I think it would be more consistent to make everything 5 days.	Thank you for your comment. This wording has been amended and clarified following further discussion by the committee, as the total duration should be 5 days.
2	Abertawe Bro Morgannwg University Health Board	Draft Guidance	General	General	Use of terminology in general – delayed prescribing – our organisation has adopted back up prescribing terminology. Delayed confers the impression that an antibiotic should be taken but not immediately. Back up implies – antibiotics are not needed but have been prescribed just in case the criteria for taking an antibiotic are triggered. A subtle distinction, but in terms of nudge theory and behavioural change, this might be an important distinction.	Thank you for your comment. This wording has been amended in the guideline following further discussion by the committee to support the use of 'back-up prescribing' terminology.
3	AccuRx	Draft guideline	3	21	Question 1: including severe frontal headache as a red flag necessitating hospital referral will present a challenge	Thank you for your comment. This was discussed further by the committee and the wording has been amended to ensure this

					for clinicians. It is too general a symptom, and likely to be present in sinusitis. In particular, I feel that nurse practitioners who may be seeing these patients, and who tend to work more strictly based on guidelines, will feel this threshold is low for referring patients to hospital. Question 3: I think the key term is "severe" and to overcome the challenge there should supporting information, such as a description of what constitutes severe or further signs to examine for and establish severity.	red flag is not listed first. The committee agreed that this reflects good practice. Thank you for your comment. These terms are outlined in more detail in the evidence review. As with all NICE guidelines the prescriber should use their clinical judgement in the care of each individual person. The committee agreed that these terms cannot be specified for a general population of people with acute sinusitis.
4	AccuRx	Draft guideline	12	Bottom of box	Question 1: "pre-existing comorbidity" is not further explained, and this will likely be too vague for clinicians, in particular nurses. Question 3: The previous guideline listed specific conditions dependent on age. This would be helpful to include again. I notice in the Equality Impact Assessment that the guideline scope does not include immunosuppression that requires management by a specialty or cystic fibrosis – how will this decision change advice such as the above? If these conditions are removed from the list that should receive antibiotics because it is beyond the guideline scope to advise on this, then this should be clearly explained to	Thank you for your comment. Pre-existing comorbidity is defined in the evidence review and linked NICE guidelines. Thank you for your comment. The section of the equality impact assessment (EIA) referred to in the comment was prior to guideline scope consultation. The EIA form for the final scope and the final scope document do not exclude these populations. Where these populations would require different management this would be specified in the guideline (specifically for antibiotic choice).

					clinicians and a suggestion of where to find guidance for these patients should be given.	
5	AccuRx	Draft guideline	General	General	I am concerned that although the draft guideline clearly states in the discussion notes that the committee has carefully considered the risks of antimicrobial resistance (AMR) in the formulation of the guidance, AMR is not mentioned to clinicians in the advice about whether to prescribe. It should be set out very clearly to clinicians that AMR is one of the serious risks associated with inappropriate prescribing, and although does not immediately cause harm to the patient, it could in the longer term. We should be encouraging clinicians to think about this in daily practice, and to inform patients that the risks of AMR play into prescribing decisions for reasons of disclosure and education. By including this in the guideline, we can prompt and remind clinicians to do this.	Thank you for your comment. The guideline wording in the background box has been amended to include the issue of antimicrobial resistance following further discussion by the committee.
6	AccuRx	Visual summary	1	Last circle	Question 4: I think symptoms and signs of a more serious illness or condition and "high-risk of complications" should have helper text in the same way as bacterial symptoms does in order to allow clinicians to follow the guideline from the visual summary. I think that a visual summary is a very handy resource for clinicians to follow and to aid joint decision making – it can	Thank you for your comment. The visual summary is intended to provide an overview of the guideline recommendations. A link is provided to the guideline where the additional detail may be needed. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can

					be shown to patients to back up decisions not to prescribe under 10 days.	be found in the guideline and evidence review for each topic.
7	AccuRx	Visual summary	1	Evidence on antibiotics	The possible adverse effects should be more specific to have greater impact e.g. if giving antibiotics, the number needed to treat (NNT) is higher than the number needed to harm (NNH). This should dissuade clinicians more effectively than more generalised statements that contain old, basic information (most clinicians are aware that antibiotics can cause nausea and diarrhoea, yet they still prescribe them).	Thank you for your comment. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic.
8	Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups	Guideline	5	15	On, the section on common signs and symptoms it would be useful to include toothache.	Thank you for your comment. This was discussed further by the committee and the wording has been amended to include dental pain.
9	Barking and Dagenham, Havering & Redbridge Clinical	Guideline	General	General	I would hope that this guidance will be shared with dentists who often see these cases.	Thank you for your comment. The guideline is for all prescribers, including dentists. This is stated in the scope for the guideline and is now reflected on the <u>antimicrobial prescribing</u> <u>homepage</u> information.

	Commissioning Groups					
10	Barking and Dagenham, Havering & Redbridge Clinical Commissioning Groups	Guideline	General	General	The guidance while thorough, as we have come to expect from NICE, does not make reference or provide a link at the end of the document to the management of Chronic Sinusitis NICE guidance for ease of use or rather "user friendliness"; for follow-up management of cases when they are deemed to have passed the stage of acute. I acknowledge the advice within this guidance to refer the patient to the hospital.	Thank you for your comment. The focus of this guideline is acute rather than chronic infection.
11	British Dental Association	Guideline	General	General	As noted on page 6, line 10, acute sinusitis – particularly with bacterial cause – may present as dental or facial pain, or possibly sinusitis secondary to a dental infection. Patients with these symptoms commonly seek treatment from a dentist. This should be recognised in the guidance. If presenting in dental practice, dental practitioners should rule out a dental cause of sinusitis and refer the patient to a GP for management where appropriate. If presenting in medical practice following non-resolution, the GP should consider referring the patient to a dentist, to rule out a dental cause, before prescribing antimicrobials.	Thank you for your comment. This was discussed further by the committee and the wording in the symptoms and signs section has been amended to include dental pain.
12	British Infection Association	General			The comments from our members are included below and demonstrate a preference for either no antibiotic treatment (where there is no systemic	Thank you for your comment. Based on evidence of no major differences in clinical effectiveness and safety between classes of antibiotics, the committee agreed that the

			involvement) or the use of amoxicillin rather than Penicillin V where antibiotics are required- in order to be consistent with other guidelines on this topic.	choice of antibiotic should largely be driven by minimising the risk of resistance. The committee recognised that this may represent a change in practice in the UK. However, in the majority of cases an antibiotic is not needed for managing acute sinusitis as this is a self-limiting infection. Phenoxymethylpenicillin has a narrower spectrum of activity than amoxicillin and its use will have the lowest risk of resistance, while having equivalent microbiological activity to amoxicillin.
13	British Infection Association	General	 Whilst complications of sinusitis are deemed rare, we wondered whether it would it be useful if some of these were specifically mentioned (especially those that are life-threatening such as meningitis and brain abscess) in order to help forearm the clinician (who may often be a non-specialist). The clinical features of serious complications can be variable - partly as a function of the offending organism(s), such features may include subtle or gradual features, and there may be irreversible injury at the point where there has been "rapid deterioration" or the patient has become "systemically very unwell". Subsequently, it may be useful were the guidance able to help provide some information about the kind of symptoms/signs that could suggest developing complications. Such 	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. Further information and evidence regarding complications are outlined in the evidence review. However, no evidence was identified regarding the issues described.

