Prophylaxis against Infective Endocarditis – Scope consultation 1 May – 29 May 2007

Order No	Organisation	Section No		Comments	Response
1	Addenbrooke's NHS Trust			This organisation was approached but did not respond	
2	Association of British Academic Oral & Maxillofacial Surgeons			This organisation was approached but did not respond	
3	Association of Medical Microbiologist (AMM)	4.1		In gathering literature evidence the followings should be taken in to account: a) The theoretical plausibility should be considered that predictable viridans streptococcal (VS) bacteraemia associated with certain dental procedures, may occasionally cause infective endocarditis (IE) in susceptible heart patients, even though it should be accepted that the great majority of cases of VS IE occur after spontaneous bacteraemias (sometimes associated with poor oral hygiene). b) The direct blood culture evidence that VS bacteraemia occurs much more often with certain dental procedures, such as extractions, than with pre-procedure/baseline blood cultures, even using lysis-filtration techniques. There is no data to indicate that routine dental fillings cause frequent VS bacteraemia and in the UK there are no anecdotal reports of IE following such a minor procedure. c) There are numerous anecdotal reports of IE following certain dental procedures, especially extractions, but relatively few reports following non-dental procedures. Therefore it may be reasonable to abandon prophylaxis for non-dental procedures. d) Before the 1980s there were reports of failure of prophylaxis against IE, often associated with low oral dose penicillin V, but very rare reports of failures after the 3g amoxicillin dose during the last 20 years. e) The limitations of recent Dutch & American epidemiological studies needs noting- few cases of dental extraction included & dental procedures of all types lumped together. There are no direct clinical data or epidemiological studies to assess the efficacy of the UK recommended 3 g amoxicillin oral dose, or 600 mg oral clindamycin dose, for preventing IE in susceptible adult patients undergoing dental extraction. Therefore it may be impossible to give a view on clinical efficacy of antibiotic prophylaxis against IE. f) The risks of antibiotic prophylaxis against IE are dependant on the route of administration, duration & dosage. These should be considered when anaphylaxis or pseudomembranous colitis are being considered in cost-benefit analysis of antibiotic prophylaxis against IE.	Thank you for this information The evidence regarding bacteraemia associated with dental procedures and IE will be presented to and considered by the GDG As for a) Evidence regarding IE and non-dental procedures will be presented to and considered by the GDG Evidence regarding the effectiveness of prophylaxis will be presented to and considered by the GDG The limitations of the evidence available for prophylaxis for IE is acknowledged. The evidence available will be reviewed and the professional and patient representatives in the GDG will further discuss and assess this The risks related to antibiotic prophylaxis will be considered by the GDG, this will include relevant health economic considerations

3.1	Association of Medical Microbiologist (AMM)	4.3		The details of dose & no of doses, route of administration as well as choice of antibiotic are important to consider. The cost of a single 3 g amoxicillin sachet, given to susceptible adults orally 1 hr before a dental extraction should be considered against the cost of carrying out the procedure itself. This dose is given by the dental practitioner & has negligible cost involved with its administration.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens Health economic implications in relation to prophylaxis will be included in this guideline
4	Barnsley Hospital NHS Foundation Trust			This organisation was approached but did not respond	
5	Berkshire Healthcare NHS Trust			This organisation was approached but did not respond	
6	Birmingham Women's Hospital			This organisation was approached but did not respond	
7	BNF publications	4.3 d		We think it would be a good idea to review the regimes (including routes of administration) because this is another controversial area between existing guidelines	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
8	Bolton Council			This organisation was approached but did not respond	

