Antimicrobial stewardship

Consultation on draft guideline
Stakeholder comments table

18 February 2015 – 17 March 2015

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

	Type	Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response
1	SH	Royal College of Paediatrics and Child Health	Full	42	8	Should read 'Use of PCT levels was significantly associated with a greater number of days without antibiotics compared with usual care' rather than '...a lower number of days without antibiotics...'. From Bouadma Lancet 2010: "Patients in the procalcitonin group had significantly more days without antibiotics than did those in the control group (14.3 days [SD 9.1] vs 11.6 days [SD 8.2]; absolute difference 2.7 days, 95% CI 1.4 to 4.1, p<0.0001).	Thank you for your comment. The wording has been amended to 'Use of PCT levels was significantly associated with a greater number of days without antibiotics compared with usual care' on page 43 of the final guideline (full version).
2	SH	Royal College of Paediatrics and Child Health	Full	58	Table 8	Reference should be to 'Manzano' (2010) not 'Manzour'.	Thank you for your comment. This has been corrected to Manzano (2010) on page 60 of the final guideline (full version).
3	SH	Royal College of Paediatrics and Child Health	Full	70-71		We support the research recommendation of RCTs to determine the value of POC tests in decision-making. However believe that the most recent, and robust evidence (e.g. Nijman BMJ 2013) in children in ED is that decision rules that integrate POC tests with clinical evaluation (using HR, RR etc.) improve discrimination between those with serious and self-limiting infections. Royal College of Paediatrics and Child Health We would advocate for RCTs using risk based decision rules which incorporate clinical evaluation alongside POC testing.	Thank you for your comment and for the additional references. The study by Nijman (2013) is not an RCT and was not included within the evidence review as the inclusion criteria for point of care tests was for RCTs only. NICE looks for RCTs first as the highest quality source of evidence and only looking at lower grades of evidence if RCT data is not available.
4	SH	Royal College of Paediatrics and Child Health	Full	26 (point 13)	36-39	Should define who should be part of the core antimicrobial stewardship team, i.e.: infectious diseases specialist and/or microbiologist, antimicrobial pharmacist and specialist nurse. Define roles.	Thank you for your comment. The GDG considered that specifying an exhaustive list of core members would not be appropriate as these will vary across different care settings and differing specialities. However the GDG have agreed that, as a minimum, an antimicrobial pharmacist and medical microbiologist should form the core of the team.
5	SH	Royal College of Paediatrics and Child Health	Full	29 (point 37)		"prescriber should consider reviewing review…", recommend changing for "prescriber should review…"	Thank you for your comment. The use of 'should' indicates that the recommendation is made based on strong evidence. A 'should consider' recommendation indicates that the recommendation is made with less certainty. The wording reflects the strength of the available evidence. Throughout the guideline the evidence was generally assessed to be of a low or very low quality and was frequently sparse. Therefore 'should consider' was used by the GDG following their discussion of the available evidence. Please also see Developing NICE guidelines: the manual (2014) for information about wording of recommendations.
6	SH	NHS Sheffield CCG	Short	8	1.1.2	We are concerned that this seems to suggest rare and serious incidents are important—our clinicians think that antimicrobial stewardship is about the safe and effective use of antimicrobials. Most are used for nonbacterial or otherwise self-limited infections. Isn't it that which drives development of resistance?	Thank you for your comment. The GDG agreed that it is important to identify incidents potentially related to antimicrobial prescribing to ensure their safe and effective use. This wording has been amended following further discussion by the GDG to specify what is meant by patient safety incidents.
7	SH	NHS Sheffield CCG	Short	9	1.1.6	Question 2: clear definitions would be really helpful for users. With this in mind, what is the definition of 'appropriate antimicrobial use'	Thank you for your comment. This wording has been amended following further discussion by the GDG about what is intended by the recommendation.
8		NHS Sheffield	Short	10	1.1.14	Similarly what is the definition of 'inappropriate antimicrobial use'	Thank you for your comment. The wording of this

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		CCG					recommendation has been amended for clarity following further discussion by the GDG.
9		NHS Sheffield CCG	Short	12	1.1.23	What factors do the GDG think that prescribers should take into account when deciding the influence of prescribing (or not) on resistance?	Thank you for your comment. Please see recommendations 23, 25, 31 and 33 in the full guideline.
10		NHS Sheffield CCG	Short	13	1.1.27	We think there are implications to consider between a situation where it is clinically safe to wait before prescribing and the practicalities of seeing the patient twice, either to confirm no treatment is indicated or to discuss and start an appropriate treatment	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG to better define the clinical situations in which microbiological cultures should be taken or should be considered for taking.
11	SH	Aneurin Bevan University Health Board	Full	General	General	There is very little reference to Consultant Microbiologists, Antimicrobial Pharmacists and Infectious Disease Physicians, other than an indication that the document may be of interest to those groups, and that pre-screening groups for adoption of new antimicrobials 'most often comprised' these individuals (Table 17, page 88 of full document). It would, we think, be very helpful to note somewhere that these are the individuals who have been particularly trained in the area of antimicrobial stewardship, and are therefore reasonable choices for Antimicrobial Stewardship or Drug and Therapeutic Committee, as well as being those most frequently asked to support antibiotic review ward rounds, investigations of adverse events due to antibiotics etc.	Thank you for your comment. The GDG considered that specifying an exhaustive list of core members would not be appropriate as these will vary across different care settings and differing specialities. However the GDG have, following further discussion, agreed that, as a minimum, an antimicrobial pharmacist and medical microbiologist should form the core of the team. The GDG agreed that membership of an antimicrobial stewardship team would depend on the knowledge, skills and experience of individuals rather than a specific job role (which may or may not be relevant to all organisations) and could include a range of clinicians from different settings. This has been clarified on page 94 (section 7.6) of the full guideline (final version).
12	SH	Aneurin Bevan University Health Board	Full	General	General	A requirement for organisations to employ an Antimicrobial Pharmacist in both care settings and at each acute site would be prudent to support implementation and provide ongoing stewardship.	Thank you for your comment. Services are commissioned and provided differently in different localities. For this reason the recommendation does not specify how to implement the recommendations, for example it may be that a single antimicrobial pharmacist may work across multiple care settings. The GDG have identified the role of antimicrobial pharmacist as a core role for the antimicrobial stewardship team (see recommendation 7).
13	SH	Aneurin Bevan University Health Board	Full	General	General	There is no mention of the role of the Consultant Microbiologist in restricting reporting of antibiotic sensitivities on likely commensal organisms, although in McNulty (2011), as referenced in page 99 in Table 19, it is noted that this has been demonstrated to have an effect on antimicrobial prescribing.	Thank you for your comment. The McNulty paper (2011) does not mention consultant microbiologist.
14	SH	Aneurin Bevan University Health Board	Short	General	General	Changing GP behaviour: prescribing statistics demonstrate that change is occurring but only in depth audit of practice will elucidate what is actually happening. A simple reduction in prescribing does not necessarily mean it is appropriate, even though it is a desirable outcome. GPs say that patient demand drives prescribing and maintaining often a delicate relationship with the patient is difficult for some GPs	Thank you for your comment.
15	SH	Aneurin Bevan University Health Board	Short	8 9 10	1.1.2 1.1.6 1.1.14	GP education would be challenging; GPs work in isolation (some in single handed practices) and unknowingly (sometimes) assume they are doing the right thing for their patients. Practice peer review has shown to be helpful in spreading the word about appropriate use and choice, but we have approx 400 GPs in our area and getting a consistent message to all and to the locums is very dependent of messages being cascaded through the practice by GP prescribing lead. To date we have had the resources to do some educational sessions but with the likely demise of the Prescribing Leads meeting our opportunities for mass GP education will become more limited.	Thank you for your comment. The GDG recognise (see section 7.6 of the full guideline) that implementation of this recommendation will be a challenge (see also the implementation section of the guideline). However the GDG agreed that there was sufficient evidence, albeit very low quality evidence, from the literature review that demonstrates that educational interventions lower prescribing rates and may lead to a decrease in inappropriate prescribing (see page 66 of the final guideline full version).

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16	SH	Aneurin Bevan University Health Board	Short	9	1.1.7	In secondary care IT or decision support systems would ideally be embedded in electronic prescribing system, so this would be challenging in areas where such a system does not exist	Thank you for your comment. The GDG further discussed and agreed the benefits and challenges for IT or decision support systems. Additional wording has been added on page 69 (section 6.5) of the final version of the guideline (full version) to give an overview of this discussion.
17	SH	Aneurin Bevan University Health Board	Short	10	1.1.10	Stocking antimicrobials in pack sizes that correspond to local guidelines on course lengths will be challenging unless there become more options available to purchase from the pharmaceutical industry and national NHS purchasing contracts reflect these options. There are currently significant cost differentials that bias against buying certain pack sizes which would need to be eliminated so as not to impact on budgets.	The original wording was not correct as this used the term 'stock'. We understand why this would be impractical and discussed this with the GDG. However, as suggested by one of the stakeholder comments to change to 'supply' we believe that this recommendation is more achievable. The aim of this recommendation is to ensure that when antimicrobials are supplied that the appropriate quantity reflecting the intended course is provided to the patient and this will prevent the likelihood of storing left over supplies for inappropriate 'future use'. Wording has been added to the linking evidence to recommendations table on page 48. In most cases supplies will be made by a pharmacy so this recommendation will be manageable in the majority of cases.
18	SH	Aneurin Bevan University Health Board	Short	10	1.1.13	Many points such as this invite the NHS as a whole to put more resources and effort into antimicrobial stewardship groups, working within primary and secondary care and across the boundaries. Sharing resources and ideas across Health Boards and nations is important to assist those that have problems addressing specific issues.	Thank you for your comment.
19	SH	Aneurin Bevan University Health Board	Short	10	1.1.14	How is inappropriate use to be identified? Sometimes this is obvious from national prescribing statistics (e.g. overuse of restricted groups) or secondary care antimicrobial usage data, but with regard to looking at appropriate prescribing for specific conditions (e.g. sore throats) then this needs more hands on audit work, ideally with a follow up peer review. To ensure sustainable change we need to build these types of audits into local prescribing schemes where GP practices or secondary care doctors do the audit themselves and discuss findings, otherwise this will require a lot of Health Board resources that we haven't got or couldn't sustain in the long term. We are not convinced that the Health Board doing this work is the way forward; peer review is a much more effective process to identify and discuss variation (identified in 1.1.18), however accessing this data would be useful to challenge those who assume high prescribing means inappropriate prescribing, especially where high COPD asthma prevalence exist.	Thank you for your comment. The wording of this recommendation has been amended to remove the wording 'appropriate use' following further discussion by the GDG. The recommendation bullet point now reads 'work with prescribers to explore the reasons for very high, increasing or very low volumes of antimicrobial prescribing, or use of antimicrobials not recommended in local (where available) or national guidelines'. See recommendation 8 in the final guideline (full version).
20	SH	Aneurin Bevan University Health Board	Short	11	1.1.15	There is some feeling among GPs that the CENTOR guideline for prescribing abs- or not prescribing abs- for a sore throat is subjective and can be used to justify prescribing an antibiotic rather than promoting an objective assessment	Thank you for your comment. The GDG was aware that there are a number of clinical decision rules available for use in clinical practice.
21	SH	Aneurin Bevan University Health Board	Short	11	1.1.18	In Wales the model of Neighbourhood Care Network (NCN) groups, and GMS national priorities could be used to support this recommendation.	Thank you for your comment.
22	SH	Aneurin Bevan University	Short	11	1.1.19	This is very relevant in the primary care models which are developing with practice nurses who have done minor illness courses seeing a lot of the patients with self limiting illnesses such as sore throats and coughs, simple	Thank you for your comment.

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		Health Board				UTIs. However they are often not prescribers and GPs are writing the prescriptions which the nurses request. The message of not prescribing antibiotics and promoting self management needs to be encouraged- are these course reviewed with this in mind? GPs need to be reminded of their responsibilities to review how the nurses are working/ and query when they are asking GPs to prescribe antibiotics if they feel it is not appropriate. This could be difficult within busy practice emergency sessions, could create conflict within the team if GPs continuously question the nurses judgment etc. This is an aspect of joint working to consider, and this statement helps and facilitates discussion for the team.	
23	SH	Aneurin Bevan University Health Board	Short	13	1.1.29	This is a perfect world scenario. These messages would be best promoted within public health- to "change the mind of the nation" with practitioners then reinforcing the messages. a) Whilst this happens to some extent, there are barriers to this recommendation with respect to both public understanding and b) time constraints.	Thank you for your comment. a) The Department of Health has also referred a separate topic to NICE to develop a guideline on Antimicrobial stewardship – changing risk related behaviours in the general population. Patient behaviour will be considered in this guidance. b) The GDG were aware that consultation time may be a concern for some prescribers in some care settings; however the GDG agreed that this recommendation constitutes best practice, which NICE aims to promote through its guidance.
24	SH	Aneurin Bevan University Health Board	Short	14	1.1.31	Having a more formal system for issuing delayed antibiotics developed nationally would be helpful – GPs have a stamp and the delayed prescription is given to the patients- but there is no way of knowing whether the prescription is used or not. This is a good example to promote GPs and pharmacy working more closely together (if the prescriptions were sent to pharmacies for patients to collect there) and could be developed in partnership with pharmacy, could be a joint indicator for GPs and pharmacy to work on together, could promote self-management by patients, and is an action which could be measured. If this statement was supported as a NICE statement it would help in practice when advising patients in consultations.	Thank you for your comment. We have passed it to the NICE implementation support team to inform their support activities for this guideline.
25	SH	Aneurin Bevan University Health Board	Short	13 14	1.1.30 1.1.34	Improving documentation in primary care is potentially challenging. **Whilst we are moving in the right direction, at present documentation is very variable, where in some practices not even indication is documented let alone symptoms, but this does not just apply to antibiotic prescribing.**	Thank you for your comment. We have passed it to the NICE implementation support team to inform their support activities for this guideline.
26	SH	Aneurin Bevan University Health Board	Full	28	4	Our Health Board will find this recommendation challenging due to a new region-wide (All-Wales) Laboratory Information Management System (LIMS) that lists susceptibility of organisms to reported antimicrobials in alphabetical order. This shortcoming has been repeatedly raised at 'Development and Standardisation Group' meetings and has been met with the usual response that the ability to alter order of reporting would be 'a major system change', and therefore very expensive to implement.	Thank you for your comment. This guideline recommends that susceptibility testing and reporting the order of susceptibilities should be in line with national and local guidelines, the choice in the local formulary and the priorities of medicines management and antimicrobial stewardship teams. Please see the NICE website on the applicability of NICE guidelines outside of England.
27	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	25	19	Evaluation of antimicrobial prescribing is not possible at present as many hospitals and community settings do not have patient-level data. Suggest antimicrobial consumption would be a better term as this data is available in most settings	Thank you for your comment. The GDG have made recommendations in anticipation of improved access to, and improved quality of, prescribing data (please note that the level recommended is prescribing data at an individual prescriber level not patient-level or consumption data).
28	SH	Scottish Antimicrobial Prescribing	Full	25	27	This recommendation will be challenging to deliver to all practitioners across all settings	Thank you for your comment. The GDG recognise (see section 7.6 of the full guideline) that implementation of this recommendation will be a challenge (see also the