14	British Infection Association	General			information could be produced for clinicians as well as in an appropriate form for the patient (e.g. patient information leaflet). With regard to the use of nasal corticosteroids: one of our members writes "I read that the committee discussed that these may be preferred when factors suggest that a bacterial cause is less likely. I wasn't sure if this information was accessible to the reader in the actual guideline recommendations."	Thank you for your comment. The evidence for nasal corticosteroids was not specifically in people that were not thought to have bacterial acute sinusitis. The statement described was the pragmatic view of the committee and not based on the evidence identified. Therefore, this is included in the committee discussions, but not specifically included in the recommendation.
15	British Infection Association	General			The summary tables for managing common infections in primary care published by PHE suggest amoxicillin as the first-line treatment and therefore we would support consistency in guidelines. References: BMJ 1996;313:325-9 Another sent as text in email as it interferes with the word formatting	Thank you for your comment. NICE is working closely with Public Health England and CKS to provide consistent prescribing guidance for managing common infections.
16	British Infection Association	Committee discussion on choice of antibiotic	13	Below line 16 (in box)	The time interval before recommending switching to a second-line antibiotic is too short (worsening symptoms on first choice taken for at least 2 to 3 days). The guideline itself acknowledges that symptoms can last 2-3 weeks, and the PHE primary care guideline states that antibiotics only "offer marginal benefit after 7 days". Perhaps worsening	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The guideline recognises that symptoms may last 2 to 3 weeks. However, if an antibiotic is prescribed in line with the recommendations the committee did not feel it was appropriate to continue the same antibiotic beyond 3 days if symptoms were 'worsening'.

			symptoms at 5-7 days would be more appropriate?
17	British Society for Antimicrobial Chemotherapy		No Comment Thank you for your comment.
18	British Thoracic Society		The Society welcomes this new guidance and is in agreement that that the vast majority of cases do not need antibiotics.
19	British Thoracic Society		 We query the recommendation that if an antibiotic is to be used, the first choice should be penicillin V. The papers quoted contain little evidence for its efficacy – almost all of the evidence is obtained using co- amoxiclav or amoxycillin, and our understanding of the bacteriology is that a significant number of these episodes are in fact due to H influ or Moraxella. In our clinical experience penicillin V is not used for sinusitis and we would be reluctant to do so without better evidence than that presented in this guideline that it is a rational choice. If the patient is really sick enough to need antibiotics then doxycycline would often be the drug of choice for BTS members. Thank you for your comment. Based on evidence of no major differences in clinical effectiveness and safety between classes of antibiotics, the committee agreed that the choice of antibiotic should be driven by minimising the risk of resistance. The committee recognised that this may represent a change in practice in the UK. However, In the majority of cases an antibiotic is not needed for managing acute sinusitis as this is a self-limiting infection. The committee discussion on choice of antibiotic section has been amended to reflect your comment.
20	British Thoracic Society	Evidence review	Also the study by Ahovuo-Saloranta that they quote is listed as withdrawn from publication on PuMed.Thank you for your comment. The committee were aware of the status of Ahovuo- Saloranta et al (2014) and the evidence

21	Department of				No comment	review has been amended to clarify this. This withdrawal is due to <u>technical reasons</u> , and is not linked to the evidence content. Thank you for your comment.
22	Health ENT UK	G	2	3	As well as patients' seeking adivce if symptoms deteriorate, it should be made explicit that certain symptoms (the red flag symptoms) should trigger urgent medical review.	Thank you for your comment. This was discussed further by the committee and the recommendations have been amended to include the review of the person.
23	ENT UK	G	2	12	The bioavailability and first pass metabolism of the newer generation intranasal corticosteroids is such that a negligible amount reaches the systemic circulation and as such side effects are actually rare, other than localised mucosal atrophy causing nosebleeds. This statement about systemic effects seems to overplay things.	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee agreed that this reflects good practice and MHRA safety advice.
24	ENT UK	G	3	26	We have concerns about the recommendation of Penicillin V as the first line antibiotic for ABRS. Whilst we can understand the desire to recommend narrow spectrum antibiotics in the interests of reducing the emergence of resistant organisms through the use of broad spectrum antibiotics, we are aware that there has already been an emergence of penicillin resistant organisms in ABRS; In 1996 92% of US isolates of M. Catarrhalis were resistant to penicillin, as were 80% of European isolates. By 2014 resistance to penicillin has exceeded 50% in some samples.	Thank you for your comment. Based on evidence of no major differences in clinical effectiveness and safety between classes of antibiotics, the committee agreed that the choice of antibiotic should largely be driven by minimising the risk of resistance. The committee recognised that this may represent a change in practice in the UK. However, In the majority of cases an antibiotic is not needed for managing acute sinusitis as this is a self-limiting infection. The committee discussion on choice of antibiotic section has been amended to reflect your comment.

25	ENT UK	G	5	16	The European consensus document on rhinosinusitis (EPOS 2012) stipulates that a diganosis of ARS requires at least two of the given listed symptoms, one of which should be nasal blockage or nasal discharge.	Thank you for your comment. The focus of the guideline is about the management of acute sinusitis. The evidence considered did not allow a recommendation regarding specific diagnostic criteria to be developed.
26	ENT UK	G	6	6	EPOS guidelines suggest 3 of the given listed symptoms should be present to confidently predicet ABRS.	Thank you for your comment. The focus of the guideline is about the management of acute sinusitis. The evidence considered did not allow a recommendation regarding specific diagnostic criteria to be developed.
27	ENT UK	E	7	18	As per comment #2	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee agreed that this reflects good practice
28	ENT UK	E	general	general	No evidence is presented either way for oral corticosteroids either as a sole agent or as an adjuvant to antibiotics, despite the literature suggesting there is an Odds Ratio of short-term improvement in sysmptoms of 1.3. Is this intentional?	Thank you for your comment. The committee agreed not to prioritise evidence on oral corticosteroids for a self-limiting infection, as this was considered to be outside current routine practice and there would be safety concerns associated with their use for managing a self-limiting infection. This is outlined in the evidence review.
29	Faculty of General Dental Practice (UK)	Guideline	6	10	The draft guideline notes that acute sinusitis, particularly with bacterial cause, may present as dental or facial pain, or possibly sinusitis secondary to a dental infection.	Thank you for your comment. The guideline is for all prescribers, including dentists. This is stated in the scope for the guideline and has been added to the guideline home page for clarification.
					Patients with these symptoms commonly seek treatment from a dentist, and this should be recognised in the guidance.	Dental pain as a symptom and sign of sinusitis has been discussed further by the committee and the wording in the symptoms and signs section of the guideline has been amended to include dental pain.