9	Britannia Pharmaceuticals Ltd			This organisation was approached but did not respond	
10	British Cardiovascular Society	General		The overwhelming consensus among cardiologists and cardiac surgeons in the UK is that it is **"unsafe"** not to provide ABP for patients with valvular heart disease or other structural "at-risk" cardiac lesions who are undergoing invasive dental or surgical procedures which cause bacteraemia. Thus, unless it can be shown **beyond any doubt** that ABP is harmful or totally ineffective, cardiac specialists in the UK and I suspect worldwide will not accept any Guidelines that preach that ABP is no longer necessary.	Thank you the GDG will include cardiologists and cardiac surgeons and co-opted experts in the area of IE will also be invited to contribute to the GDG
10.1	British Cardiovascular Society	3a.		This section understates the destructive cardiac and devastating extracardiac complications of Infective Endocarditis (IE). In order to indicate why those who care for patients with IE favour continuing antibiotic prophylaxis (ABP) based on clinical experience and an understanding of the pathogenesis rather than randomised clinical trial evidence, it is important to stress the consequences of failing to prevent IE. The consequences include the destructive cardiac and the devastating vasculitic and embolic complications that may occur which result in the prolonged in-hospital/ITU stay, the need for other surgical procedures besides cardiac surgery, the enormous expense of IP care (drugs, investigations etc) for those who survive the condition, the long-lasting disability that may occur in some of those with complications and the cost to the families of the 20-30% of patients who unfortunately die despite all the treatment and surgery available. Patients and their relatives (and eventually their lawyers) will want to know why everything was not done to try and prevent IE when it was known that the patient was at increased risk because of the known cardiac pathology.	Thank you, the potentially significant mortality and morbidity of IE are acknowledged and the GDG will have professional and patient representative members who will be very aware of the potential effects of IE on the individual and their relatives
10.2	British Cardiovascular Society	3c.		There is evidence that ABP can reduce or abolish bacteraemia. We have never seen (or heard of anyone who has seen) anaphylaxis from oral ABP given to patients to prevent IE. There is no evidence that ABP to prevent IE gives rise to AB-resistant micro-organisms in the community as a whole.	Thank you. Appropriate evidence relating to harms as well as risks of ABP will be considered by the GDG
10.3	British Cardiovascular Society	3d.		The concern "that the likelihood of preventing IE by using ABs is less than the risk of ABs causing serious adverse effects" is not a realistic concern to cardiologists and cardiac surgeons. Most would think that this is an absurd suggestion.	Thank you. This is a concern of some microbiologists and dentists.
10.4	British Cardiovascular Society	4.3b		Other procedures being performed in "at-risk" cardiac patients should include: Cardiac Opthalmological Dermatological Other - Burns - Acupuncture - Body piercing - Tattooing	Thank you. Your comments have been noted, however this is outside the remit of the scope, it is not possible for this guideline to address all groups of interventional procedures. The sites covered include all those important groups for which AB prophylaxis should be considered. Acupuncture, body piercing and tattooing

					are not NHS procedures, the scope does include information needs and advice regarding body piercing and tattooing that involves damage to mucosal tissue
10.5	British Cardiovascular Society	4.3d		If the ABs are to be specified, it would seem odd not to offer advice on the route of administration.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
11	British Dental Association	3d	line 1	Please replace “UK guidance” with “international guidance” [so that current European guidelines & new US guidelines can be included]	Thank you, international guidance will be considered, however as NICE guidelines refer specifically to the NHS, the current status in the UK has been stated
11.1	British Dental Association	3c	lines 3&4	Please insert “laboratory” before “animal models” (2 instances)	Thank you, this has been done
11.2	British Dental Association	3b	line 3	Please replace “…good oral hygiene...” with “…good oral health...”	Thank you, this has been done
11.3	British Dental Association	3b	lines 9-11	Please replace “…view that cumulative bacteraemia is likely to cause IE, particularly in the case of dental procedures (including dentogingival…” with “…view that cumulative bacteraemia, caused by everyday activities like eating and toothbrushing, is more likely to cause IE than one off dental procedures (including dentogingival...”	Thank you, this has been changed.
11.4	British Dental Association	4.1.2		We agree that this group could be excluded but it should be noted that they often have poor oral health as a result of sugar-containing methadone therapy	Thank you
11.5	British Dental Association	4.3d		Please include this if possible as it is significant	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for

					national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
11.6	British Dental Association	4.3c	bullet 2	Please replace “oral chlorhexidine” with “chlorhexidine mouthwash”	Thank you, this has been done
12	British Dental Health Foundation			This organisation was approached but did not respond	
13	British Heart Foundation			This organisation was approached but did not respond	
14	British Society for Antimicrobial Chemotherapy	General		We note with interest that the scope does not include mention of orthopedic procedures or clean skin surgeries (by GPs / dermatologists). While these are generally considered to be 'clean' operations a case was reported by the Medical Protection Society where a legal case was brought against a hospital after endocarditis developed after an arthoscopy [reference awaited]. Whilst we anticipate that such cases would be rare, it would nonetheless be very helpful to all practitioners if some statement concerning clean procedures were included. A statement might exclude these from consideration. Alternatively a more definite statement might be made which could be relied upon in court. **WE RECOMMEND THAT CONSIDERATION BE GIVEN TO ADDRESSING “CLEAN” PROCEDURES AND THE DEVELOPMENT OF A CLEAR STATEMENT FOR PRACTITIONERS.**	Thank you. It is not possible for this guideline to address all groups of interventional procedures. The sites covered include all those important groups for which AB prophylaxis should be considered.
14.1	British Society for Antimicrobial Chemotherapy	General		NICE should encourage the need for future research to try to obtain data which is presently lacking---particularly multicentre controlled trials of prophylaxis of extractions in susceptible patients with native valve disease.	Thank you, NICE guidelines identify research recommendations where they are considered appropriate, it is anticipated that research recommendations will be made in this guideline
14.2	British Society for Antimicrobial Chemotherapy	General		The Society welcomes the opportunity to comment on these guidelines.	Thank you.
14.3	British Society for Antimicrobial Chemotherapy	General		Full account should be taken of the BSAC guidelines that have already addressed many of the issues proposed in the scope. **Guidelines for the antibiotic treatment of endocarditis in adults: report of**	Thank you, previous guidelines will be identified and considered within the systematic literature searching