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		Group (SAPG)					implementation section of the guideline). However the GDG agreed that there was sufficient evidence, albeit very low quality evidence, from the literature review that demonstrates that educational interventions lower prescribing rates and may lead to a decrease in inappropriate prescribing (see page 66 of the final guideline full version).
29	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	25	31	This recommendation will be challenging to deliver to all prescribers/prescribing leads across all settings	Thank you for your comment. We have passed it to the NICE implementation support team to inform their support activities for this guideline.
30	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	25	34	Why do all prescribers need to know about national antimicrobial prescribing trends? This data is unlikely to change prescribing behaviours.	Thank you for your comment. The GDG agreed that it was important to include national prescribing trends in reviews of prescribing data. An overview of where current local prescribing sits within a national picture is beneficial to prescribers and likely to act as a driver to reduce national variation.
31	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	26	1	Does this recommendation mean electronic prescribing systems? If yes perhaps better to say so.	Thank you for your comment. This recommendation does not specifically mean electronic prescribing, though that is one system that could be used. The GDG are, however, aware that electronic prescribing systems are not currently available in all care settings. The wording of recommendation 6 (final guideline, full version) has been amended to provide more clarity of the GDG's intended meaning.
32	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	26	25	Monitoring of antimicrobial resistance in specific organisms is already done in all UK nations so what specifically is this recommendation suggesting over and above current practice?	Thank you for your comment. This recommendation specifically addresses the gaps in the monitoring of antimicrobial resistance by recommending that organisations prioritise the monitoring of antimicrobial resistance, this will allow for collection of data of patterns and trends on emerging resistance at a local level that may not [yet] be of national significance. Please note that the guideline applies to all care settings. .
33	SH	Sheffield Antimicrobial Prescribing Group (SAPG)	Full	26	30-34	These seem to duplicate previous recommendations	Thank you for your comment. Recommendation 12 (in the full version of the guideline consultation draft) has been removed following further discussion with the GDG.
34	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	26	37	The antimicrobial stewardship team should deliver the programme not just be part of it.	Thank you for your comment. Recommendation 7 (in the full version of the final guideline) suggests a role and function of the antimicrobial stewardship team. The recommendation wording has been amended make the GDG's intended meaning clearer.
35	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	26	38	It would be helpful to specify what type of practitioners the core members should be.	Thank you for your comment. The GDG considered that specifying an exhaustive list of core members would not be appropriate as these will vary across different care settings and differing specialities. However the GDG have, following further discussion, agreed that, as a minimum, an antimicrobial pharmacist and medical microbiologist should form the core of

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							the team. The GDG agreed that membership of an antimicrobial stewardship team would depend on the knowledge, skills and experience of individuals rather than a specific job role (which may or may not be relevant to all organisations) and could include a range of clinicians from different settings. This has been clarified on page 94 (section 7.6) of the full guideline (final version).
36	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	27	8	This could be covered by 'trends in antimicrobial use'	Thank you for your comment. The GDG considered that it would be useful to specifically mention both very high, changing or very low volumes of antimicrobial prescribing. The focus of antimicrobial stewardship is to ensure that prescribing occurs when it is clinically indicated and not when there is no clinical indication. The GDG members were concerned that not including this range of possibilities may lead to an assumption that this refers only to high volumes of prescribing.
37	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	27	24	This recommendation duplicates recommendations within the initial section on antimicrobial stewardship programmes	Thank you for your comment. The recommendations in the initial section relate to actions at the organisational level. This recommendation relates to the communication across and between all care settings and organisations.
38	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	28	2	All health and social care staff should be aware of local guidelines not just prescribers	Thank you for your comment. The GDG agree with your comment that all health and social care staff should be aware of local guidelines and the guideline is aimed at health and social care staff and relevant organisations. However the GDG felt that the recommendation about local prescribing guidelines needed to be more specific to prescribers of antimicrobials.
39	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	28	4	The phrase 'the order in which susceptibility of organisms is reported' is not clear	Thank you for your comment. The GDG have reviewed this wording with NICE's editorial team and believe it to be clearly understood in practice.
40	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	28	12	For prescribers 'likely impact on antimicrobial resistance' would be better phrased in terms of patient care as 'risks and benefits to patients'	Thank you for your comment. The wording of the recommendation has not been changed. The intention is that it considers the likely impact on antimicrobial resistance associated with prescribing antimicrobials, not the risks and benefits to an individual patient in line with the review question.
41	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	28	25	Should 'obtaining microbiological cultures' be rephrased as taking microbiological samples and reviewing the results' to reflect what requires to be done.	Thank you for your comment. This wording has been reworded following further discussion by the GDG. It now contains more detail about the nature of the illness and settings in which a sample should be taken or considered before antimicrobial prescribing occurs.
42	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	28	28	Although CRP testing in primary care is supported by evidence this service is not currently widely funded.	Thank you for your comment.
43	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	29	12-18	The first two bullets refer to primary care and the third to hospital practice. Should this be 2 separate recommendations?	Thank you for your comment. This recommendation relates to situations where immediate prescribing is not appropriate and the discussions that should occur with patients and/or carers. This is not healthcare setting dependent.
44	SH	Scottish	Full	29	32	Should the first bullet refer to antimicrobial resistance at personal and	Thank you for your comment. The wording of this

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		Antimicrobial Prescribing Group (SAPG)				population level	recommendation has been amended to reflect your comment.
45	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	29	31	More detail is needed. Although some indications e.g. UTI prophylaxis should be limited to 6 months others such as post-splenectomy cover is lifelong.	Thank you for your comment. Recommendation 37 (full guideline, final version) has been reworded to state 'Prescribers should not issue repeat prescriptions for antimicrobials unless needed for a particular clinical condition or indication. They should avoid issuing repeat prescriptions for longer than 6 months without review, and should ensure adequate monitoring for individual patients to reduce adverse drug reactions and to check whether continuing an antimicrobial is really needed.'
46	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	30	1-2	Should OPAT be mentioned here?	Thank you for your comment. Recommendation 39 (full guideline, final version) already states that it applies to intravenous antimicrobial prescriptions in all care settings (including community and outpatient services) so this would include outpatient antimicrobial therapy. However the GDG felt that the mention of a single service when many such services could be mentioned would be inappropriate.
47	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	General		The guideline is very generic and although it identifies what requires to be done to effectively implement stewardship it does not give details of how to do it which may limit its impact on practice.	Thank you for your comment. The GDG have amended the wording of recommendations in order to make clear who should take action. A 'who to take action' table will be added to the full version of the guideline. For further details of how the guideline recommendations could be put in to practice please see the section on implementation.
48	SH	Scottish Antimicrobial Prescribing Group (SAPG)	Full	General		In terms of healthcare staff the guideline focuses on prescribers but pharmacists and nurses/midwives also have a role as part of the multi-professional approach to stewardship.	Thank you for your comment. The guideline is aimed at all health and social care practitioners.
49	SH	Derby Hospitals NHS Foundation Trust	Short	8	1.1.2	It is very difficult in secondary care to provide feedback to individual prescribers on their antibiotic consumption, unless the hospital uses electronic prescribing, and even then it would be very time-consuming for the antimicrobial stewardship team to produce reports on an individual prescriber level.	Thank you for your comment. The GDG have made recommendations in anticipation of improved access to, and improved quality of, prescribing data. The GDG recognises that e-prescribing is aspirational and not yet available in all settings.
50	SH	Derby Hospitals NHS Foundation Trust	Short	9	1.1.5	It is not clear what this recommendation means, although it becomes clearer if one also looks at page 51 of the full version. It might be helpful to add "with the purpose of determining if the episode is linked to inappropriate antibiotic prescribing"	Thank you for your comment. This wording has been amended following further discussion by the GDG. A rationale has been added to the recommendation.
51	SH	Derby Hospitals NHS Foundation Trust	Short	8	1.1.1	Primary care organisations need the specialist support of a clinical microbiologist and an antimicrobial pharmacist to establish an antimicrobial stewardship program	Thank you for your comment. The GDG considered that specifying an exhaustive list of core members would not be appropriate as these will vary across different care settings and differing specialities. However, the GDG have, following further discussion, agreed that, as a minimum, an antimicrobial pharmacist and medical microbiologist should form the core of the team. The GDG agreed that membership of an antimicrobial stewardship team would depend on the knowledge, skills and experience of individuals rather than a specific job role (which may or may not be relevant to all

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							organisations) and could include a range of clinicians from different settings. This has been clarified on page 94 (section 7.6) of the full guideline (final version).
52	SH	Derby Hospitals NHS Foundation Trust	Short	12	1.1.20	This is a general comment really, but there is a lack of national guidance to aid antibiotic prescribing in secondary care in some conditions e.g. SIGN guidelines on surgical prophylaxis make recommendations on when to give prophylaxis, but not on which antibiotics to use.	Thank you for your comment. The treatment of specific clinical conditions is outside of the scope for this guideline. Please also note that NICE has produced a guideline on Surgical site infection (NICE guideline CG74) and has a related Quality standard for Antibiotic prophylaxis.
53	SH	Derby Hospitals NHS Foundation Trust	Short	12	1.1.21	Include something about ensuring easy access to up to date guidelines e.g. through electronic solutions such as a Smartphone app	Thank you for your comment. We have passed it to the NICE implementation support team to inform their support activities for this guideline.
54	SH	Derby Hospitals NHS Foundation Trust	Short	3	General	Under "audience" it does not mention hospital nurses, who can play a key role in prompting IV to oral switches, use of stop dates and duration of treatment.	Thank you for your comment. Please note that his section states the audience as "Health and social care practitioners (a term used to define the wider care team of hospital staff…)". This definition includes hospital nurses.
55	SH	Derby Hospitals NHS Foundation Trust	Short	11	1.1.18 1.1.19	We would support peer review of prescribing. Our medical staff undertake very regular audits of their own antibiotic prescribing which is then reviewed by either the microbiologists or antimicrobial pharmacist, and feedback given. This has been effective in drawing attention to the guidelines and improving the overall process of antibiotic prescribing. Recommendation 1.1.19 regarding the influence of senior prescribers is very important in secondary care, and this audit process has been an effective way of engaging senior medical staff.	Thank you for your comment.
56	SH	Derby Hospitals NHS Foundation Trust	Short	13	1.1.27	We agree with this statement, but would suggest another one saying that prescribers should send appropriate microbiological cultures in all cases (not just those where considering whether to treat) and should review results and de-escalate treatment where possible.	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG to better define the clinical situations in which microbiological cultures should be taken or should be considered for taking.
57	SH	Astellas Pharma Ltd	Full	99		In the 'Call for Evidence' regarding the question of adoption of new antimicrobials, the summary of responses includes the statement 'Another concern was that newer antimicrobial may not have a clinical advantage over current therapies (an example given was fidaxomycin (sic) versus vancomycin for the treatment of *C. difficile*)...'. This statement is not true, as the registration studies of fidaxomicin (Louie NEJM 2011; 364: 422-32, Cornely Lancet Infect Dis 2012; 12: 281-9) show a clinical advantage of fidaxomicin over vancomycin in terms of prevention of recurrence, an important clinical consideration in the treatment of *C diff .* Indeed, the NICE Evidence Summary ESNM1 states "Evidence from two double-blind, randomised controlled trials indicates it is non-inferior to vancomycin in curing patients with mild to severe CDI. Its side-effect profile appears similar to that of oral vancomycin and it may have advantages in reducing the rate of recurrence." (https://www.nice.org.uk/advice/esnm1) Additionally the Public Health England updated guidance on the management and treatment of *clostridium difficile* infection 2013 states that fidaxomicin is superior to vancomycin in reducing recurrence and in sustained clinical cure	Thank you for your comment. This section has been reworded following further discussion by the GDG. The example used has been removed.