					If presenting in dental practice, dental practitioners should assess for a dental cause of sinusitis, and where this is ruled out, refer the patient to a general medical practitioner for management where appropriate. If presenting in general medical practice following non-resolution, the general medical practitioner should, before prescribing antimicrobials, consider referring the patient to a dentist in case of a dental cause,	
30	MSD				No comment	Thank you.
31	Neonatal and Paediatric Pharmacists Group (NPPG)	guideline	general	general	We welcome the development of this guideline and are pleased to see the inclusion of children and young people.	Thank you for your comment.
32	Neonatal and Paediatric Pharmacists Group (NPPG)	Visual summary	general	general	The visual summary is clear and a good, brief synopsis of the guideline content. We would recommend that a date is included on it for version control.	Thank you for your comment. The visual summary has been amended to reflect your comment and date of publication added.
33	NHS Bath and North East Somerset CCG	Visual summary	general	general	GPs, Pharmacists and NMPs who responded to the CCG call for comments all stated that they liked the visual format. It was however considered not suitable for issue to patients due to the wording used in the self-care information section. However a version suitable for patients and aligned to the current Public Health England TARGET Treating Your Infection Patient Information Leaflet that is widely used	Thank you for your comment. The guideline and visual summary are written for prescribers but could be used to support shared decision-making in a consultation with a person. Diagrams to support shared decision-making have been included on the NICE website on the <u>information for the</u> <u>public</u> tab of the guideline page. NICE can only refer in a guideline to resources produced by external organisations that have been formally endorsed by the <u>NICE Endorsement Programme</u> .

					in primary care settings would be welcomed	
34	NHS Bath and North East Somerset CCG	Visual summary	general	general	Why is the third circle visually larger than the other two? It suggests content is more important or urgent	Thank you for your comment. The content of the circle determined the size, the format has been amended in response to your comment.
35	NHS Bath and North East Somerset CCG	Visual summary	general	general	Use of small x on icons is overwhelmed by larger capsule icon and suggest put a x across whole capsule icon to clearly communicate No antibiotic messaging	Thank you for your comment. Your comments on the format were considered by the committee and the visual summary has been amended by the NICE publishing team.
36	NHS Bath and North East Somerset CCG	Visual summary	general	general	Bacterial cause may be more likely if several of the following are present: unclear how many need to be present and if so what action is required? Needs more clear directive content as users are not going to routinely refer to full guidance within consultations	Thank you for your comment. This was discussed further by the committee and the wording has not been amended. The evidence considered does not allow the recommendation to be more specific regarding number criteria suggesting a bacterial cause. The guideline and visual summary also assume prescribers will use their clinical judgement when implementing the recommendations
37	NHS Bath and North East Somerset CCG	Visual summary	general	general	The visual would be improved if diagnostic guidance/criteria were included and symptoms were detailed in the symptoms bar	Thank you for your comment. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic
38	NHS Bath and North East Somerset CCG	Visual summary	general	general	It is very useful to include antibiotic choice/dosing tables on reverse. Please consider addition of intranasal steroid choice/dosing as well	Thank you for your comment. The remit of the guidelines is to tackle antimicrobial resistance, therefore only antimicrobials are included in the table.
39	NHS Bath and North East Somerset CCG	Visual summary	general	general	Adopting and implementing use of the visual summary will challenge current formulary presentation. This was noted and discussed but not seen to be a	Thank you for your comment

40	NUIC Dath and	Vievel	gaparal	reneral	deterrent to adoption. It was also considered possible to incorporate into local use of Map of Medicine pathways	Thenk you for your commont. Unfortunately
40	NHS Bath and North East Somerset CCG	Visual summary	general	general	Please consider including Sno med/Read codes into the visual summary for all actions, including use of a delayed antibiotic strategy as this supports improvement in primary care coding of infection management and local implementation activity	Thank you for your comment. Unfortunately due to the number of possible codes related to the diagnosis and management of sinusitis it has not been possible to include this within the visual summary. Your comment has been forwarded to the NICE implementation team and will be explored in future digital developments.
41	NHS Bath and North East Somerset CCG	Guideline	3	26	All comments about choice of narrow spectrum antibiotic penicillin were positive and welcomed this approach	Thank you for your comment.
42	NHS Bath and North East Somerset CCG	Guideline	5	4	Welcome the inclusion of self-care guidance as this aligns to the CCG priority to promote self-care where appropriate to do so, and particularly in upper respiratory tract infections	Thank you for your comment.
43	NHS Bath and North East Somerset CCG	Guideline	8	general	Please define high dose nasal corticosteroid for each steroid. Concern that this may not align with the licenced indication, legal classification and patient information of current products that can be purchased OTC. This will impact on local implementation, particularly self-care as the CCG now promotes self-purchase of nasal corticosteroids for hayfever, and GP practices no longer routinely prescribe these products.	Thank you for your comment. The footnote on page 2 of the guideline recognises that nasal corticosteroids are not licensed for the management of acute sinusitis, so use for this indication would be off label. The recommendation wording has been amended to specify that use of a high dose nasal corticosteroid for managing sinusitis will be a prescribing decision, taking account of relevant professional guidance, and taking full responsibility for the decision. The definition of 'high dose' has been amended, but dose equivalence tables are not available for nasal corticosteroids.

44	NHS Bath and North East Somerset CCG	Guideline	general	general	Please include NNT and NNH ideally in the visual guide as primary care clinicians state they like to use these within shared decision making within consultations	Thank you for your comment. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic
45	NHS Bath and North East Somerset CCG	Guideline	general	general	Specific request from primary care clinicians for a Patient Information Leaflet containing detailed self-care advice for patients to manage acute sinusitis	Thank you for your comment. Please note that NICE can only refer to resources produced by external organisations that have been through the NICE <u>Endorsement</u> <u>Programme</u> .
46	NHS Bath and North East Somerset CCG	Guideline	15	12	Request to include clear evidence to support shared decision making for the use of a 5 day (as opposed to longer) course. Clinicians would like to have this in the visual guide, and aligns to requests for NNT and NNH in comment 12	Thank you for your comment. This was discussed further by the committee and the wording has not been amended. The supporting evidence is located in the evidence review. Additionally, diagrams to support shared decision-making have been included on the NICE website on the <u>information for the public</u> tab of the guideline page.
						Thank you for your comment. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic
47	NHS Bath and North East Somerset CCG	Guidance	14	1	Guidance states move to second choice antibiotic 2-3 days after start of 5 day first choice antibiotic. How does this align with use (or not) of a delayed	Thank you for your comment. Please note that the guidance on second choice of antibiotic relates to worsening symptoms after 2 to 3 days. The guidance on delayed

					antibiotic strategy based on similar advice p12 line1 to issue a delayed antibiotic prescription for use if symptoms deteriorate within the next 7 days?	prescribing relates to no improvement in symptoms.
48	NHS England	Guideline	3	25,26	Overall, support the recommendations set out in this guidance and agree with the new recommendations outlining an algorithm for "choice of antibiotics". This supports NHS England's goals of minimising the risk of antimicrobial resistance, by recommending the use of a narrow-spectrum antibiotic as a first choice and reserving broad- spectrum antibiotics for second choice treatment.	Thank you for your comment.
49	NHS England	Guideline	2	7-14	We support the recommendation to withhold antibiotics where appropriate and offer nasal corticosteroids. We note that the recommendations suggest "off- label" use of high-dose nasal corticosteroids although NICE should consider whether prescribers may require further guidance on this.	Thank you for your comment. The footnote attached to this recommendations gives further advice on off-label prescribing. The recommendation wording has been amended to specify that use of a high dose nasal corticosteroid for managing sinusitis will be a prescribing decision, taking account of relevant professional guidance, and taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and</u> <u>managing medicines and devices</u> for further information.
50	NHS England	General	General	General	We note that the engagement strategy for implementing this guideline needs to be carefully considered. This includes engaging with clinicians about their antibiotic prescribing behaviours for	Thank you for your comment. Your comment has been forwarded to the NICE implementation team.

				patients with sinusitis. We note that the provided algorithm for "choice of antibiotics" and the "visual summary" are both good ways of starting to communicate this change and providing a useful framework for prescribers.	
51	NHS England	1	9-10	 People presenting with symptoms for around 10 days or less 9 Do not offer an antibiotic prescription. Even if severe? Even with suspected systemic infection or complication? Even just post dental surgery/work? Suggest rephrasing to enable clinical judgement as appropriate for acute presentation 	Thank you for your comment. This was discussed further by the committee and an additional recommendation has been included to provide guidance around reassessing people as necessary. The guideline includes a separate recommendation to offer an immediate antibiotic for people who are 'systemically unwell, have symptoms and signs of a more serious illness or condition, or are at high-risk of complications'. As with all NICE guidelines health professional's own clinical judgement should be used when implementing the recommendations.
52	NHS England	2	3	seeking medical help if symptoms deteriorate rapidly or significantly, Clarify as to deterioration criteria	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. This requires the prescriber to exercise clinical judgement in their care of each individual person, and cannot be specified for a general population of people with acute sinusitis.
53	NHS England	2	4	not improve after 3 weeks, or they become systemically very unwell. Define classification of symptoms for systemically unwell – sentence above states fever	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. NICE guidelines on <u>respiratory tract</u> <u>infections</u> and <u>sepsis</u> provide further information. However, there is no specific definition of 'systemically very unwell' as this

					is based on the prescribers clinical judgement when managing each individual person.
54	NHS England	2	14-15	 Consider no antibiotic prescription or a delayed antibiotic prescription (see the recommendations on choice of antibiotic), taking account of: 16 evidence that antibiotics make little difference to how long symptoms 17 last, or the proportion of people with improved symptoms 18 possible adverse effects, particularly diarrhoea and nausea 19 factors that might make a bacterial cause more likely (see symptoms 20 and signs). 21 Consider use of microbiological or diagnostic test on synovial fluid? 	Thank you for your comment. The remit of this guideline is the management of acute sinusitis, not methods of diagnosis. NICE are not aware of any valid microbiological tests for sinusitis that involve testing synovial fluid (fluid from synovial joints such as the knee or elbow).
55	NHS England	3	6	 returning for another appointment if symptoms significantly worsen 4 despite taking the antibiotic, or the antibiotic has been stopped because 5 it was not tolerated. Use of diagnostic test of microbiology? Stopping antibiotics if no bacteria is detected or switching if resistant bacteria are isolated/detected is not mentioned 	Thank you for your comment. The remit of this guideline is the management acute sinusitis, not methods of diagnosis. Please see the <u>European Position Paper on</u> <u>Rhinosinusitis and Nasal Polyps</u> (2012) which states that 'imaging, haematological and microbiological investigations and endoscopy are not routinely required in the diagnosis of acute rhinosinusitis.'

56	NHS England	3	8	People presenting at any time who are systemically very unwell, Systemically very unwell - as defined by?	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. NICE guidelines on <u>respiratory tract</u> <u>infections</u> and <u>sepsis</u> provide further information. However, there is no specific definition of 'systemically very unwell' as this is based on the prescribers clinical judgement when managing each individual person.
57	NHS England	4		Second choice (worsening symptoms on first choice taken for at least 2 to 3 days Use of diagnostic test of microbiology? Stopping antibiotics if no bacteria is detected or switching if resistant bacteria are isolated/detected is not mentioned	Thank you for your comment. The remit of this guideline is the management of acute sinusitis, not methods of diagnosis. Please see the <u>European Position Paper on</u> <u>Rhinosinusitis and Nasal Polyps</u> (2012) which states that 'imaging, haematological and microbiological investigations and endoscopy are not routinely required in the diagnosis of acute rhinosinusitis.'
58	NHS England	6	5-7	Factors that might make a bacterial cause more likely 5 It is difficult to distinguish viral and bacterial acute sinusitis. Multiple factors of 6 the following may be more associated with a bacterial cause. There is no mention of bacterial testing to identify a bacterial cause and obtain sensitivities.	Thank you for your comment. The remit of this guideline is the management of acute sinusitis, not methods of diagnosis. Please see the <u>European Position Paper on</u> <u>Rhinosinusitis and Nasal Polyps</u> (2012) which states that 'imaging, haematological and microbiological investigations and endoscopy are not routinely required in the diagnosis of acute rhinosinusitis.'
59	NHS England	All	All	There is no description as to who this guideline is for. It is for GPs and dentists? There is no mention of post dental surgery/work sinusitis or sinusitis linked to dental abscess. Please ensure	Thank you for your comment. The guideline is for all prescribers, including GPs and dentists. This is stated in the scope for the guideline and has been added to the antimicrobial prescribing guideline homepage.

					comprehensive guideline and dental colleagues are consulted. What percentage of presentations are post dental work/linked to dental signs and symptoms?	The symptoms and signs section of the guideline has been amended to include reference to dental pain. NICE is not aware of the number of presentations linked to dental symptoms and signs.
60	NHS England	Visual Summary	General	General	Is the third cycle larger, to represent something, if not, we would suggest that they are all the same size.	Thank you for your comment. The content of the circle determined the size, the format has been amended in response to your comment.
61	NHS England	Visual Summary	General	General	We suggest the cross, to indicate "no antibiotic use" should be more prominent.	Thank you for your comment. Your comments on the format were considered by the committee and the visual summary has been amended by the NICE publishing team.
62	NHS Sheffield CCG	Visual summary			The format/presentation I generally like. I like the positive directive approach taken coupled with the easy to read/understand content. Two pages is the absolute maximum length that is justified I believe	Thank you for your comment.
63	NHS Sheffield CCG	Guideline	3	26	A concern is over the recommended choice of antibiotic. Locally we generally match our local antimicrobial recommendations with the national template: Public Health England - Management of infection guidance for primary care for consultation and local adaptation, May 2017. The antibiotic choice recommended in this NICE draft is not in line with either the PHE and consequently the local Sheffield guidance. I accept the right of the NICE draft to recommend their choice based on the evidence examined i.e. Penicllin	Thank you for your comment. NICE is working closely with Public Health England and Clinical Knowledge Summaries (CKS) to provide consistent prescribing guidance for managing common infections.