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						(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/321891/Clostridium_difficile_management_and_treatment.pdf) We are disappointed that a false statement regarding fidaxomicin has been included in a section relating to evidence. It is our understanding that these Medicines Practice Guidelines should not be making recommendations regarding specific medicines, and are surprised that the GDG decided to include this non-evidence based comment. This incorrect statement should be removed.	
58	SH	Astellas Pharma Ltd	Full	48/49	General	This section on the use of narrow spectrum antibiotics does not reflect the Department of Health UK 5 year AMR Strategy 2013-2018 that encourages prescribing of narrow spectrum antibiotics, in order to minimise antibiotic resistance. In the introduction the DH state: 'We have focused on setting an ambition to reduce overall antibiotic prescribing, **encourage narrow spectrum prescribing.....**' The GDG acknowledge that narrow spectrum antibiotics are a way to reduce antibiotic resistance, but express concerns on feasibility due to lack of susceptibility testing in primary care. Astellas do not consider that the current lack of susceptibility testing in primary care should reduce the aspiration for this guideline. The example of *c.diff* treatment is a perfect illustration of where a narrow spectrum agent is ideal as it limits further damage to the gut flora and improves patient outcomes compared to traditional broad spectrum drugs, furthermore susceptibility testing is not required for selection of *c.diff* treatment agent and therefore not a barrier to the preferential use of a licensed narrow spectrum antibiotic in favour of a broad spectrum agent. Additionally the use of a narrow spectrum agent in this condition prevents the emergence of VRE (vancomycin resistant enterococci) which can be difficult to treat and is associated with complications in susceptible patients.	Thank you for your comment. Section 5.5 has been reworded following further discussion by the GDG. Section 5.5 (page 50 of the final guideline full version) now includes how evidence on narrow versus broad spectrum antimicrobials was included in the literature review process and reference to the UK 5 Year Antimicrobial Resistance (AMR) Strategy 2013–2018, Annual progress report and implementation plan, 2014 and also contains the GDG discussion of Healthcare Acquired Infection and AMR risk and clinical benefits of broad and narrow spectrum antimicrobials.
59	SH	Alere Ltd	Full	General	General	We would like to make a number of general comments at the outset, which provide the context for our more detailed, specific comments listed below. We are particularly concerned that this draft guideline does not take into other evidence-based conclusions and recommendations made in other NICE guidelines. As a consequence of what appears to be a rather selective approach to evidence inclusion, key evidence (including that from Randomised Controlled Trials (RCTs)) underpinning other relevant NICE guidelines has been excluded from this antimicrobial stewardship guideline. Not only does this result in inconsistencies between different guidelines, it also has the potential to confuse healthcare professionals tasked with implementing final recommendations. For example, in the recently-published NICE clinical guideline on pneumonia (NICE CG191) point of care testing with the C-Reactive Protein (CRP) test was recognised as an important intervention which can assist primary care practitioners when making antibiotic prescribing decisions. Not only is that NICE CG191 recommendation barely referenced in this draft guideline, but much of the evidence base underpinning it has been excluded from consideration here. Conversely, there are a number of references to NICE CG69, but we would maintain that this guideline is based on out-of-date evidence and is in urgent	Thank you for your comment. Only studies that met the inclusion criteria were included for this review question. For CG191, studies that met the inclusion criteria (as stated in the review protocol) were included where they met the inclusion criteria for the review question. The studies identified for this review question were consistent with the studies in CG191 where they were RCTs. The recommendation regarding point of care C-reactive protein testing within this guideline is consistent with the recommendation in NICE guideline on pneumonia (CG191). The GDG did not feel able to make any general recommendations over and above those already recommended in the pneumonia guideline based on the included evidence. The GDG discussion relating to this has been clarified in the linking evidence to recommendations table (page 71 of the final guideline [full version]). The development of this guideline has followed the processes

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						need of review.	outlines in Developing NICE guidelines: the manual (2014). NICE CG69 has been assessed through the NICE surveillance programme and is considered to be current and not requiring an update. The surveillance and updating process for published guidelines is in Developing NICE guidelines: the manual (2014). In line with this process please email nice@nice.org.uk and provide any relevant evidence as rationale for an update of this guideline.
60	SH	Alere	Full	General	General	While we appreciate that the scope for this guideline made clear that individual infections/conditions would not be considered, we feel that the resulting recommendations are too general and unspecific to have a significant impact on practice or to be of practical use to most healthcare professionals. Many of the recommendations do not distinguish between primary and secondary care, for example, even though the antimicrobial stewardship and guideline implementation challenges may be very different in each setting, 78.5% of antibiotics are prescribed in primary care and there should be a clear focus on strategies aimed to improve prescribing decisions in GP practice and community out of hours settings (Public Health England, 2014)	Thank you for your comment. The GDG have amended the wording of recommendations in order to make clear who should take action. A 'who to take action' table has been added to the full (final version) of the guideline (page 32, section 4.3). For further details of how the guideline recommendations could be put in to practice please see the section on implementation.
61	SH	Alere	Full	General	General	Thirdly, and partly as a result of this generic approach, some of the recommendations will be extremely challenging to implement, particularly in a primary care setting, where a decision whether or not to prescribe an antibiotic treatment needs to be made in a matter of minutes, not days. Again, it is disappointing, therefore, that the point of care CRP test does not feature more prominently in this guideline. A point of care CRP test is very easy to run and does not require technical or complex training. It takes just 4 minutes to achieve a quantitative result. The use of point of care testing is widespread in UK primary care. Specifically, point of care CRP is already used routinely in primary care in a number of other countries (including Denmark, Norway, Sweden, Germany, The Netherlands, Switzerland and Finland) where it has helped reduce the rates of antibiotic prescribing by as much as 36% (Little et al. 2013; Hopstaken et al. 2003; Cals J et al. 2010a; Jakobsen 2010; Diederichsen et al. 2000; Bjerrum et al. 2005; Verlee et al., 2012; Bjerrum et al., 2011; Huang et al., 2013; Llor et al. 2014; Andreeva and Melbye 2014). The use of point of care CRP in the UK is increasingly gaining ground.	Thank you for your comment. Only studies that met the inclusion criteria were included for this review question. Point-of-care tests had been included in the original review protocol but were not specifically included in the original search and on reviewing this, the GDG, considered that a separate search for all POC tests was warranted as they have the potential to contribute to the decision-making on the initiation of antimicrobial therapy. The recommendation regarding point of care C-reactive protein testing within this guideline is consistent with the recommendation in NICE guideline on pneumonia (CG191). For CG191, studies that met the inclusion criteria (as stated in the review protocol) were included where they met the inclusion criteria for the review question. The studies identified for this review question were consistent with the studies in CG191 where they were RCTs. The GDG did not feel able to make any general recommendations over and above those already recommended in the pneumonia guideline based on the included evidence. The GDG discussion relating to this has been clarified in the linking evidence to recommendations table (page 71 of the final guideline [full version]). The development of this guideline has followed the processes outlines in Developing NICE guidelines: the manual (2014).

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							NICE CG69 has been assessed through the NICE surveillance programme and is considered to be current and not requiring an update. The surveillance and updating process for published guidelines is in Developing NICE guidelines: the manual (2014). In line with this process please email nice@nice.org.uk and provide any relevant evidence as rationale for an update of this guideline.
62	SH	Alere Ltd	Full	General	General	By using the point of care CRP test as an aid to help primary care practitioners to differentiate from those who do not require antibiotics and conversely better identify which patients require antibiotics, this recommendation has the potential to optimise prescribing practice, promoting rational prescribing of antibiotics in accordance with the Department of Health's Antimicrobial Resistance Strategy, promoting good antimicrobial stewardship practices and, ultimately, improving patient safety. The use of point of care CRP also acts as a behaviour change catalyst improving the patient experience of the consultation and reducing the expectation of an inappropriate prescription (Little P et al. 2013; Bjerrum L et al. 2011; Cals JWL et al. 2009; Cals JW et al. 2013; Coenen S. 2012).	Thank you for your comment. The Department of Health has referred a topic to NICE to develop a guideline on Antimicrobial stewardship – changing risk related behaviours in the general population. Patient behaviour will be considered in this guideline. Thank you for the additional references, these have not been included within the evidence review for the following reasons (please note that the inclusion criteria for point of care tests was for RCTs only); • Little (2013), not a CRP or procalcitonin test, no baseline of previous prescribing practice • Cals (2009 and 2010), are included as part of the Aabenhus Cochrane review • Bjerrum (2005), not an RCT Coenen (2012), not an RCT
63	SH	Alere	Full	26	5-12	In NICE CG191, the point of care CRP test was recognised as an important intervention that can assist primary care practitioners when making antibiotic prescribing decisions. The point of care CRP test should be added to the list of interventions here which organisations should consider using for the purposes of antimicrobial stewardship.	Thank you for your comment. The GDG agreed that due to the remaining uncertainty for all point-of-care tests (including C-reactive protein testing, [see page 71 of full guideline [final version]]) a further specific or stronger recommendations beyond what is recommended in NICE CG191 could not be made. Recommendation 30 relates to point of care tests as one of the recommendations on antimicrobial prescribing.
64	SH	Alere Ltd	Full	27	12	We would propose to add an additional bullet point to the ways in which the antimicrobial stewardship team should be supported, namely: "Provide appropriate support for primary care point of care CRP testing for respiratory tract infections as in NICE CG191."	Thank you for your comment. The GDG agreed that due to the remaining uncertainty for all point-of-care tests (including C-reactive protein testing, [see page 71 of full guideline [final version]]) a further specific or stronger recommendations beyond what is recommended in NICE CG191 could not be made. Recommendation 30 relates to point of care tests as one of the recommendations on antimicrobial prescribing.
65	SH	Alere Ltd	Full	28	25-27	We do not believe this is a practical recommendation, and certainly not in a primary care setting. It takes 48-72 hours to return a result from a microbiological culture. A primary care practitioner needs to be able to make a prescribing decision in minutes, not days. A better approach would be to promote more widespread use of rapid point of care testing where this is appropriate, for example, such as the CRP test and other specific tests (such as UAT Legionella, UAT S. *pneumoniae*, HIV, MRSA, C. *Difficile*), where required.	Thank you for your comment. The wording of this recommendation has been amended following further discussion by the GDG to better define the clinical situations in which microbiological cultures should be taken or considered for taking.
66	SH	Alere Ltd	Full	28	28-29	It is important to note that the Pneumonia guideline (NICE CG191) does not make point of care test recommendations in general; it recommends that prescribers consider using only one specific test in primary care; namely, the	Thank you for your comment. Thank you for your comment. The wording of recommendation 30 (see full guideline, final version) has been amended to reflect your comment. The GDG

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						point of care CRP test. This should be made clear in this recommendation no.28. It is recommended that clinicians "consider" UAT S. *pneumoniae* and UAT Legionella tests in secondary care.	did not find any evidence for other point-of-care tests in other care settings. The diagnosis and treatment of specific clinical conditions (for example S. *pneumoniae and Legionella)* is outside of the scope of this guideline.
67	SH	Alere Ltd	Full	29	10-11	One of the difficulties is that it is not always apparent is whether the presenting patient has a self-limiting condition or not. This recommendation would, therefore, be more helpful to practitioners if it was made clear that the prescribing decision - at least for respiratory tract infections - can be guided by appropriate use of point of care CRP, as recommended in NICE CG191. Moreover, it is important to note that NICE CG69, which addresses self-limiting infections, does NOT make a recommendation for the use of point of care CRP. It is this type of inconsistency and contradiction between different guidelines and recommendations that are confusing for practitioners, and will make it more difficult to implement the antimicrobial stewardship priorities outlined in the present draft. We would recommend an urgent review and update of NICE CG69 in the light of the available published evidence.	Thank you for your comment. The GDG has made a separate recommendation regarding point of care C - reactive protein testing (recommendation 30). NICE CG69 has been assessed through the NICE surveillance programme and is considered to be current and not requiring an update. The surveillance and updating process for published guidelines is in Developing NICE guidelines: the manual (2014). In line with this process please e-mail nice@nice.org.uk and provide any relevant evidence as rationale for an update of the guideline.
68	SH	Alere Ltd	Full	32	1-4	This research recommendation implies that there is currently no RCT evidence in place to show that use of point of care testing is clinically and cost-effective. This is in conflict with NICE CG191 where RCTs for lower respiratory tract infections were analysed and the point of care CRP test was recommended as an intervention which practitioners should consider using. NICE CG191 also reported RCT data on use of Legionella and S. *pneumoniae* point of care testing in secondary care. The recently-published paper by Hunter (Hunter, 2015) provides new evidence for the cost-effectiveness of the point of care CRP intervention in primary care. .	Thank you for your comment. The research recommendation and discussion reflected in the linking evidence to recommendations table noted that there is limited evidence to support point-of-care tests in general but that there are some specific conditions and clinical situations where point-of-care tests have been found to be clinically and cost effective. However, this is not the case for other conditions and clinical situations and this is why the GDG agreed a research recommendation is needed. The study by Hunter (2015) has now been included in the guideline.
69	SH	Alere Ltd	Full	36	Table 5	For reasons that are unclear, none of the point of care CRP RCTs are included in Table 5. We would urge the Guideline Development Group to revisit the evidence base considered in NICE CG191 and the Cochrane Review (Aabenhus *et al*. 2014).	Thank you for your comment. The point of care test studies that have been included and are considered as part of the chapter on decision making rather than antimicrobial resistance and are available in Table 8 (page 58 of the final guideline [full version]), this includes the Cochrane Review (Aabenhus *et al.* 2014). This evidence was not eligible for inclusion in the section on antimicrobial resistance as the studies do not measure this as an outcome.
70	SH	Alere Ltd	Full	41	9	There are 3 health economic studies relating to the point of care CRP test that have been excluded from consideration (Cals *et al*., 2011; Oppong 2013; Hunter 2015). NICE CG191 also reviewed a number of other health economic studies that would appear to be relevant to the review question for this guideline.	Thank you for your comment. Please note that the Hunter (2015) study was published after the dates of the literature search but has subsequently been included within section on decision making (page 61, section 6) of the guideline in line with NICE processes for consultation. This study addresses some of the uncertainty related to the cost effectiveness of point-of-care C-reactive protein testing in primary care but has a number of limitations (see page 64 of the final guideline [full version]). Neither of the papers by Cals and colleagues (2011) or Oppong and colleagues (2013) include the outcome of resistance in their economic models and so do not answer the

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							review question 'What interventions, systems and processes are effective and cost effective in reducing antimicrobial resistance without causing harm to patients?'.
71	SH	Alere Ltd	Full	42	35, Table 6	Point of care CRP should be included in Table 6 as per NICE CG191.	Thank you for your comment. The reflection of the discussion of point of care tests is included in Table 13 (section 6.5 of the final guideline [full version) in the trade-off between benefits and harms section.
72	SH	Alere Ltd	Full	43	35, Table 6, Relative Values of Different Outcomes	It is not true to state that few studies have been conducted in a primary care setting. Several point of care CRP studies are specific to primary care and have been reviewed previously – see the Cochrane Review for example (Aabenhus *et al*. 2014). This Review showed that from randomised and cluster randomised clinical trials there was a significant reduction in prescribing of antibiotics by GPs for patients presenting with symptoms of RTI when GPs used point of care CRP.	Thank you for your comment. Please note this study would not have been included as it does not answer the review question of 'What interventions, systems and processes are effective and cost effective in reducing antimicrobial resistance without causing harm to patients?' as there are no outcomes of resistance in this systematic review or any of the studies included within it. The relevant studies from the Aabenhus et al. (2014) Cochrane review have been included with the point of care test evidence review (Table 13, section 6.5 of the final guideline [full version]).
73	SH	Alere Ltd	Full	43	35, Table 6, Relative Values of Different Outcomes	Reduced antibiotic prescribing is linked to reduced resistance, so interventions such as point of care CRP which can aid the prescribing decision and which may, therefore, reduce prescribing should be specifically included. As noted above, point of care CRP is already used routinely in primary care in a number of other countries (including Denmark, Norway, Sweden, Germany, The Netherlands, Switzerland and Finland) where it has helped reduce the rates of antibiotic prescribing by as much as 36% (Little *et al*. 2013; Hopstaken *et al*. 2003; Cals *et al*. 2010a; Jakobsen 2010; Diederichsen *et al*. 2000; Bjerrum *et al*. 2005; Verlee *et al*., 2012; Bjerrum *et al*., 2011; Huang *et al*., 2013; Llor *et al*. 2014; Andreeva and Melbye 2014). Point of care CRP has been studied over 3.5 years in the Netherlands and there are many positive outcomes: reduced antibiotic prescribing, no subsequent increase in GP office visits for similar illness episodes in patients who had the CRP test (Cals *et al.,* 2013).	Thank you for your comment and thank you for the additional references. Only studies that met the inclusion criteria were included for this review question. These have not been included within the evidence review for the following reasons (please note that the inclusion criteria for point of care tests was for RCTs only); • Little (2013), not a CRP or procalcitonin test, no baseline of previous prescribing practice • Hopstaken (2003), not an RCT • Cals (2010), is included as part of the Aabenhus Cochrane review • Jakobsen (2010), not an RCT • Diederichsen (2000), is included as part of the Aabenhus Cochrane review • Bjerrum (2005), not an RCT • Verlee (2012) NICE were unable to retrieve this paper due to insufficient bibliographic information received. • Bjerrum (2011), not an RCT • Huang (2013), not an RCT • Llor (2014), not an RCT • Andreeva and Melbye (2014), is included as part of the Aabenhus Cochrane review and is a follow-up study considering episodes of respiratory tract infection and percentage treated with antibiotics – this review question considers decision-making at the time of consultation, therefore this was excluded. Evidence related to point-of-care testing has been covered in