					 V, but it is at variance to the PHE/local guidance i.e. amoxicillin. It would be unhelpful to prescribers to be faced with a different recommendation as long as this discrepancy exists. 	
64	NHS Sheffield CCG	Guideline	3	25	A similar concern is over the duration of first line and alternative antibiotic courses. Again there is variance between NICE (5 days) and PHE/local (7 days). Again, it would be unhelpful to prescribers to be faced with a different recommendation as long as this discrepancy exists.	Thank you for your comment. NICE is working closely with Public Health England and Clinical Knowledge Summaries (CKS) to provide consistent prescribing guidance for managing common infections.
65	NHS West Kent Clinical Commissioning Group	Evidence Review	14	General Choice of antibiotic & Course length	This recommendation will be a challenging change in practice because current Primary care & Secondary care Infection Guidance suggest use amoxicillin 500mg TDS x 7 days as first line. However, penicillin is listed alongside, again 7 days for primary care use	Thank you for your comment.
66	NHS West Kent Clinical Commissioning Group	Evidence Review	29	6.1.1	Question 2 Would implementation of any of the draft recommendations have significant cost implications? If prescribers choose top priced nasal corticosteroids this may have cost implications, depending on how often sprays are advised. Maybe you could specify generic/ cheapest option in	Thank you for your comments. This was discussed further by the committee and the recommendations have not been amended. The formulary choice of nasal corticosteroid is for local consideration and determination. Prescribing outside of the local formulary is beyond the scope of this guideline. The resource implications sections in the guideline and the evidence review provide

					guidance? Also prescribers may not heed to guidance and give antibiotics as well? Patients may continue with spray for longer than necessary or attempt to purchase similar OTC?	further information on costs which can be considered when making prescribing decisions.
66	NHS West Kent Clinical Commissioning Group	Visual Summary		Specific Questions	This is excellent and I personally would not change anything	Thank you for your comment.
67	NHS West Kent Clinical Commissioning Group	Guideline		Specific Questions	High dose nasal corticosteroids- as above line 2	Thank you for your comment. However it is not clear where this comment relates to in the draft guideline.
68	NHS West Kent Clinical Commissioning Group	Guideline		Specific Questions	Change in practice- in West kent- use of penicillin instead of amoxicillin may be difficult for older practitioners to change behaviour.	Thank you for your responses to the questions. These have been considered by the committee and no changes have been made to the guideline or the evidence review. Prescribers need to educate people about the use of antibiotics. The guideline has been amended to clarify that previous antibiotic choice may impact on resistance and therefore may affect current prescribing decisions. Because a person has had 1 antibiotic previously doesn't necessarily mean the same one will be effective again.
69	NHS West Kent Clinical Commissioning Group	Guideline		Specific Questions	Key issue/learning points- now 5 days course – our guidance says 7 days. Use of penicillin not amoxicillin and suggestion of nasal spray	Thank you for your comment. Your comment has been forwarded to the NICE implementation team.
70	North of England Commissioning Support (NECS)	Guideline review	3	26	First line choice is not consistent with current PHE guideline recommendations	Thank you for your comment. NICE is working closely with Public Health England and Clinical Knowledge Summaries (CKS) to

					Nor are the alternative treatment options	provide consistent prescribing guidance for managing common infections.
71	North of England Commissioning Support (NECS)	Visual summary	2		As Above	Thank you for your comment
72	PARI Medical Ltd	Draft Guideline	2	13	 Please consider adding: Consider nebuliser therapy with pulsating aerosol – isotonic or hypertonic saline solutions suitable for nebulisation Nebulization is recommended in French treatment guidelines for : Oedematous, purulent and subacute (from 4 to 12 weeks) rhinosinusitis as well as chronic rhinosinusitis, Treatment of post operative persistent rhino-sinusal suppuration (> 1 month), The nebulization prescription dose is twice a day for at least 7 days. (taken from the French national guidelines for aerosol therapy in sinusitis "ORL France"; File:///C:/Users/mapter/Downloads/Recommandation_nebulisation_2014.pdf) Point 1 above is 'Recommendation 2' 	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The recommendations reflect the findings of the evidence review. Please note that chronic sinusitis is out-of-scope for this guideline as it covers only acute sinusitis.

					Point 2 above is 'Recommendation 11, 12 & 13'	
73	PARI Medical Ltd	Draft Guideline	5	22	 Please consider adding: Nasal saline with nebuliser therapy / pulsating aerosol Pulsating aerosol effectively deposits the active agent in the paranasal sinuses Möller W. et al (2009): Ventilation and aerosolized drug delivery to the paranasal sinuses using pulsating airfl ow a preliminary study. Rhinology, 47, 405-412, 2009 Schuschnig U. et at (2006): Comparison of delivery efficiency in a nasal case model of fluticasone propionate suspensions and a novel solution aerosolized via the PARI VibrentTM Case studies amongst ENT doctors in Germany and Austria report that ARS and CRS patients using the drug delivery system PARI SINUS therapeutically benefit in terms of symptom relief, quality of life and the course of the disease. The results suggest the possibility for a reduction of oral antibiotics, nasal steroids and functional endoscopic sinus surgeries. This survey, first clinical data [3-6] and ongoing trials nourish the anticipation that this principle is a valuable treatment 	 Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee were satisfied that the recommendations reflect the findings of the evidence review: The study by Moeller et al (2009) was out-of-scope as its population (healthy volunteers) is not that of the guideline The study by Schuschnig et al (2006) could not be found and does not appear to be publically available The conference posters and presentations by Mentzel et al (2013) and Hanga et al (2012) do not meet the inclusion criteria for the evidence review as stated in the review protocol.

antion in the nortfolic of
option in the portfolio of
conservative therapy approaches
for ARS and CRS.
Mentzel et al (2013) Inhalation
therapy with vibrating aerosols –
an advanced approach for the
treatment of acute and chronic
rhinosinusitis? Poster
Presentation EAACI-WAO
Congress 2013 June 22-26
2013, Milano – Italy
Also please add - Nasal steroid with
nebuliser therapy / pulsating aerosol
Pulsating aerosol effectively
deposits the active agent in the
paranasal sinuses
• Möller W. et al (2009):
Ventilation and aerosolized drug
delivery to the paranasal
sinuses using pulsating airfl ow
– a preliminary study.
Rhinology, 47, 405-412, 2009
 Schuschnig U. et at (2006):
Comparison of delivery effi
ciency in a nasal case model of
•
fluticasone propionate
suspensions and a novel
solution aerosolized via the
PARI VibrentTM
Pilot studies report impressive
symptom relief and clear
improvement in quality of life
Hanga D., Baumann I., Rohde
S., Schipper J., 83rd Annual
Meeting of the German Society

					of Oto-Rhino-Laryngology, Head and Neck Surgery, oral presentation, 16 - 20 May 2012	
74	Partnership of East London Cooperatives Limited (PELC)	guideline	1	9	Saying around 10 days leaves to interpretation would be better to be specific "for 10 days or less"	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee was not able to make such a specific recommendation based on the findings of the evidence review. The recommendation wording reflects the need for clinical judgement to be made by the responsible clinician on an individual patient basis.
75	Partnership of East London Cooperatives Limited (PELC)	guideline	2	4	Should add to "offer written information re spotting sepsis	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The evidence review and guideline refer to other NICE guidelines where this information is provided.
76	Partnership of East London Cooperatives Limited (PELC)	guideline	2		Saying around 10 days leaves to interpretation would be better to be specific "for 10 days or more"	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee was not able to make such a specific recommendation based on the findings of the evidence review. The recommendation wording reflects the need for clinical judgement to be made by the responsible clinician on an individual patient basis.
77	Royal College of Nursing	General	General	General	The Royal College of Nursing welcomes proposals to develop this guideline. The RCN invited members who care for people with sinusitis to review the draft	Thank you for your comments.

					document on its behalf. The comments below reflect the views of our members.	
78	Royal College of Nursing	Guideline	6	15	Self-Care – nasal saline: The King review like the Kassey (2010) shows little reduction in time. Both reviews show that the research is limited in this area. In clinical practice nasal saline irrigation is recommended as it seems to help clear/loosen/encourage the movement of nasal secretions. It may not reduce symptom resolution time, but seems to aid secretion movement. It should remain as an option for people to try.	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended as your comments were seen to already reflect what is outlined in the guidance and the evidence review.
79	Royal College of Nursing	Guideline	7	9	Oral decongestants – agree re lack of RCT's. Clinical experience seems to show that oral decongestants help ease the symptoms of nasal blockage and this may aid the aeration of the sinuses.	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The evidence review identified no RCT evidence for use of oral decongestants in people with acute sinusitis.
80	Royal College of Nursing	Questions	Question s	Questions	Question 1 - Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.The impact will be communicating the non-prescribing of antibiotic. The change needs to be adequate symptom control of pain and nasal block.Question 2 - Would implementation of any of the draft recommendations? There are	Thank you for your response to the questions. These have been considered by the committee and no changes have been made to the guideline recommendations or the evidence review. The formulary choice of inhaled corticosteroid is for local consideration and determination.
					no obvious cost implications, however, this depends on which nasal	The guideline recognises the importance of self-care and recommendations are based on

			corticosteroid is recommended/prescribed.Question 3 – What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)Although the self-care items have limited evidence, they do not seem to cause harm, apart from prolonged use of nasal decongestants. Therefore, to overcome the challenge of not prescribing antibiotics being able to offer a selection of self-care options such as nasal saline, oral decongestants, ?inhalations alongside adequate analgesia may enable people to manage the symptoms better.	the evidence identified. However, a person is still able to purchase an over the counter product if they wish to do so.
81	Royal College of Nursing	Visual summary	 Suggest consider the following for the visual summary: Self-care box being a list of things people could try Guidance on how to administer nasal steroid spray, so that it is sprayed onto the nasal wall and not the septum. Spraying on to the septum causes dryness and epistaxis Depending on who the visual summary is for, terms like "double sicking" make little sense. May want to include a red flag list for complications 	Thank you for your comments. The visual summary is intended to provide an overview of the guideline recommendations. A link has been provided to the full guideline and evidence review where the additional detail is provided. Your suggestions will be considered by the NICE publishing team. The term 'double-sickening' has been removed from the visual summary. The provision of guidance about how to administer a nasal corticosteroid is outside the scope of the guideline. However, the wording of the recommendation has been amended to reflect your comment. Specific information about how to administer a nasal

			 In general, the visual summary is a useful format 	corticosteroid is given in the patient information leaflet and further advice can be sought from a health professional, such as a pharmacist if the person still has problems.
82	Royal College of General Practitioners		There appears to a variety of different clinical interpretations of the terminology of sinusitis compared to rhinitis or rhinosinusitis? (A considerable number of GPs, consultants and patients appear to have different ideas). If it is not clear what "sinusitis" is then it may be unclear in what situations the guidance is indicated.	Thank you for your comment. This was discussed further by the committee and the wording has not been amended. Clarification regarding what is 'acute sinusitis' is provided in the guideline and in the evidence review.
83	Royal College of General Practitioners	Q1	This is a sensible implementable guideline on sinusitis. that is likely to be welcomed by clinicians within general practice as backing to promote the better use of antibiotics Having read the short guideline and the evidence sections, it is accurate and allows clinical decision making with guidance. The recommendations are clear and easy to implement.	Thank you for your comment.
84	Royal College of General Practitioners	Q2	High dose intranasal steroid scripts are likely to increase	Thank you for your comment. The committee considered the resource implications of implementing the guideline when reviewing the evidence and developing recommendations. Implementation of the guideline is likely to result in fewer antibiotic prescriptions. Additionally we agree that the number of nasal steroids prescriptions is

				likely to increase as for some areas this is a change in practice.
85	Royal College of General Practitioners	Q3	GPs prescribe antibiotics by age not weight and would in practice be unlikely to weigh the kids so an additional column with dose by age (assuming average weight) would mirror actual practice and usability.	Thank you for your response to the question. The committee have considered your response and have not amended the guideline. The prescribing information has been taken directly from the British National Formulary for children (BNFc).
			Can NICE ask a pharmaceutical company to make a 500mg penV tablet as 8 x 250mg tablets a day must affect patient adherence.	Thank you for your comment. Unfortunately this is outside of the NICE remit. Where evidence was identified on medicines adherence, this has been considered in the development of the recommendations. NICE has published a guideline on <u>Medicines</u> <u>adherence</u> .
			A simple handout to be given to patients to explain why an antibiotics is not needed, when they should use delayed antibiotics and when they should re-consult.	Thank you for your response to the questions. The committee have considered your response and have not amended the guideline. NICE can only refer to resources produced by external organisations that have been through the NICE <u>Endorsement</u> <u>Programme</u> .
86	Royal College of General Practitioners	Q4	Is this form useful for health professionals and the public? Yes Is there anything you would improve about it? Yes	Thank you for your responses to questions.
			It was not clear if this guidance is indicating erythromycin instead of clarithromycin in pregnancy or as 1 st line for all the nearby antibiotics.	The committee have considered your response and have amended the guideline format to make this clearer. The prescribing

			Guidance would always be better with a row which says Pregnancy and runs through options Is the summary too simple? Is more detailed information needed from the guideline to safely follow the recommendations? No its good but links to clinical signs of concern or when to refer would be helpful for those that want them The visual summary is useful and clear	information has been taken directly from the BNF. Thank you for your response. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic
87	Royal College of General Practitioners	Q5	High dose intranasal steroids is new and how to use them as drops would be unknown to most GPs so a link to expand this guidance if including it would be helpful.	The provision of guidance about how to administer a nasal corticosteroid is outside the scope of the guideline. However, the wording of the recommendation has been amended to reflect your comment. Specific information about how to administer a nasal corticosteroid is given in the patient information leaflet and further advice can be sought from a health professional, such as a pharmacist if the person still has problems.
			Consideration should be given to excluding it so it is not misused and patients so acutely ill their blocked nose is such a problem might be being assessed in ENT anyway actually.	Thank you for your response. Please note that the recommendation is based upon the clinical evidence of trials with sinusitis taking intranasal corticosteroids.
			Changing type of antibiotic used will be challenging as the document contradicts itself. There is a statement	Based on evidence of no major differences in clinical effectiveness and safety between classes of antibiotics, the committee agreed

				that the commonest causes of acute sinusitis are Strep p, Haem I, Moraxella c and Staph a, the latter 3 of which are beta lactamase producers yet the first line recommendation is Pen V which the latter 3 bacteria are resistant too. The evidence from the Cochrane Review indicates there is little to choose between the antibiotics but this does not seem biologically plausible. If GPs are going to give antibiotics they will want to give one that they think will work. Our local antibiotic formulary (North Staffordshire) recommends doxycycline/clarithromycin as first line and the producers of local formularies as well as GPs will need to be convinced if implementation is to take place. The key learning points for GPs are No antibiotic if <10d Topical steroids >10d Antibiotic >3w or if sudden deterioration or delayed antibiotic no better after 7 days Pen V	that the choice of antibiotic should largely be driven by minimising the risk of resistance. The committee recognised that this may represent a change in practice in the UK. However, In the majority of cases an antibiotic is not needed for managing acute sinusitis as it is a self-limiting infection.
88	Royal College of General Practitioners	Draft guideline	P13	Choice of antibiotic. The document sets out very clearly arguments for not prescribing antibiotics, or for using delayed prescriptions. It also (p13) quotes a variety of evidence that found no difference in effectiveness between	Based on evidence of no major differences in clinical effectiveness and safety between classes of antibiotics, the committee agreed that the choice of antibiotic should largely be driven by minimising the risk of resistance. The committee recognised that this may represent a change in practice in the UK.