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							the section on decision making (section 6.5 of the final guideline [full version]). Point-of-care tests had been included in the original review protocol but were not specifically included in the original search and on reviewing this, the GDG, considered that a separate search for all POC tests was warranted as they have the potential to contribute to the decision-making on the initiation of antimicrobial therapy. The recommendation regarding point of care C-reactive protein testing within this guideline is consistent with the recommendation in NICE guideline on pneumonia (CG191). The studies included in CG191 were included where they met the inclusion criteria for the review question. The studies identified for this review question were consistent with the studies in CG191 where they were RCTs. Only studies that met the inclusion criteria were included. The GDG did not feel able to make any general recommendations over and above those already recommended in the pneumonia guideline based on the included evidence. The GDG did not feel able to make any general recommendations over and above those already recommended in the pneumonia guideline based on the included evidence. The GDG discussion relating to this has been clarified in the linking evidence to recommendations table (page 71 of the final guideline [full version]).
74	SH	Alere Ltd	Full	45	Table 6, First line	We would propose adding a further bullet point: "For respiratory tract infections, consider using the point of care CRP test in accordance with NICE CG191."	Thank you for your comment. Table 6 considers the linking of evidence to recommendations in relation to reducing antimicrobial resistance. The point of care test review is in the review on decision-making.
75	SH	Alere Ltd	Full	45	Table 6, Fourth paragraph	For emerging infections, it is simply not feasible or practical to wait for the results of a microbiological culture. This is particularly the case in a primary care setting where the decision whether or not to prescribe must be made within a matter of minutes.	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG to better define the clinical situations in which microbiological cultures should be taken or should be considered for taking.
76	SH	Alere Ltd	Full	46	First paragraph	Contrary to what is stated in NICE CG191, NICE CG69 does not recommend that practitioners consider using point of care CRP for respiratory tract infections generally. This is at odds with the available published evidence base. It is this type of inconsistency and contradiction between different guidelines and recommendations that are confusing for practitioners, and will make it more difficult to implement the antimicrobial stewardship priorities outlined in the present draft. We would recommend an urgent review and update of NICE CG69 in the light of the available published evidence.	Thank you for your comment. NICE CG69 has been assessed through the NICE surveillance programme and is considered to be current and not requiring an update. The surveillance and updating process for published guidelines is in Developing NICE guidelines: the manual (2014). In line with this process please e-mail nice@nice.org.uk and provide any relevant evidence as rationale for an update of the guideline.
77	SH	Alere Ltd	Full	55	26-37	As noted above in comments 8 and 11, many CRP studies (including RCTs) have been excluded from consideration. For example, Llor *et al. 2014;* Van Vugt *et al*, 2013; Huang *et al,* 2013. We would like to understand the reason for this exclusion.	Thank you for your comment and for the additional references. However, these have not been included within the evidence review for the following reasons (please note that the inclusion criteria for point of care tests was for RCTs only);

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							• Huang (2013), not an RCT • Van Vugt (2013), not an RCT • Llor (2014), not an RCT.
78	SH	Alere Ltd	Full	58	Table 8	We are surprised to note that the following studies appear to have been excluded from the list of CRP-specific studies included: Llor *et al*. 2014; Melbye, 1995; Diederichsen *et al,* 2000; Cals *et al,* 2010a; Cals *et al*, 2009; Little *et al*, 2013; Andreeva and Melbye 2014. Also of relevance are the systematic review by Huang (Huang *et al.,* 2013), a diagnostic study comparing CRP to current practice (Van Vugt *et al,* 2013), a clinical practice audit (Llor *et al.* 2014) and long-term follow up to an RCT (Cals *et al*. 2013).	Thank you for your comment and for the additional references. These have not been included within the evidence review for the following reasons (please note that the inclusion criteria for point of care tests was for RCTs only); • Little (2013), not a CRP or procalcitonin test, no baseline of previous prescribing practice • Hopstaken (2003), not an RCT • Cals (2010), is included as part of the Aabenhus Cochrane review • Cals (2009), is included as part of the Aabenhus Cochrane review • Jakobsen (2010), not an RCT • Diederichsen (2000), is included as part of the Aabenhus Cochrane review • Bjerrum (2005), not an RCT • Huang (2013), not an RCT • Llor (2014), not an RCT • Melbye (1995), not in English • Andreeva and Melbye (2014), is included as part of the Aabenhus Cochrane review • Van Vugt (2013), not an RCT • Cals (2013) is a follow-up study considering episodes of respiratory tract infection and percentage treated with antibiotics – this review question considers decision-making at the time of consultation, therefore this was excluded. Evidence related to point-of-care testing has been covered in the section on decision making (section 6.5 of the final guideline [full version]).
79	SH	Alere Ltd	Full	59	2	A useful addition to the health economic evidence base is provided in the 2015 Hunter paper (Hunter 2015).	Thank you for your comment. Please note that the Hunter (2015) study was published after the dates of the literature search but has subsequently been included within section on decision making (page 61, section 6) of the guideline in line with NICE processes for consultation. This study addresses some of the uncertainty related to the cost effectiveness of point-of-care C-reactive protein testing in primary care but has a number of limitations (see page 64 of the final guideline [full version]).
80	SH	Alere Ltd	Full	65	18-20	The evidence analysis of the point of care tests is in conflict with recommendation from NICE CG191 and conclusions of the Cochrane Review (Aabenhus R *et al,* 2014).	Thank you for your comment. This clinical evidence statement reports the findings of a single RCT in relation to antibiotic prescribing. It is not an analysis of the evidence overall and

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							does not reflect any subsequent discussion of the overall evidence by the GDG and therefore does not conflict with recommendations of NICE CG191 or the conclusions of the Cochrane review. The evidence from the Aabenhus (2014) Cochrane review is presented previously in this paragraph.
81	SH	Alere Ltd	Full	66	Table 11, Trade-off between benefits and harms	It is not helpful or accurate to assume that point of care testing is homogenous and that all tests are supported by an equal evidence base. NICE CG191 does not make point of care test recommendations in general; it recommends that prescribers consider using only one specific test in primary care; namely, the point of care CRP test. This should be made clear here.	Thank you for your comment. The references to point of care tests overall, is considered in the explanation of the requirements for their use; any test used would provide rapid results and be cost effective. Where the evidence has been reviewed for the C – reactive protein and procalcitonin tests separately and discussed by the GDG, this is reflected in the wording of linking evidence to recommendations table. Table 13 (page 67 of the full guideline [final version]) has been amended to reflect your comment and add clarity.
82	SH	Alere Ltd	Full	68	Second paragraph, last sentence	It is important to note that the evidence shows that using point of care CRP results in reduced prescription fulfilment when antibiotic prescribing is delayed (Cals *et al* 2010a).	Thank you for your comment. The GDG were aware of the outcomes for included studies, however as set out in the review protocol for this review question the outcomes for this review question were in relation to decision-making for prescribing at the point of consultation (see appendix C). The GDG were aware of the evidence from the Cals *et al* (2010) study which was included as part of the review in the decision making section of the guideline (section 6.5).
83	SH	Alere Ltd	Full	68	Fourth paragraph	There is limited evidence base supporting inclusion of a rapid primary care point of care test for procalcitonin and no published data to support the GDG's conclusions, in primary care far as we are aware. The Cochrane review stated 'The only point-of-care biomarker of infection currently available to primary care identified in this review was C-reactive protein' (Aabenhus, *et al*, 2014). NICE CG191 and the Cochrane review (Aabenhus,*et al,* 2014) both concluded that point of care CRP was the only suitable point of care test for primary care and assessment of lower respiratory tract infections based on the published literature. Procalcitonin (PCT) is currently used as a test in secondary care.	Thank you for your comment. Only studies that met the inclusion criteria were included for this review question. Point-of-care tests had been included in the original review protocol but were not specifically included in the original search and on reviewing this, the GDG, considered that a separate search for all POC tests was warranted as they have the potential to contribute to the decision-making on the initiation of antimicrobial therapy. The recommendation regarding point of care C-reactive protein testing within this guideline is consistent with the recommendation in NICE guideline on pneumonia (CG191). For CG191, studies that met the inclusion criteria (as stated in the review protocol) were included where they met the inclusion criteria for the review question. The studies identified for this review question were consistent with the studies in CG191 where they were RCTs. The GDG did not feel able to make any general recommendations over and above those already recommended in the pneumonia guideline based on the included clinical and cost-effective evidence. The GDG discussion relating to this has been clarified in the

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							linking evidence to recommendations table (page 71 of the final guideline [full version]).
84	SH	Alere Ltd	Full	68	Fourth paragraph, final sentence	This conclusion is in conflict with the conclusions reached in NICE CG191. a) The use of point of care CRP has been compared to patient communication alone, and has been found to reduce antibiotic prescribing as a result of delayed prescription (Cals *et al*., 2010b). b) Moreover, NICE CG191 makes no comment on the value of rapid tests in a secondary care setting, such as those recommended in that guideline (UAT Legionalla and *S. Pneumoniae*).	Thank you for your comment. a) The GDG agreed that there was insufficient evidence (not an absence of evidence) for point-of-care tests for reducing antimicrobial prescribing compared to other interventions. This is not in conflict with NICE CG191. Please note that the study referred to (Cals 2010b as per your submitted list of references) is not a randomised controlled trial of an intervention but a qualitative study of GPs' attitudes to and experiences of introducing C-reactive protein (CRP) point-of-care testing (POCT) for lower respiratory tract infections (LRTI) in primary care. b) Unfortunately the point of your comment is unclear as page 68, fourth paragraph; final sentence makes no mention of NICE CG191. Please note that we cannot respond to comments on other NICE guidelines as part of this consultation.
85	SH	Alere Ltd	Full	69	Economic considerations	In contradiction to other parts of the draft guideline (see comment 22 above), the GDG appears to have concluded here that the evidence supported a conclusion that CRP is cheaper and more clinically useful than procalcitonin.	Thank you for your comment. The GDG reviewed and agreed with the conclusions in CG191. Section 6.5 (page 73) has been reworded to clarify that it is the conclusions of NICE CG191 that are being discussed. The GDG for this guideline did not draw any separate conclusions.
86	SH	Alere Ltd	Full	70	14	While we recognise that the Hunter 2015 publication provided here constitutes new economic evidence, we would urge the GDG to review it, as it addresses some of the uncertainties referred to.	Thank you for your comment. Please note that the Hunter (2015) study was published after the dates of our literature search but has subsequently been included within section on decision making (page 61, section 6) of the guideline in line with NICE processes for consultation. This study addresses some of the uncertainty related to the cost effectiveness of point-of-care C-reactive protein testing in primary care but has a number of limitations (see page 64 of the final guideline [full version]).
87	SH	Alere Ltd	Full	70	20	While we recognise that the Hunter 2015 publication provided here constitutes new economic evidence, we would urge the GDG to review it, as it addresses some of the uncertainties referred to.	Thank you for your comment. Please note that the Hunter (2015) study was published after the dates of our literature search but has subsequently been included within section on decision making (page 61, section 6) of the guideline in line with NICE processes for consultation. This study addresses some of the uncertainty related to the cost effectiveness of point-of-care C-reactive protein testing in primary care but has a number of limitations (see page 64 of the final guideline [full version]).
88	SH	Alere Ltd	Full	70	24-26	This statement is incorrect. Studies by both Cals and Little looked at the impact of patient-professional communication as a comparator to point of care testing (Cals *et al.,* 2010b; Little *et al.,*, 2013).	Thank you for your comment. This guideline is focused on prescribers and the organisations that employ them. The Department of Health has referred a topic to NICE to develop a separate guideline on Antimicrobial stewardship – changing risk related behaviours in the general population. Communication with patients will be considered in this guidance. The research recommendation has been changed to

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							clarify that it refers to interventions as comparators.
89	SH	Alere Ltd	Full	70	29	There are Dutch studies that include the outcomes and other data which the GDG is referring to and which were evaluated by the GDG for NICE CG191 (Cals *et al.*, 2010a; Cals *et al.,* 2013).	Thank you for your comment. Please note that the GDG was aware (page 70, lines 18 – 20) of 'clinical evidence reviewed indicated that the use of these tests could reduce antimicrobial use without leading to an increase in re-consultations or reduced patient satisfaction'. However the studies cited (and referred to by the GDG) were mainly relating to POC CRP testing and not other types of POC tests for which greater uncertainty remains, please note: • Cals (2010), is included as part of the Aabenhus Cochrane review Cals (2013) is a follow-up study considering episodes of respiratory tract infection and percentage treated with antibiotics – this review question considers decision-making at the time of consultation, therefore this was excluded.
90	SH	Alere Ltd	Full	70	30-33	This research recommendation is in direct conflict with the recommendations in NICE CG191.	Thank you for your comment. The recommendation in CG191 is to consider a point-of-care CRP test if after clinical assessment a diagnosis of pneumonia has not been made and it is not clear whether antibiotics should be prescribed. This is not contradicted by this research recommendation which acknowledges that there is some evidence relating to the use of point-of-care tests compared with standard care/guidelines. But this research recommendation notes that there is a lack of evidence that considers point-of-care tests with other measures that may reduce antimicrobial prescribing (these measures may be non-invasive and require less practitioner time/training or equipment).
91	SH	Alere Ltd	Full	71	9	This was already completed as part of NICE CG191 where many more publications were included in the analysis. Both delayed prescribing and communication training have been compared to point of care CRP testing in published RCTs (Cals *et al.,* 2010; Cals *et al.,* 2009, Little *et al*, 2013). We would welcome clarification on the "other methods of reducing antimicrobial use" which the GDG is referring to.	Thank you for your comment. The GDG discussed and agreed that while there have been a very small number of studies that have included comparisons between point-of-care testing and other interventions aimed at reducing antimicrobial use, there are still a large number of interventions that have not been studied in this way. The choice of comparators would be up to the researcher(s) to decide.
92	SH	Alere Ltd	Full	71	22, Table PICO format, Intervention	For point of care CRP this has already been completed and reviewed by NICE CG191 and Cochrane (Aabenhus *et al,* 2014). It would be useful to state which other point of care tests would be considered useful for research.	Thank you for your comment. The GDG discussed and agreed that while there have been a very small number of studies that have included comparisons between point-of-care test and other interventions aimed at reducing antimicrobial use, there are still a large number of interventions that have not been studied in this way. The choice of comparators would be up to the researcher(s) to decide.
93	SH	Alere Ltd	Full	71	22, Table PICO format, Comparators	We would welcome clarification on what is meant by "other methods of reducing antimicrobial use" in the context of comparators to point of care tests for respiratory tract infections.	Thank you for your comment. The GDG discussed and agreed that while there have been a very small number of studies that have included comparisons between point-of-care test and other interventions aimed at reducing antimicrobial use, there are still a large number of interventions that have not been studied in this way. The choice of comparators would be up to the researcher(s) to decide.