				 different antibiotics (p12 & 13), though all is graded low quality. The difficulty is that the committee ends up recommending penicillin V, as least likely to cause additional resistance. However earlier in the document (p9, lines 8-9) the possible causative organisms are mostly those likely to be resistant to penicillin V. In other words, they have recommended an antibiotic that looks as if it is being used as a placebo. The committee may have come to this conclusion on the grounds that GPs are likely to overprescribe, so that avoiding harm has priority. However, if a GP is only prescribing in the circumstances that the committee advise, then it will not be sensible to use Pen V. 	However, In the majority of cases an antibiotic is not needed for managing acute sinusitis as it is a self-limiting infection.
89	Royal College of General Practitioners	Draft guideline	P13	The advice to follow local guidelines, included in paragraph 1.2.3 of the Evidence Review, was not included in the guideline	Thank you for your comment. The committee considered your comment and did not amend the guideline to avoid duplication. The section referred to is taken from the NICE guideline on <u>Antimicrobial stewardship</u> . Reference to antimicrobial resistance will be provided on the common infections home page, as this comment applies to all antimicrobial prescribing guidelines.
90	Royal College of General Practitioners	Evidence review	1.3	It was surprising that this helpful safety netting advice given in the Evidence Review was similarly omitted from the guideline	Thank you for your comment. The committee considered your comment and did not amend the guideline. Safety netting advice is from the NICE guideline on <u>Antimicrobial</u> <u>stewardship</u> .

91	Scottish Antimicrobial Prescribing Group	Visual summary	Suggest that stats highlighted somewhere i.e. only 0.5-2.2% have bacterial involvement; and the rarity of complications – 1:2.5-4.3 million. Stats show most people don't need an antibiotic at all and will get better in 2-3 weeks. At some point in the algorithm (before and/or after the 10 day symptom cut- off) there should be a trigger bullet point to visit a dentist and exclude any dental pathology/infections that could mimic signs and symptoms of acute sinusitis.	Thank you for your comments. These figures are already in the background section of the guideline. The visual summary is an overview of the recommendations to support prescribing decisions in line with a health professional's own clinical judgement. More detailed information about the recommendations can be found in the guideline and evidence review for each topic Thank you for your comment. The guideline recommendation wording has been amended to include reference to dental pain and to consider alternative diagnosis.
92	Scottish Antimicrobial Prescribing Group	Page 2 of guidance	It would also be useful to link to the TARGET patient leaflets as there is always a risk 'delayed' prescribing isn't always done 'properly' if the education is skipped over.	Thank you for your comment. NICE can only refer to resources produced by external organisations that have been through the NICE <u>Endorsement Programme</u> . However, this was discussed further by the committee and the recommendation wording has been amended to reflect the need to give written and verbal advice.
	Scottish Antimicrobial Prescribing Group	Page 6 of guidance	Regarding nasal saline irrigation, which seems to be used routinely by ENT (usually in chronic sinusitis). The suggestion here is that there is no evidence for this in acute setting, but very often we are looking at an acute on chronic situation, or symptomatic relief. I also thought there was some evidence of reducing viral load and thus spread? It gives us something to suggest and an avenue for self-care, which might reduce antibiotic prescribing, and indeed follow up	Thank you for your comment. This was discussed further by the committee and the recommendation has not been amended. The committee agreed that the guideline is clear that there is not enough evidence to recommend nasal saline irrigation based on its effect on symptoms, but is something that can be tried to relieve congestion. Please note the guideline covers acute sinusitis only, not chronic sinusitis.

					appointments. So suggest reword to be a bit more positive e.g. saline douches may have symptomatic benefit (and ? reduce spread) Local guidance does not include decongestant nasal sprays as an alternative, and the community pharmacy minor ailment formulary has saline nasal drops for congestion.	
93	Scottish Antimicrobial Prescribing Group	General comments re questions			A 'no antibiotic' strategy will have biggest impact on practice and have some cost benefits. It will also be most difficult to implement to manage patient expectations of receiving an antibiotic. Major role for community pharmacists in supporting self-care and triaging patients to keep them away from GP Practices unless symptoms are prolonged or severe.	Thank you for your response to the questions. This information will be considered when we are devising the implementation plan for the guidelines.
94	Society of Homeopaths		General	General	Antibiotic resistance, sinusitis and homeopathy The World Health Organisation (WHO) and other agencies 1,2 warn of an approaching era in which antibiotics will no be longer effective, and suggest alternative approaches, including the development of novel therapies to treat both mild and serious infections. 2,3 With a growing body of clinical evidence, a strong safety record and evidence of cost-effectiveness 4–6, homeopathy represents one potential therapeutic solution to antibiotic reduction.	Thank you for your comments and references. The committee agreed not to prioritise homeopathy as this was not considered to be routine prescribing practice. This is outlined in the evidence review. The guideline only covers acute sinusitis, not chronic sinusitis.

	As a CAM therapy, homeopathy has been subject to criticism for its use of infinitesimal doses to treat a host of different aliments, with insufficient proof that such doses can have an effect. Yet, despite a long history of scientific controversy, homeopathy has proved resilient, is geographically widespread 7 and is an accepted part of the medical system in countries such as India 8, France 9 and Switzerland 10. Advantages of homeopathy include ease of application and safety, with no contraindications existing in the treatment of the very young 11 and old, besides careful selection of remedy and dosage. Whereas antibiotics and over the counter medications do not improve the body's future response to infection	
	the body's future response to infection, homeopathy purports to do so. Several well designed clinical trials in which homeopathy was used for sinusitis have been conducted showing positive results. A randomized, double- blind study by Friese and Zabalotnyi (2007)12 investigated the efficacy and tolerability of a homeopathic combination remedy for the treatment of acute rhinosinusitis. 144 patients with acute rhinosinusitis were treated in a either with a homeopathic remedy (n=72) or placebo (n=72). In the treatment group, the average sum	