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94 - 148						Stakeholder comments withdrawn	
149	SH	The Royal College of Pathologists				As a general point, I think it is worth noting that the subject area is very important and the concept of improving antimicrobial prescribing practice is an essential component of the strategy to combat antibiotic resistance. Improving the quality of antibiotic stewardship programmes in the whole healthcare economy is, again, a very important priority.	Thank you for your comment.
150	SH	The Royal College of Pathologists				The draft guideline asks for the most important challenges. I think that antibiotic stewardship activities are more developed within hospitals than they are in the community. They also vary in the current approach. Community prescribing is high volume low complexity, whereas hospital prescribing is more focussed but of higher acuity by the very nature of the patient population. This means that the target audience of the various recommendations is different and the challenge will be to bring these together in common initiatives.	Thank you for your comment. The GDG have amended the wording of recommendations in order to make clear who should take action. A 'who to take action' table has been added to the full version of the guideline (page 32, section 4.3 of the final guideline [full version]). We have passed it to the NICE implementation support team to inform their support activities for this guideline.
151	SH	The Royal College of Pathologists				Also, the quality of available prescribing information varies from hospital to community and from one region to another. Although a lot of work is being done to improve this, it may be difficult for some areas to access the information they need to implement the recommendations at the moment.	Thank you for your comment. The GDG have made recommendations in anticipation of improved access to, and improved quality of, prescribing data.
152	SH	The Royal College of Pathologists				On page 25 lines 25-26 there is discussion about healthcare facilities needing to review patient safety incidents relating to antibiotics. I think it will be difficult for most to measure this and it may need to be defined. Collecting information on rare or serious infections seems a strange term to use – I expect it is referring to resistant organisms, but it could be interpreted as an imported tropical disease, for example, which would miss the point.	Thank you for your comment. This recommendation wording has been amended following further discussion by the GDG to clarify what is meant by patient safety incidents.
153	SH	The Royal College of Pathologists				Finally, there isn't very much about analysis of patient outcome. One of the key objectives of antibiotic stewardship is about improving the management of infection and therefore assessment or review of patient outcomes would be essential. Most of the focus of the guideline is about reducing unnecessary antibiotic use, which is important, but making sure that patients are treated promptly with the appropriate antibiotic would also be important.	Thank you for your comment. Patient outcomes were considered throughout the development of the guideline (see the review protocols in appendix C). The wording for recommendations 2, 4, 5 and 40 in the final version of the full guideline have been amended following further discussion by the GDG in relation to your comment. The later point of your comment is reflected in the recommendations.
154	SH	Royal College of Physicians (RCP)	Short	10 of 34	Section 1.1.14	This section states that organisations should review prescribing and resistance data. In section 1.1.2 which states that organisations should consider monitoring and evaluating antimicrobial prescribing and how this relates to local resistance patterns. This should be clarified	Thank you for your comment. The updated recommendations have been reworded to clarify that the two recommendations have different purposes (recommendations 3 and 8 of the full guideline [final version]).
155	SH	Royal College of Physicians (RCP)	Full	15	37	Dentists and non-medical prescribers (eg podiatrists) should be specifically named in the list of professional groups mentioned as they are also prescribers.	Thank you for your comment. The wording for section 2.5 (page 16 of the full guideline [final version]) has been amended following further discussion by the GDG to include the words dentists and podiatrists.
156	SH	Royal College	Full	99		Summary of Call for Evidence Table. "Another concern was that newer	Thank you for your comment. This section has been reworded

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		of Physicians (RCP)				antimicrobials may not have a clinical advantage over current therapies (an example given was fidaxomycin versus vancomycin for the treatment of *C. difficile*) and often the newer therapy may come at a substantially higher cost than the current therapy." This is incorrect. There is good quality evidence from clinical trials that fidaxomicin is superior to vancomycin for the treatment of CDI e.g. 50% reduction in recurrence rate. See following references: • Louie TJ, et al. *Fidaxomicin versus vancomycin for Clostridium difficile infection. N Engl J Med 2011;364:422-31.* • Cornely OA, et al. *Fidaxomicin versus vancomycin for infection with Clostridium difficile in Europe, Canada and the USA: a double-blind, non-inferiority, randomised controlled trial. Lancet Infect Dis 2012;12:281-9.*	following further discussion by the GDG.
157	SH	DH advisory committee on antimicrobial resistance and healthcare associated infections (ARHAI)	Full	General	General	The Guideline Development Group and colleagues from NICE are to be congratulated on their excellent work to review the scientific literature and support clinicians and policy-makers with guidance on antimicrobial stewardship. a) It is regrettable, in hindsight, that the scope of the literature search was limited to research reporting the outcome of antimicrobial resistance. Whilst this is the primary outcome of interest, the limitations of the published research evidence in this field mean that restricting to studies reporting a resistance outcome prevents recommending interventions proven to influence prescribing as a valid process outcome measure. Proposals for updating this guidance should broaden the scope to include studies reporting prescribing outcomes. b) For the same reason, evidence other than randomised controlled trials should be considered, in the absence of RCT evidence, in order to provide some guidance to clinicians.	Thank you for your comment. a) Of the 4 review questions included in this guideline only 1 question was limited to the outcome of research reporting antimicrobial resistance (see section 5, Reducing antimicrobial resistance). The other 3 review questions (including decisions to prescribe) were not restricted to emergence of resistance as an outcome and included the critical outcomes of: • Professional belief systems and their attitude to the use of antimicrobials • No harm./unintended consequences • Patient-reported outcomes, such as medicines adherence related specifically to issues of antimicrobial stewardship, patient experience, patient satisfaction with decision making, patient information and patient expectations • Antimicrobial use by appropriate measures (may be a reduction) • Planned and unplanned contacts with health professionals or services (re-consultations) • Volume of antimicrobials prescribed • Uptake over time by geographical area • Cost and uptake • Inclusion in any national guidance • Inclusion in local formularies • Adoption of guidance and implementation • Financial incentives • Change in prescribing habits/data, - for example, from antimicrobials that have been in use for several years to newer antimicrobial agents • Laboratory reporting – for example, what sensitivities are shown, the order of the antimicrobials to prescribe, hiding of specific antimicrobials • National laboratory information management systems such as clinical decision support systems • Commissioning of services relating to antimicrobials • Yellow card reporting of side effects and adverse drug

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							reactions of 'new antimicrobials' Please see appendix C for review protocols that include identified outcomes to be considered during the evidence review. b) Please note that it was agreed by the GDG in advance of the systematic review process that in the absence of RCT evidence NICE would include other study types in the reviews. The highest quality evidence (usually RCTs) is searched for first and broadening the search only if sufficient higher quality evidence does not exist. This was the case for 3 of the 4 review questions. Please see the sections on decision making, barriers to decision making and the timely adoption and diffusion of new antimicrobials in the full guideline.
158	SH	ARHAI	Full	9	38	Consider adding further text about broad-spectrum antimicrobials. Two important concepts to communicate, as set out in the CMO report. Firstly, broad-spectrum agents tend to remain effective against micro-organisms resistant to narrower spectrum antimicrobials and should therefore be held in reserve for the most vulnerable patients (immunocompromise or serious life/limb-threatening infection) or those with risk factors for infection with multi-drug resistant pathogens. Increased use of these "last-line" treatment options is associated with increased resistance and therefore minimising unnecessary use of broad-spectrum agents is imperative [Harris AD 2002, http://www.ncbi.nlm.nih.gov/pubmed/11774081; Pakyz AL 2009, http://www.ncbi.nlm.nih.gov/pubmed/19273670; Lai CC 2011, http://www.ncbi.nlm.nih.gov/pubmed/21436153] Secondly, broad-spectrum antimicrobials cause significant collateral damage to normal flora, leading to a predisposition to healthcare-associated infections caused by inherently resistant organisms - including *Clostridium difficile* and MRSA - and therefore should only be used in those patients for whom the potential additional benefit of broad-spectrum agents outweighs the risk [Slimings C 2014, http://www.ncbi.nlm.nih.gov/pubmed/24324224; Tacconelli E 2008, http://www.ncbi.nlm.nih.gov/pubmed/17986491].	Thank you for your comment. Although the cited studies do not meet the inclusion criteria for this review question as set out by the GDG, this section has been reworded following further discussion by the GDG. Section 5.5 (page 50 of the final guideline full version) now includes how evidence on narrow versus broad spectrum antimicrobials was included in the literature review process and reference to the UK 5 Year Antimicrobial Resistance (AMR) Strategy 2013–2018, Annual progress report and implementation plan, 2014 and section 5.6 also contains the GDG discussion of Healthcare Acquired Infection and AMR risk and clinical benefits of broad and narrow spectrum antimicrobials.
159	SH	ARHAI	Full	25	3	Implementation. A sizeable number of NHS Trusts (>45) have subscribed to a smartphone and desktop application for dissemination of antimicrobial treatment and stewardship guidelines (MicroGuide, Horizon Strategic Partners) and yet more Trusts have developed in-house "apps". The success of these mobile device applications suggests that they are an effective way of disseminating and implementing guidance. NICE may wish to highlight this approach to dissemination and implementation.	Thank you for your comment. This information will be considered as part of the implementation needs analysis. Organisations can submit their own examples of how they have put NICE recommendations into practice. More information about this can be found on the NICE website
160	SH	ARHAI	Full	25	10	Are all of the recommendations based upon the expert opinions of the guideline development group (as indicated by use of the term "Consider")? Please highlight any recommendations that are supported by high-quality evidence.	Thank you for your comment. Section 1.5 of the full version of the guideline explains the strength of recommendations; the wording is based on the quality of the underpinning evidence and reflects the benefits and trade-offs from the included

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							evidence. Evidence was sought for all review questions but that there were many areas in this field where evidence was insufficient to make strong recommendations.
161	SH	ARHAI	Full	25	15	Would the GDG consider using the phrase "allowing for resources needed" rather than "taking account of the resources needed"?	Thank you for your comment. The GDG agreed that the purpose of the recommendations was to set out key principles. Details of the resources needed are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for people and local governance arrangements in order to ensure consistency with the requirement for local flexibility. Wording and formatting was considered by the NICE publishing team. This wording has not been amended.
162	SH	ARHAI	Full	25	21	Could the guidance clarify whether organisations should consider providing feedback to individual prescribers or groups of prescribers?	Thank you for your comment. The wording for recommendation 2, 2nd bullet (in the full version of the guideline draft for consultation) has been amended following further discussion by the GDG to include the word 'individual'.
163	SH	ARHAI	Full	25	23	Consider removing the example of using professional regulatory numbers and leave it to the discretion of organisations regarding how they provide feedback.	Thank you for your comment. The GDG agree that there are a range of ways of providing feedback to prescribers but discussed and agreed that providing individual prescriber feedback through the use of regulatory number was felt to be a particularly useful example to highlight. The GDG agreed that the example was relevant to the recommendation and therefore the wording has not been amended.
164	SH	ARHAI	Full	25	26	Providing feedback on patient safety incidents relating to antimicrobials is reasonable but hospital admissions for rare or serious infections are not patient safety incidents (unless the admission was avoidable) and this example should be removed.	Thank you for your comment. This wording has been amended following further discussion by the GDG to specify what is meant by patient safety incidents.
165	SH	ARHAI	Full	25	34	In order to provide updates on national and local prescribing patterns, organisations must have open access to national prescribing data from Public Health England.	Thank you for your comment. Please note that access to prescribing data in England is through NHS Business Services Authority and HSCIC not Public Health England. Please note this data would only be available for primary care.
166	SH	ARHAI	Full	25	35	If a national resistance surveillance system is provided by Public Health England, then why not include national as well as local resistance patterns in this bullet point? It is important to draw attention to the underlying biases in surveillance data to avoid over-estimating the prevalence of resistance in a patient population due to sampling bias.	Thank you for your comment. This wording has been amended following further discussion by the GDG to include national as well as local resistance.
167	SH	ARHAI	Full	26	1	The phrase "identifying and reviewing previous and current antimicrobial prescribing" is open to wide interpretation. This recommendation requires more explicit description of precisely what is intended.	Thank you for your comment. This wording has been amended following further discussion by the GDG. Examples have been added to the recommendation wording (identifying and reviewing patients who are admitted to hospital with potentially avoidable severe infections [such as E. coli, mastoiditis, pyelonephritis, empyema, meningitis] or associated complications [such as quinsy and brain abscess] in order to determine if the admission is linked to a previous prescribing decision).
168	SH	ARHAI	Full	26	20	IT or decision-support systems can play a vital role in stratifying patients at high risk of morbidity/mortality (immunocompromise or severe life/limb-threatening infection) or at high risk of infection with multi-drug resistant	Thank you for your comment. IT systems and decision-support systems are included in the recommendations, particularly to support antimicrobial stewardship in organisations and in

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						pathogens and thereby guiding proportionate empirical prescribing of broad-spectrum or narrow-spectrum antimicrobials [Sintchenko V 2005, http://www.ncbi.nlm.nih.gov/pubmed/15802478; Thursky K 2006, http://www.ncbi.nlm.nih.gov/pubmed/18550680]. I strongly recommend that this principle is highlighted in this section, alongside the decision whether to prescribe an antimicrobial or not.	prescriber decision making. Thank you for the additional references, these studies are not RCTs and therefore were not eligible for inclusion within the review on decision-making.
169	SH	ARHAI	Full	26	22	Clarification of the phrase "information about antimicrobial use" is required here.	Thank you for your comment. This wording of this recommendation has been amended following further discussion by the GDG and after your comment.
170	SH	ARHAI	Full	26	28	Stocking appropriate pack sizes may be beyond the control of an individual organisation. Suggest "Organisations should supply antimicrobials in pack sizes…."	The original wording was not correct as this used the term 'stock'. We understand why this would be impractical and discussed this with the GDG. However, as suggested by one of the stakeholder comments to change to 'supply' we believe that this recommendation is more achievable. The aim of this recommendation is to ensure that when antimicrobials are supplied that the appropriate quantity reflecting the intended course is provided to the patient and this will prevent the likelihood of storing left over supplies for inappropriate 'future use'. Wording has been added to the linking evidence to recommendations table on page 48. In most cases supplies will be made by a pharmacy so this recommendation will be manageable in the majority of cases.
171	SH	ARHAI	Full	26	30	Should organisations not also monitor for unintended consequences of stewardship interventions by monitoring clinical outcomes such as length of stay, mortality and readmission?	Thank you for your comment. The GDG discussed whether this was feasible and noted similar evidence from the call for evidence in relation to the effects of stewardship interventions on resistance (see page 104 of the final guideline [full version]). The GDG recognised that it would be very difficult outside of a research context to identify the specific causes (such as the unintended consequences of a specific stewardship intervention) against a background of multiple infection control and stewardship programme interventions. Research recommendation 1 (one or more randomised controlled trials should be undertaken to determine whether short versus longer courses of antimicrobials, directly administered (or observed) therapy, continuous versus intermittent therapy and inhaled antimicrobials reduce the emergence of resistance and maintain patient outcomes compared with usual care in the UK setting) specifies that clinical outcomes should be included in these research programmes.
172	SH	ARHAI	Full	26	33	Repeat of section 4.2.2 (page 25, line 22).	Thank you for your comment. Recommendation 12 (in the full version of the guideline consultation draft) has been removed following further discussion with the GDG.
173	SH	ARHAI	Full	27	16	Suggest adding advisory statement recommending that organisations consider encouraging and supporting prescribers to prescribe narrow-spectrum antimicrobials in preference to broad-spectrum antimicrobials where safe and effective, to minimise unnecessary selection pressure for multi-drug resistance and reduce collateral damage to the microbiota.	Thank you for your comment. Although the cited studies do not meet the inclusion criteria for this review question as set out by the GDG, this section has been reworded following further discussion by the GDG. Section 5.5 (page 50 of the final guideline full version) now includes how evidence on narrow

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							versus broad spectrum antimicrobials was included in the literature review process and reference to the UK 5 Year Antimicrobial Resistance (AMR) Strategy 2013–2018, Annual progress report and implementation plan, 2014 and section 5.6 also contains the GDG discussion of Healthcare Acquired Infection and AMR risk and clinical benefits of broad and narrow spectrum antimicrobials.
174	SH	ARHAI	Full	27	40	Consider using the phrase "informed by local and national resistance patterns" rather than "supported by…".	Thank you for your comment. This change has been made.
175	SH	ARHAI	Full	28	2	Would it be possible for NICE to encourage organisations to consider including a patient stratification system within guidelines to identify patients at high risk of morbidity/mortality or at high risk of multi-drug resistant pathogens and to advise on appropriate treatment? Conversely, patients identified as low risk require a different treatment approach.	Thank you for your comment. The consideration of a patient stratification system is outside the scope of this guideline.
176	SH	ARHAI	Full	28	3	Medical microbiologists and laboratory scientific officers play a vital stewardship role by rejecting specimens for culture when infection is unlikely (e.g. catheter urines) and by interpreting culture results to identify non-pathogenic normal flora and reporting results with appropriate interpretive commentary. Laboratories also influence the choice of antimicrobial prescribed by censoring results to suppress reporting of broad-spectrum antimicrobials. These important aspects of stewardship should be acknowledged and encouraged in this section of the guideline.	Thank you for your comment. This guideline includes antimicrobial stewardship programmes and teams it does not include individual roles as there are many of these that contribute to antimicrobial stewardship and these will vary between differing healthcare settings. This guideline recommends that susceptibility testing and the reporting order of susceptibilities should be in line with national and local guidelines, the choice in the local formulary and the priorities of medicines optimisation and antimicrobial stewardship teams.
177	SH	ARHAI	Full	28	10	The Royal College of Physicians published excellent guidance for individual prescribers in 2011 entitled "RCP insight Effective antibiotic prescribing – Top Ten Tips". Some of the points suggested in Top Ten Tips have not been covered in this section of the NICE guideline, such as "Institute antibiotic treatment immediately in patients with life-threatening infection." The RCP also emphasised responsible choice of antimicrobials with the recommendations "Prescribe in accordance with local policies and guidelines, avoiding broad spectrum agents." and "Always select agents to minimise collateral damage (ie selection of multi-resistant bacteria/Clostridium difficile)." The NICE guideline development group may wish to incorporate these principles into recommendations for individual prescribers.	Thank you for your comment. This guideline was developed using the methodology in the NICE guidelines manual, using the remit of the scope (which was finalised following a consultation process). The 'Royal College of Physicians - Top Ten Tips' does not provide any detail on what process was followed to produce the tips and what evidence they are based on. However the RCP may wish to submit their tool to the NICE endorsement programme. More information about this can be found on the NICE website.
178	SH	ARHAI	Full	28	23	Prescribers should also document infection severity to validate choice of antimicrobial treatment.	Thank you for your comment. The GDG agreed that severity of infection is subjective. This would differ depending on the infection and therefore the recommendation wording has not been amended.
179	SH	ARHAI	Full	28	25	Potential for misinterpretation in this statement. Suggest: "Prescribers should consider obtaining microbiological cultures and waiting for culture results before deciding whether to prescribing an antimicrobial for a non-severe infection, providing it is safe to withhold treatment until the results are available." This is to distinguish this statement from the routine investigation of infection in patients for whom antimicrobials are started immediately.	Thank you for your comment. The wording of this recommendation has been amended following further discussion by the GDG. It now contains more detail about the nature of the illness and settings in which a sample should be taken or considered before antimicrobial prescribing occurs.
180	SH	ARHAI	Full	30	32	Participation of a medical microbiologist/infection specialist should be considered essential in the introduction of any new antimicrobial, not only for	Thank you for your comment. This guideline includes antimicrobial stewardship programmes and teams it does not

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						their medical and microbiology expertise but also to ensure that appropriate systems are established in the laboratory for susceptibility testing and reporting.	include individual roles as there are many of these that contribute to antimicrobial stewardship and these will vary between differing healthcare settings. This guideline recommends that susceptibility testing and reporting the order of susceptibilities should be in line with national and local guidelines, the choice in the local formulary and the priorities of medicines optimisation and antimicrobial stewardship teams.
181	SH	ARHAI	Full	31	34	a) There is a substantial unmet need for formal evidence based Clinical Infection Syndrome NICE guidelines and quick reference guides on the diagnosis and management of common infections in hospitalised patients. Primary care guidelines are available from Public Health England but nothing exists for NHS hospitals. b) Much of the guidance in this draft document is predicated on local guidelines being fit-for-purpose but local resources are just not available in most NHS organisations for systematic review of the evidence and guidelines typically reflect local opinion rather than formal published evidence. c) The importance of guidelines is evident from systematic reviews of stewardship interventions in hospitals and this draft guideline should call for a formal programme of research (i.e. systematic review of the literature) into the diagnosis and management of common infections in hospitalised patients. d) Flexibility can be offered for local hospitals to select from a range of equivalent treatment options according to local antimicrobial susceptibility patterns but the fundamentals such as diagnosis, pathogen epidemiology, severity assessment, resistance-risk assessment, dosing regimens, source control, intravenous-to-oral switch criteria and course length should be common to all NHS hospitals and NICE guidelines would reduce uncertainty and duplication of effort across the NHS.	Thank you for your comment. a) The treatment of specific clinical conditions is outside of the scope for this guideline. b) The fitness for purpose of relevant local guidelines is partially addressed through the recommendations in this guideline (i.e. through recommendations for systems, interventions and processes for the introduction of new antimicrobials). Where local guidelines are not available the recommendations in this guideline refer the reader to national guidance. c) The treatment of specific clinical conditions is outside of the scope for this guideline and the GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for. d) The diagnosis, frequency and distribution of specific pathogens, severity assessment and dosing regimens for specific pathogens are outside the scope for this guideline. Evidence, considered by the GDG, for resistance risk assessment, IV to oral switch and course length are included within this guideline.
182	SH	ARHAI	Full	91	General	There is a clear need to develop a more formal method of assessing the complex HTA and HEA issues related to the introduction of new antibiotics into the NHS. The complexity of the new Gram-negative agents currently under development are such that it is not realistic to expect local decisions to fully assess the costs, risks and benefits of their introduction without a central process. This could be potentially led by an expert NICE TA Antibiotic Group	Thank you for your comment. The GDG recognise that issues related to the adoption of antimicrobials can be complex, however commissioning bodies already routinely undertake the development of local formularies and new drugs using evidence of effectiveness and cost effectiveness and NICE has already issued a guideline (developing and updating local formularies) in respect of this.
183	SH	British Dental Association	Full	General	General	The BDA recognises AMR as an urgent public health issue and supports efforts to improve antimicrobial stewardship. Our response focuses mainly on general dental practice. We have been urging the Department of Health, in its current process of dental contract reform, to build in stewardship measures by focusing on prevention and improving oral health while also recognising the need for appropriately funded time for the appropriate treatment of dental emergencies. Much of the draft guidance, in particular the recommendations for prescribers (1.1.23-1.1.35 in the short version) is in harmony with existing sources of prescribing guidance for dentists (principally the BNF dental list, FGDP(UK) guidance and SDCEP guidance) along with GDC ethical requirements and	Thank you for your comment. The GDG was aware of the limitations of the dental practitioners and the nurse prescribers' formularies. Please note that GDG included representation from dentistry.

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						CQC systems requirements. Dentists in general practice are expected to be familiar with these sources and aware of the need to prescribe responsibly to minimise the spread of AMR. It should be noted that dentists are permitted to prescribe only a small, closely circumscribed list of oral antibiotics as specified by the BNF dental list.	
184	SH	British Dental Association	Short	1.1.1 - 1.1.22		a) The term "organisation", as used in this context, is not applicable to the general dental practice model and the recommendations for organisations are not appropriate for dentists. Since dentists are contractually obliged to follow NICE guidance, it is essential that they be excluded from the requirements in this section. As mentioned above, dentists fall within the category of "prescribers" and should be exclusively defined as such within the guidance. The BDA would be pleased to work with NICE to clarify recommendations appropriate for dentists. b) Looking beyond the requirements applicable to dentistry, we note that more specific wording is needed throughout the section on "organisations", as no distinction is currently made between actions intended for commissioners and those for providers.	Thank you for your comments. a) The GDG do not agree that the term organisations (as defined in section 1.3 of the guideline) should exclude any single group of providers. Please note there are no 'requirements' set out in this guideline only recommendations. Also, as set out in section 2.4, no single group within the definition of organisations is solely responsible for delivering the recommendations set out in the guideline; it is anticipated that health and social care providers and commissioners of services will need to work together to ensure that patients benefit from the good practice recommendations in this guideline. **b) Please note that the guideline has separate recommendations for prescribers and organisations (including commissioners). . The GDG have amended the wording of recommendations in order to make clear who should take action. A 'who to take action' table will be added to the full version of the guideline.**
185	SH	British Dental Association	Short	1.1.2 - 1.1.20		a) The BDA recognises the importance of collecting prescribing information and its value in modifying behaviour. Studies of audit-feedback interventions in dentistry, including the RAPiD trial in Scotland, have demonstrated the power of providing individual prescribing data, along with a local comparator, to trigger a reduction in the number of prescriptions issued – particularly among the highest prescribing groups. b) However, we are concerned that the recommendations for organisations (1.1.2-1.1.20) imply a requirement for collection of dental prescribing data that is not consistent with the systems currently in place. This has been recognised on page 87 of the full guidance document but is not reflected in the draft recommendations. Specifically, the GDG noted that "in dental practices documenting interventions can be either electronic and/or paper…[and] there are no systems for prescribing electronically". Without the ability to prescribe electronically, dentists would face an excessively onerous and time-consuming task in providing comprehensive prescribing data. c) The BDA would support a transition to electronic prescribing and recording if appropriately funded and underpinned with IT resources. However, we note that this would apply to NHS practice only and would not facilitate data collection from private practice; privately-issued prescriptions are not consistently monitored during CQC inspections. d) We are currently working with Public Health England to explore data collection and monitoring of prescribing in general dental practice, and we would be pleased to discuss with NICE any recommendations that emerge.	a) Thank you for your comment. b) Thank you for your comment. The GDG has made recommendations in anticipation of improved access to, and improved quality of, prescribing data. Please note that the implementation section of the guideline contains further details regarding the use of IT systems as it has been highlighted as an implementation priority. c) Thank you for your comment. The settings section of the scope states that the guideline will cover 'All publicly funded health and social care commissioned or provided by NHS organisations, local authorities (in England), independent organisations or independent contractors' and that 'This guideline may also be relevant to individual people and organisations delivering non-NHS healthcare services'. d) Thank you for your comment. e) Thank you for your comment.