score dropped from initially 12.1+/-1.6 to 5.9+/-2.0 points after 7 days. In the placebo group it decreased from 11.7+/-1.6 to 11.0+/-2.9 points (p<0.0001). After 21 days, 90.3% of the homeopathic treatment group were free from complaints, whereas in 88.9% of the placebo group the complaints remained unchanged or became worse. The authors concluded that the homeopathic product allowed an effective and tolerable treatment of acute rhinosinusitis. An observational study by Witt et al (2009)13 showed relevant improvements that persisted for 8 years in patients seeking homeopathic treatment because of sinusitis. The treatment group included 134 adults (mean age 39.8 ± 10.4 years, 76.1% women), treated by 62 physicians. Patients (97.0%) had previously been treated with conventional medicine. The extent to which the observed effects are due to the life-style regulation and placebo or context effects aresociated with the treatment needs clarification in
with the treatment needs clarification in future explanatory studies. A multicentre observational study carried out in India by Nayak et al14 sought to test the therapeutic

					usefulness of homeopathic medicine in the management of chronic sinusitis (CS)on 550 patients. Symptoms were assessed using the chronic sinusitis assessment score (CSAS). There was a statistically significant reductions in CSAS (. P = 0.0001, Friedman test) after 3 and 6 months of treatment, and improved radiological appearance. No complications were observed during treatment. The authors concluded that homeopathic treatment may be effective for CS patients, however controlled trials are required for further validation. References – as listed in the original documents	
95	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	2	9-10	Certainly within the secondary care setting we are seeing prescriptions for nasal corticosteroids being used for treatment of sinusitis. In practice nasal corticosteroids are also being prescribed in children under 12 years of age, however as the guideline state 'high dose' it seems reasonable to only routinely recommend for children > 12 years of age. It would be useful to state the equivalent doses of other nasal steroids such as budesonide and fluticasone.	Thank you for your comment. The committee considered your comment and agreed to amend the definition of 'high dose' to include the doses of nasal corticosteroids used in the studies. Not all available nasal corticosteroids were used in the studies and dose equivalence tables are not available for nasal corticosteroids.
96	UK Clinical Pharmacy	Draft guideline	4 + 13	1	Fully appreciate that phenoxymethylpenicillin is narrow	Thank you for your comment. NICE is working closely with Public Health England

	Association (UKCPA) Pharmacy Infection Network				spectrum and therefore supports principles of antimicrobial stewardship, however in reality for children four times a day administration ideally on an empty is not very practical. Current practice at many paediatric hospitals is to use amoxicillin as first line antibiotic. Amoxicillin is also listed as first line antibiotic in the current NICE Clinical Knowledge Summary for sinusitis and the current Public Health England 'Management of infection guidance for primary care for consultation and local adaptation'. Amoxicillin is better tolerated in children and the three times a day dosing regimen allows school aged children to avoid having to take doses during school hours. Need to balance the risks of lack of adherence leading to potential development of resistance / use of broader spectrum antimicrobials. This would be a significant change to current practice. There is no dosing listed for children < 1 year of age – is there an expectation that these children be referred to hospital?	and Clinical Knowledge Summaries (CKS) to provide consistent prescribing guidance for managing common infections Where the evidence provided findings regarding safety and tolerability, this was included in the evidence review. The guideline includes dosage and course length for children aged 1 month to 11 months (from the BNF for children). However, the committee agreed that a specific diagnosis of acute sinusitis (rather than a general diagnosis of an upper respiratory tract infection) would be difficult to diagnosis in an under 1 month old and is highly unlikely in this age group.
97	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	4 + 13	1	Whilst doxycycline is licensed in children 12 years and over in practice its use is limited in children of all ages.	Thank you for your comment. The committee considered your comments and did not amend the guideline. The prescribing information has been taken directly from the BNF for children.

98	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	4	1	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. 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. The committee considered your comments and did not amend the guideline. The prescribing information has been taken directly from the BNF for children. The guideline includes dosage and course length for children aged 1 month to 11 months (from the BNF for children). However, the committee agreed that a specific diagnosis of acute sinusitis (rather than a general diagnosis of an upper respiratory tract infection) would be difficult to diagnosis in an under 1 month old and is highly unlikely in this age group.
99	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	3	26	There needs to be clarification of 'penicillin allergy' and remove intolerance.	Thank you for your comment. This was discussed further by the committee and the guideline has not been amended as the course of action would be the same.
100	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	General	General	Concern has been voiced that the advice on escalating to co-amoxiclav may result in lots of people being escalated unnecessarily. 2-3 days seems a short period of time to review improvement and no real definition of what would be red flag type symptoms for worsening. There is the potential for a lot of patients who don't get any better on two days Penicillin V to be escalated to co-amoxiclav when the cause of the problem is likely to be viral.	Thank you for your comment. Please note that the guidance on 2nd choice of antibiotic relates to worsening symptoms after 2 to 3 days. The guidance on delayed prescribing relates to no improvement in symptoms. However, in the majority of cases an antibiotic is not needed for managing acute sinusitis as it is a self-limiting infection.

101	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	14	1	Patients who do not respond to treatment may have a viral infection (rather than needing co-amoxiclav) and the patient should be re-assessed rather than automatically prescribing co-amoxiclav.	Thank you for your comment. This was discussed further by the committee and the recommendation has been amended to include reassessment.
102	UK Clinical Pharmacy Association (UKCPA) Pharmacy Infection Network	Draft guideline	3	26	The advice to contact a local microbiologist if not responding and pen allergy – what is the purpose of this? Do you think there are likely to be MC&S results that will facilitate a proper discussion? I feel this is unlikely so am not sure what such a conversation would add. Is this just because you don't want to advocate the use of a respiratory fluoroquinolone?	Thank you for your comment. The committee agreed that advice from a local microbiologist was needed when there is treatment failure on second line treatment. If this is the case, this may be indicative of a more serious or resistant infection.
103	Walgreens Boots Alliance	Visual summary	General	General	We consider that the visual guide is very clear and should be helpful for healthcare professionals. Additional guidance may be needed around recommended dosages and cautions in use for high-dose nasal corticosteroids, and on treatments or dosages for children aged 12 and under	Thank you for your comment. The committee considered your comment and agreed to amend the definition of 'high dose' to include the doses of nasal corticosteroids used in the studies. Not all available nasal corticosteroids were used in the studies and dose equivalence tables are not available for nasal corticosteroids. No evidence was identified regarding the effect of nasal corticosteroids in children aged 12 and under, so no recommendations were made.
104	Walgreens Boots Alliance	Guidance	3	2	We note that the draft guidance (and visual guide) make reference to referring patients who have had no improvement after 10 days back to self- care, which potentially includes nasal decongestants. These are typically only indicated for 10 days of self-treatment and would thus contain information	Thank you for your comment. The committee have considered your comments but have not amended the guideline. The guideline is aimed at prescribers and clinical judgement is required when applying the recommendations on an individual patient basis, for example the health professional asking about previous treatments used or taken. This should take

					advising patients to seek medical advice after this. This "circular logic" could create confusion in the minds of patients.	account of over-the-counter medicines (see <u>GMC Prescribing and managing medical</u> <u>devices 2013</u>).
105	Wiltshire Council - Public Health Wiltshire Council	Visual summary	general	general	Useful to use the visual summary with patient so they can see the nationally produced guidance. A simple one sided version may be useful for the patient to take away.	Thank you for your comment.
106	Wiltshire Council - Public Health		general	general	Should this be linked to smoking cessation support?	Thank you for your comment. The literature review included searching for evidence for smoking cessation related to sinusitis. No relevant studies were identified.