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						e) We are also aware of the Information Standard in development that would require the use of a unique professional regulatory number to enable all prescriptions issued to be attributed to an individual practitioner; we note the discussion of this on page 87 of the full guidance. This would address the difficulty of attributing prescriptions issued in private dental practice. The BDA supports the use of individual prescribing data as a motivator for behaviour modification but is wary of the unintended consequence of the creation of a punitive system.	
186	SH	Royal Pharmaceutical Society (RPS)	Full	General	General	The Royal Pharmaceutical Society (RPS) welcomes guidance on antimicrobial stewardship (AMS); as the professional body for pharmacists and pharmacy we are committed to supporting AMS. We are pleased to note that NICE has acknowledged the important role pharmacists can play in AMS, as prescribers, providers of pharmaceutical care and in public health. Our view is that antimicrobial resistance (AMR) is a global public health issue which has an immense impact on society and requires action at a local, national and global level. We are working in partnership with a number of organisations, including the Royal College of General Practitioners, the Royal College of Nursing and the Royal College of Physicians in collaboration with the Faculty of Public Health, Public Health England and the Department of Health to begin to address this global issue. The RPS "*New Medicines, Better Medicines, Better Use Of Medicines*" guide (http://www.rpharms.com/promoting-pharmacy-pdfs/nmbmbu---full-report.pdf) makes a recommendation around Stimulating New Antimicrobial Development and Improving Antimicrobial Stewardship, which links well to NICE recommendations. We are also supporting our members and the pharmacy profession with AMS, running national campaigns, developing online resources, and signposting to relevant training and organisations.	Thank you for your comment.
187	SH	Royal Pharmaceutical Society (RPS)	Full	12	17, 18	We would recommend that pharmacies are included in the list of organisations. Community pharmacies provide a range of enhanced services as well as supplying medicines and advice on how to use medicines effectively. There are opportunities for pharmacists and their teams to raise awareness, provide information and support patients and the public in understanding AMR through the numerous interactions they have every day. It is estimated that there are 1.6 million visits a day to community pharmacies in England of which 1.2 million is for health related reasons, illustrating the potential reach they have with the public.	Thank you for your comment. This wording has been amended following further discussion by the GDG. The wording now includes reference to pharmacies.
188	SH	Royal Pharmaceutical Society (RPS)	Full	26	28	We agree that organisations should stock antimicrobials in pack sizes that correspond to local guidelines on course length, as it also helps to reduce medicines wastage (another campaign we are supporting). However we'd like NICE to note that medicines manufacturers do not always produce convenient or a wide enough range of different pack sizes for prescribing	The original wording was not correct as this used the term 'stock'. We understand why this would be impractical and discussed this with the GDG. However, as suggested by one of the stakeholder comments to change to 'supply' we believe that this recommendation is more achievable. The aim of this

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						needs. An example is trimethoprim 200mg tablets which usually comes in a pack size of 14 tablets, which poses a risk of over-prescribing and over-supply, particularly when only a 3 day course (6 capsules) is required, and the additional risk of patients extending their treatment period, or saving unused antibiotics for when required use. There are also practical issues for the pharmacy where the quantity prescribed does not match pack sizes, which results in splitting of packs, an inefficient process.	recommendation is to ensure that when antimicrobials are supplied that the appropriate quantity reflecting the intended course is provided to the patient and this will prevent the likelihood of storing left over supplies for inappropriate 'future use'. Wording has been added to the linking evidence to recommendations table on page 48. In most cases supplies will be made by a pharmacy so this recommendation will be manageable in the majority of cases.
189	SH	Royal Pharmaceutical Society (RPS)	Full	28 29	30-36 1-3, 10-28	We support the recommendations that prescribers should take time to discuss relevant points about antibiotic use and infections with the patient and/or family, and provide suitable advice on non-antibiotic therapies. The RPS provides similar advice in our professional guidance for members, e.g. the "*Chloramphenicol 0.5%w/v eye drops and 1%w/v ointment P medicine quick reference guide".* We would also like to highlight that prescribers can also suggest to patients go to community pharmacies for advice on treatments that can relieve symptoms if antibiotics are not appropriate.	Thank you for your comment.
190		Royal Pharmaceutical Society (RPS)	Full	30	Section on new antimicrobials	The recommendations in the RPS "*New Medicines, Better Medicines, Better Use Of Medicines*" guide for stimulating new antimicrobial development and improving antimicrobial stewardship are: • Educate the public and patients on the use of antimicrobials and their place in therapy • Encourage further development of antimicrobial stewardship by healthcare professionals to maintain the effectiveness of current and any future antimicrobials • Support the discovery and development of new antimicrobials or treatment methods, by developing new financial incentives RPS supports initiatives that will stimulate the discovery and development of new antimicrobials, and the appropriate prescribing and use of any new antimicrobials when they become available.	Thank you for your comments.
191	SH	Royal Pharmaceutical Society (RPS)	Short	General	General	We ask that recommendation and comments made in reference to the full version are also reflected in the short version.	Thank you for your comment. The short guideline will be based on the content of the full guideline and recommendation wording will reflect this.
192	SH	Baxter Healthcare	Full	General	General	We are concerned that the implementation of the recommendations within the guidelines will be significantly challenging because antimicrobial stewardship is not a high priority for Trusts as it is for the government.	Thank you for your comment. Your comment has been considered as part of the implementation of the guideline process and consideration given as to how to address the priority of antimicrobial stewardship.
193	SH	Baxter Healthcare	Full	General	General	Baxter would recommend that organisations consider providing IT or decision support systems that link to local prescribing policies and hospital formularies. Organisations should consider linking this IT or decision support systems to	Thank you for your comment. The GDG has further discussed and agreed the benefits and challenges for IT or decision support systems. Additional wording has been added on page 69 (section 6.5) of the final version of the guideline (full version) to give an overview of this discussion.

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						pharmacists and microbiologists so that they can use it to: - monitor appropriate prescribing - alert prescribers if there is an issue with a prescribed antimicrobial e.g. a mismatch with the drug and the organism - alert prescribers if there is an issue with a patient whose cultures show that they have an infection but have not been prescribed an antimicrobial agent	
194	SH	Baxter Healthcare	Full	General	General	Education should also be provided to **healthcare workers involved in ensuring and implementing antimicrobial stewardship. E.g. nurses and pharmacists.**	Thank you for your comment. The evidence for educational interventions was linked to prescribers (not just doctors) the term prescriber includes non-medical prescribers.
195	SH	Baxter Healthcare	Full	General	General	Prescribers should properly document their prescribing and review decisions in patient records. (This is a consistent issue identified in antimicrobial prescribing and usage audits). Other things to be documented include (may apply more within the hospital setting): - stop or review dates or duration of treatment - any reasons for change, continued use or stoppage of an antimicrobial(s).	Thank you for your comment. Recommendation 32 has been reworded following further discussion by the GDG and now includes more specific wording about the recording of prescribing information (including planned duration of treatment and recording the plan of care). The wording in section 5.5 has been amended to clarify the need for documenting reasons for a change in, continued use of or stopping of, an antimicrobial.
196	SH	Baxter Healthcare	Full	General	General	a) ***Under prescribing intravenous antibiotics:*** OPAT- OPAT patients are usually on longer term IV antibiotic therapy. There should be a recommendation as to reviewing these patients and their therapy in line with their clinical condition. ***b) Under Antimicrobial guidelines:*** Antimicrobial stewardship programmes usually have a list of **restricted antimicrobials** included within the antimicrobial prescribing policy and the use of this restricted list can be monitored. This list could be made up of antibiotics with high risk of causing healthcare associated infections like C.diff	a) Thank you for your comment. The review of longer term therapy, over 6 months, is covered by recommendation 37 in the full version of the final guideline. b) Thank you for your comment. The monitoring of unintended consequences of prescribing is covered by recommendations 3, 5 and 6. The GDG did not agree that a list of restricted use antimicrobials necessarily correlates with Healthcare Acquired Infection and that there may well be other reasons for the inclusion of an antimicrobial on a list of restricted antimicrobials.
197	SH	Baxter Healthcare	Full	General	General	a) For Antimicrobial Stewardship to result in effective antimicrobial medicine use, technology must be an integral part of its systems and processes. b) Baxter Healthcare stresses that IT consideration is more strongly recommended in this guideline. We propose wording to be changed from "should consider" to "should", on the grounds that the accuracy and timely availability of data is important to the overall ability to deliver Antimicrobial Stewardship. c) Baxter recommends a two-phase technology system where an Electronic Prescribing and Medicines Administration (EPMA) system controls dosage and appropriateness of therapy, and a medication system monitors the post-prescribing phase of treatment to ensure the most appropriate and safest medication is being used.	a) Thank you for your comment. Please note that recommendations 9 and 10 include the use of IT or decision support systems and recommendation 32 makes reference to the use of electronic patient records. b) Thank you for your comment. Section 1.5 of the guideline explains the strength of recommendations; the wording is based upon the quality of the underpinning evidence and reflects the benefits and trade-offs from the included evidence. All the evidence included in the review from RCTs of IT and decision support systems was found to be of very low quality. c) Thank you for your comment. The GDG found no evidence in relation to the technology referred to by the stakeholder.
198	SH	Baxter Healthcare	Full	26	28-29	'***Organisations should stock antimicrobials in pack sizes that correspond to local guidelines on course lengths.'*** Baxter Healthcare would like to comment on the feasibility of the proposed approach.	The original wording was not correct as this used the term 'stock'. We understand why this would be impractical and discussed this with the GDG. However, as suggested by one of the stakeholder comments to change to 'supply' we believe that this recommendation is more achievable. The aim of this

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						Organisations' ability to stock antimicrobials in pack sizes that correspond to local guidelines on course lengths will be dependent on all the required pack sizes being available to meet all local guidelines for all indications across the UK. Course lengths may differ by indication for the same drug, or even between different policies. This will also be difficult to implement for long term requirements and, for instance, IV. It would not be possible to stock 6 month's pack size of daily IV antibiotics. We suggest that this strong recommendation takes into account practical restrictions associated with the implementation of the recommendation.	recommendation is to ensure that when antimicrobials are supplied that the appropriate quantity reflecting the intended course is provided to the patient and this will prevent the likelihood of storing left over supplies for inappropriate 'future use'. Wording has been added to the linking evidence to recommendations table on page 48. In most cases supplies will be made by a pharmacy so this recommendation will be manageable in the majority of cases.
199	SH	Merck Sharp & Dohme Ltd	Short	General	General	MSD thanks NICE for the opportunity to comment on the draft Medicines Practice Guideline. MSD feels that the content is appropriate, particularly with regards to the adoption of new antimicrobials, and we welcome the statements that acknowledge the importance of prescribing the most clinically appropriate antimicrobials, with the shortest effective course and the most appropriate dose being selected.	Thank you for your comment.
200	SH	Leeds North CCG	Short	9	22	1.1.7 - We have been told not to use the term 'delayed prescribing' – is it suitable to have this term in this guidance?	Thank you for your comment. The wording for recommendations 10 and 34 of the full guideline and section 6.5 (page 70 of the full guideline, final version) has been amended to reflect the preferred term of 'back-up' prescribing following further discussion by the GDG and to reflect your comment.
201	SH	Leeds North CCG	Short	10	5	1.1.10 - This is impossible in primary care – maybe this needs to be clarified.	The original wording was not correct as this used the term 'stock'. We understand why this would be impractical and discussed this with the GDG. However, as suggested by one of the stakeholder comments to change to 'supply' we believe that this recommendation is more achievable. The aim of this recommendation is to ensure that when antimicrobials are supplied that the appropriate quantity reflecting the intended course is provided to the patient and this will prevent the likelihood of storing left over supplies for inappropriate 'future use'. Wording has been added to the linking evidence to recommendations table on page 48. In most cases supplies will be made by a pharmacy so this recommendation will be manageable in the majority of cases.
202	SH	Leeds North CCG	Short	General	General	There doesn't appear to be much advice in the guidance about working together i.e. primary, secondary and tertiary care. Also needs to include community pharmacy.	Thank you for your comment. The GDG agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for people and local governance arrangements.
203	SH	Leeds North CCG	Short	General	General	There needs to be advice on auditing prescribing and to have continuous audits in place.	Thank you for your comment. The GDG was aware that audit is important however no evidence was found to support recommendations for audit. Please note that following further discussion by the GDG recommendation 3 of the full guideline

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							now includes a reference to audit based upon GDG member opinion.
204	SH	Leeds North CCG	Short	General	General	There is not much advice on patient education and involvement. I feel they are key players in the over prescribing of antimicrobials.	Thank you for your comment. The Department of Health has referred a topic to NICE to develop a guideline on Antimicrobial stewardship – changing risk related behaviours in the general population. Patient behaviour will be an explicit focus of this guideline.
205	SH	RCGP				I fully support the contents of antimicrobial stewardship consultation. There are several recommendations for which the tools are not currently in place in General Practice or inadequate.	Thank you for your comment. We have passed it to the NICE implementation support team to inform their support activities for this guideline
206	SH	RCGP				Recommendation 12 (page 12) requires the clinical systems to produce individual GPs and training GPs with feedback in simple form with both local and national comparison regularly as we used to have with PACT data. However unless this is part of QOF, it is unlikely the systems will be able to provide this easily and will considerable input from individual practices in setting up searches. Many GPs work across several organisations including out of hours so may have difficulty collating and comparing their data	Thank you for your comment. This recommendation has been incorporated into others related to feedback and prescribing. The GDG have made recommendations in anticipation of improved access to, and improved quality of, prescribing data. It is anticipated that individual practices will, through Clinical Commissioning Groups and Commissioning Support Units support share the work of collating and scrutinising prescribing data. In many places the necessary systems are already available.
207	SH	RCGP				a) Recommendation 28 (Page 28) requires point of care testing with C Reactive Protein and presepsin in the future. This testing is not widely available or standardised and is an additional cost to practices. If a standard test was made available free at the point of use by practices it is likely that this important technology would be adopted to help distinguish infection. b) Further research to incorporate this as part of the CRB65 risk assessment would be useful.	a) Thank you for your comment. This recommendation does not require the use of point of care testing it recommends that prescribers consider using the test in line with the recommendations set out in the NICE guideline for pneumonia. b) Thank you for your comment. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.
208	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	8	Section 1.1.2, second bullet point	The meaning of the following sentence requires further clarification: "Providing feedback to prescribers in all care settings about • Patient safety incidents related to antimicrobials, including hospital admissions for rare or serious infections or associated complications" We assume this implies that admission for rare or serious infections or complications implies a possible failure to administer antibiotics in a timely manner prior to hospital admission. However, it could also be interpreted to mean that there should be an assessment of how patients with rare or serious conditions were treated following admission. We also suggest that severe allergic reactions are included as part of the examples.	Thank you for your comment. This wording has been amended following further discussion by the GDG to specify what is meant by patient safety incidents. Please note that severe allergic reaction (anaphylaxis) has been included in the recommendation.
209	SH	Public Health England (incorporating the English Surveillance	Short	10 of 34	Section 1.1.14	This section states that organisations should review prescribing and resistance data. This seems at variance with section 1.1.2 which states that organisations should consider monitoring and evaluating antimicrobial prescribing and how this relates to local resistance patterns.	Thank you for your comment. The updated recommendations have been reworded to clarify that the two recommendations have different purposes (recommendations 3 and 8 of the full guideline [final version]).

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		Programme for AMR usage and resistance (ESPAUR))					
210	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	13 of 34	Section 1.1.28	We suggest that the following statement is ambiguous and needs further clarification: "Prescribers should consider point of care testing in primary care as described in the NICE guideline on pneumonia". It is unclear whether the considering of point of care testing is specifically relating to patients presenting with pneumonia, or whether it is meant as a generic statement that refers to patients presenting with any type of infection, and uses the NICE pneumonia guideline as an exemplar.	Thank you for your comment. The wording for recommendation 30 in the full guideline (final version) has been amended to 'Prescribers should consider point-of-care testing in primary care for patients with suspected lower respiratory tract infections, as described in the NICE guideline on pneumonia.' The wording has been amended following further discussion by the GDG to clarify this in relation to the indication for pneumonia and reference to the corresponding guideline.
211	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	13 of 34	Section 1.1.29	Mention could be made of using patient information leaflets about antibiotic prescribing. Such leaflets are available to GP through the TARGET antibiotics toolkit.	Thank you for your comment. The Department of Health has referred a topic to NICE to develop a guideline on Antimicrobial stewardship – changing risk related behaviours in the general population. Public health education and patient behaviour will be an explicit focus of this guideline. Developers of tools may wish to submit their tool to the NICE endorsement programme. More information about this can be found on the NICE website.
212	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	14 of 34	Section 1.1.33	This states that "When a decision to prescribe an antimicrobial has been made, prescribers should take into account the benefits and harms for an individual patient associated with the particular antimicrobial" This might be better phrased as: "When a decision has been made that antimicrobial treatment is appropriate, prescribers should take into account the benefits and harms for an individual patient when deciding which antimicrobial to prescribe"	Thank you for your comment. The wording of the recommendation was considered by the GDG and the NICE editorial team. No changes have been made as the GDG felt that the use of the word 'appropriate' would be unclear when translating the recommendation in to practice.
213	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	15 of 34	Section 1.1.37	This states: "Prescribers should consider reviewing intravenous antimicrobial prescriptions at 48–72 hours in all care settings (including community services) to determine if the antimicrobial needs to be continued, and if so whether the intravenous antimicrobial can be switched to an oral antimicrobial." This does not seem to be consistent with the Start Smart then Focus guidance which indicates this should happen.	Thank you for your comment. The use of should and should consider reflect the strength of the available evidence. The evidence for recommendation 39 was low or very low in quality. Therefore 'should consider' was used by the GDG following their discussion of the available evidence.
214	SH	Public Health England (incorporating	Full	15	37	Dentists should be specifically named in the list of professional groups mentioned as they are also prescribers.	Thank you for your comment. The wording has been amended following further discussion by the GDG to include the words dentists and podiatrists.

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		the English Surveillance Programme for AMR usage and resistance (ESPAUR))					
215	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	16	18	The list of exclusions is helpful	Thank you for your comment
216	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	25	12	We suggest that the term organisation (commissioner and providers) is too vague. We suggest that it would be more helpful to define the recommendation for each organisation: NHSE, CCG, LA Public Health, PHE, acute trusts, GP practices, dental practices, community NHS providers, care homes etc. This will help organisations to understand how they can contribute/implement the guideline in a meaningful way. We feel that the statements made are currently very generic and may be difficult to put into practice in the new health and social care landscape if clear parameters are not set for each organisation.	Thank you for your comment. The GDG have amended the wording of recommendations in order to make clear who should take action. A 'who to take action' table will be added to the full version of the guideline. For further details of how the guideline recommendations could be put in to practice please see the section on implementation
217	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	25	29,30	Standard 3. There is a risk that this standard will be interpreted in different ways by providers "Organisations should clearly define roles, responsibilities and accountability within an antimicrobial stewardship programme". We therefore suggest that this needs to be elaborated on in order to help organisations to operationalise the guidance. We suggest that a table could be included illustrating key roles within an antimicrobial stewardship programme, what those roles do, and who they would report to, including key deliverables. As this standard is about accountability, this needs to be very clearly defined.	Thank you for your comment. The GDG agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for people and local governance arrangements. It is therefore not possible to prescribe specific AMS responsibilities to a single set of roles that will be applicable in all local areas. We have passed your comment to the NICE implementation support team to inform their support activities for this guideline.
218	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	28	25	Consideration – We suggest that if antibiotics are required at once, a sample can still be taken (if it can be promptly obtained) as this can later inform antibiotic choice especially if the patient does not respond to the first antibiotic prescribed. This could improve patient outcome.	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG to better define the clinical situations in which microbiological cultures should be taken or should be considered for taking.

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219	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	29	6	Bullet point 1 – Suggest this is changed to "when an antimicrobial is considered" This will then lead logically to the next bullet point which is about documenting decisions to prescribe antibiotics or not.	Thank you for your comment. The wording of this recommendation has been amended to 'When an antimicrobial is a treatment option 'rather than 'when an antimicrobial is considered' as suggested, following discussion with the NICE editorial team. .
220	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	29	31,32	Standard 35. "Prescribers should not issue repeat prescriptions for antimicrobials for longer than 6 months. A more frequent review may be needed for individual patients." This is a very long time period and the supporting information does not provide much detail. There is a risk that this standard could be misinterpreted and misused and should be more specific in order to avoid misinterpretation. For example does this apply to all indications equally (i.e. prevention of UTI, osteomyelitis)?; and when should a microbiologist be consulted in this process? The rationale/evidence behind the 6 month timescale quoted should be clearly explained.	Thank you for your comment. The linking evidence to recommendations table does note that a more frequent review may be needed depending on the individual circumstances of the patient. Although no evidence was available on which to base the recommendation for the 6 month timescale the GDG agreed that it represented a frequency of review that would limit any burden of prescriber review balanced against the need for a regular review of antimicrobial prescribing and the risk of antimicrobial resistance.
221	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	99		Summary of Call for Evidence Table. "Another concern was that newer antimicrobials may not have a clinical advantage over current therapies (an example given was fidaxomycin versus vancomycin for the treatment of *C. difficile*) and often the newer therapy may come at a substantially higher cost than the current therapy." We do not agree with this example and would want to see the evidence to support this statement. There is good quality evidence from phase 3 clinical trials and additionally from post-hoc analyses and real world data that fidaxomicin (spelt incorrectly in the draft guideline twice on page 99 of the full version and also in the short version on page 28) is superior to vancomycin for the treatment of CDI e.g. 50% reduction in recurrence rate. See following references: • Louie TJ, et al. *Fidaxomicin versus vancomycin for Clostridium difficile infection. N Engl J Med 2011;364:422-31.* • Cornely OA, et al. *Fidaxomicin versus vancomycin for infection with Clostridium difficile in Europe, Canada and the USA: a double-blind, non-inferiority, randomised controlled trial. Lancet Infect Dis 2012;12:281-9.* • Eyre DW, et al. Whole-genome sequencing demonstrates that fidaxomicin is superior to vancomycin for preventing reinfection and relapse of infection with Clostridium difficile. J Infect Dis. 2014 May 1;209(9):1446-51. • Crook DW, et al; Study 003/004 Teams. Fidaxomicin versus vancomycin for Clostridium difficile infection: meta-analysis of pivotal randomized controlled trials. Clin Infect Dis. 2012 Aug;55 Suppl 2:S93-103. • Wilcox MH. Progress with a difficult infection. Lancet Infect Dis. 2012 Apr;12(4):256-7. • Optimer Pharmaceuticals Inc. Anti-Infective Drugs Advisory Committee	Thank you for your comment. This section has been reworded following further discussion by the GDG.

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						Meeting Briefing Document. Dificid™ (fidaxomicin tablets) for the treatment of *Clostridium difficile* infection (CDI), also known as *Clostridium difficile*-associated diarrhoea (CDAD), and for reducing the risk of recurrence when used for treatment of initial CDI. NDA 201699, April 5, 2011. *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM249354.pdf*	
222	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	7	1	Regarding the term antimicrobial stewardship the document states: "The term 'antimicrobial stewardship' is defined as 'an organisational or healthcare-system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness" Antimicrobial Stewardship is more than preserving for future effectiveness According to Doron and Davidson (2011) (6) three major goals for antimicrobial stewardship are to: • optimise therapy for individual patients • prevent overuse, misuse and abuse • minimise development of resistance at patient and community levels Doron S, Davidson LE. Antimicrobial stewardship. Mayo Clin Proc 2011; 86(11): 1113–23	Thank you for your comment. The full version of the guideline contains both the definition and the goals of antimicrobial stewardship as stated in your comment (taken from The annual report of the Chief Medical Officer, volume two, 2011: Infections and the rise of antimicrobial resistance).
223	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	9&14	1.1.7 & 1.132	Both of these sections refer to "delayed prescribing" PHE research suggests that the term "back-up prescribing" has been shown to be better understood by patients as delayed suggests automatic use of antibiotics at a future date (manuscript in preparation). This term is already being used in other recent PHE publications, most notably: TARGET antimicrobial stewardship toolkit patient leaflets- http://www.rcgp.org.uk/clinical-and-research/target-antibiotics-toolkit/patient-information-leaflets.aspx Behaviour change and antibiotic prescribing in healthcare settings: literature review and behavioural analysis- https://www.gov.uk/government/publications/antibiotic-prescribing-and-behaviour-change-in-healthcare-settings	Thank you for your comment. The wording for recommendation10 and 34 of the full guideline and section 6.5 has been amended following further discussion by the GDG and to reflect your comment
224	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Short	9	1.1.8	The short guideline states: Organisations, when developing care pathways, should consider including: • information about antimicrobial use • advice about who a patient should contact if they have concerns about infection after discharge from secondary care. We suggest that advice should be provided to patients if they have concerns about infection after primary or secondary care contact.	Thank you for your comment. This wording has been amended following further discussion by the GDG. The wording is now generic and is applicable to consultation in either primary or secondary care settings.
225	SH	Public Health England (incorporating the English Surveillance	Short	10	1.1.9	The Short guideline states: Organisations should consider prioritising the monitoring of antimicrobial resistance, to support antimicrobial stewardship across all care settings, taking into account the resources and programmes needed. We suggest that this point should be a 'should' not 'should consider"	Thank you for your comment. Section 1.5 of the full guideline explains the strength of recommendations; the wording of recommendation 12 is based upon sparse and low quality underpinning evidence and reflects the benefits and trade-offs from the included evidence.

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		Programme for AMR usage and resistance (ESPAUR))					
226	SH	Public Health England (incorporating the English Surveillance Programme for AMR usage and resistance (ESPAUR))	Full	10&11	1.1&1.2.1	We suggest that the resources for organisations and health professionals in section 1.1 and the regulatory requirements in section 1.2.1 should also be included as part of the short document.	Thank you for your comment. The short version of the guideline is based on content from the full version of the guideline and consists principally of the full list of recommendations. The template of contents for the short version is determined by the NICE publishing team and is consistent across other guidelines.
227	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Short	General	General	Overall I think that the document is good. It is more detailed and specific than the 2011 DoH document.	Thank you for your comment.
228	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Short	General	General	Helpful to see that AMT (or the renamed AST) is more jointly focused with Primary care and secondary care reps. (This will be quite a change in practice).	Thank you for your comment.
229	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Short	7	General	(Other Healthcare professionals)There is an absence, generally, in the document re: AMS for Dentists. This seems to be an area where the prescribing is unknown (and anecdotally we get comments re: low doses of amoxicillin etc)	Thank you for your comment. Dental practitioners are included within the scope of the guideline. No relevant evidence regarding dental AMS was excluded from the systematic searches for this guideline. The guideline uses the generic term prescriber to refer to all health professionals who are able to prescribe antimicrobials, this would include dentists. We have added dentists and podiatrists to page 3 of the short version of the guideline to match the final version of the full guideline.
230	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Short	General	General	Other NMPs such as physiotherapists and podiatrists – should these be specified?	Thank you for your comment. We have added dentists and podiatrists to page 3 of the short version of the guideline to match the final version of the full guideline. The guideline uses the generic term 'prescriber' when describing all prescribers

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231	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Short	14	1.1.31	I think that it is important to add a statement about not prescribing antibiotics	Thank you for your comment. Please note that recommendation 33 recommends not prescribing an immediate antimicrobial and recommendation 31 recommends discussing the need for an antimicrobial prescription and alternative options with the patient.
232	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Full	26	1	Point 5 is vague – doesn't specify which severe infections organisations should be identifying	Thank you for your comment. The wording of the recommendation has been amended to provide more clarity following further discussion by the GDG. . Examples have been added to the recommendation wording (identifying and reviewing patients who are admitted to hospital with potentially avoidable severe infections [such as E. coli, mastoiditis, pyelonephritis, empyema, meningitis] or associated complications [such as quinsy and brain abscess] in order to determine if the admission is linked to a previous prescribing decision.)
233	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Full	29	29	Point 34 should be a must	Thank you for your comment. Section 1.5 of the full version of the guideline explains the strength of recommendations; the wording is based on the quality of the underpinning evidence and reflects the benefits and trade-offs from the included evidence. As set out in Developing NICE guidelines: the manual (2014) NICE only use the word 'must' in a recommendation if there is a legal duty to apply a recommendation, or the consequences of not following a recommendation are extremely serious.
234	SH	United Kingdom Clinical Pharmacy Association – Pharmacy Infection Network	Full	30	12	Point 40 and 41 – all ideal but there is no mention about the how much extra staff that will be required to implement all these recommendations	Thank you for your comment. The consideration of possible staffing needs is outside of the scope for this guideline.
235		The Royal College of Nursing	General	General	General	The Royal College of Nursing welcomes proposals to develop the guideline on Antimicrobial Stewardship. We invited some of our members who are responsible for infection control and prevention and medicine management in their work area to review and comment on the draft guideline. They have indicated that there are no additional comments to make on the draft document at this stage.	Thank you for your comment.
236		The Royal College of	NICE	20	4.1	Please note that XX [name removed in line with process] was involved in the development of this draft guideline.	Thank you for your comment. This anomaly has been amended in the current version of the guideline.

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		Nursing				We ask that you acknowledge XX involvement by including details in the list of guideline development group members.	

Registered stakeholders