				the Working Party of the British Society for Antimicrobial Chemotherapy J. Antimicrob. Chemother., Dec 2004; 54: 971 - 981.	
14.5	British Society for Antimicrobial Chemotherapy	General		**WE RECOMMEND** that the short title be amended to Prophylaxis **against** infective endocarditis.	Thank you. We have changed both the full and short title to address this point.
14.6	British Society for Antimicrobial Chemotherapy	4.1.1		**WE RECOMMEND** that the scope makes specific reference to adults and children with known underlying structural defects including diseased native valves as well as non-native valves.	Thank you, the underlying structural defects includes native and non-native valves, the structural defects will be more clearly defined in the guideline
14.7	British Society for Antimicrobial Chemotherapy	4.3c		Antimicrobial regimen to be used: This **must** include duration and doses.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
14.8	British Society for Antimicrobial Chemotherapy	4.3a & 4.3g		**WE RECOMMEND** that consideration is given to categorising groups of people according to degree of risk [HIGH, MODERATE, and LOW]. (For example prosthetic heart valve patients could be high risk, aortic valve native valve disease a moderate risk, & mitral valve prolapse a low risk. The lowest risk category might not need prophylaxis)	Thank you, it is intended, to ensure clarity, to compile the groups into those who are considered at risk of IE and those who are not.
14.9	British Society for Antimicrobial Chemotherapy	4.3d		In addition to the choice of antibiotic, the cost effectiveness of prophylaxis and risks of adverse drug reaction may be markedly influenced by the details of route of administration, timing, duration and regimen used. **WE RECOMMEND THAT THE FOLLOWING ARE COVERED BY THE SCOPE:** • **CHOICE OF ANTIBIOTIC** • **ROUTE(S) OF ADMINISTRATION OF ANTIBIOTIC** • **TIMING OF TREATMENT** • **DURATION OF TREATMENT** • **REGIMEN USED**	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of

					administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
14.10	British Society for Antimicrobial Chemotherapy	4.4		The section on dental procedures should consider the inadequacy of published epidemiological studies in relation to dental extractions since there is very limited data available, with only small numbers of cases of dental extraction studied. There is also an almost complete lack of data on epidemiological observations on extractions in children. Indirect data about dental procedures involves examination of dental bacteraemia studies. But, there is controversy about the interpretation of results concerning dental extractions compared with minor procedures such as routine dental fillings & daily activities such as tooth brushing. Many papers do not clearly single out viridans streptococcal bacteraemia rates which is the main type of bacteraemia relevant to the pathogenesis of endocarditis. **WE RECOMMEND THAT THE SCOPE OF THE GUIDELINES INCLUDES A DETAILED EXAMINATION OF THE STREPTOCOCCAL BACTERAEMIA EVIDENCE.** The Guidelines team should be open to the concept that it may be impossible to estimate the degree of risk of a dental procedure because of the lack of data---especially as IE is rare & the apparent risk of any procedure must be small. An analogy can be made with deep infection risks of hip-joint replacement—it took an MRC trial involving thousands of patients to show the benefit of laminar air flow/antibiotic prophylaxis. ***[Lowell ,OM et al Infection and sepsis after operations for total hip or knee replacement: influence of ultra clean air, prophylactic antibiotics and other factors Hyg(London)1984;93,505-29] [BMJ,1982,285,10*]** **WE RECOMMEND THAT THE GUIDANCE ACKNOWLEDGES THAT THE ABSENCE OF ADEQUATE EVIDENCE,BECAUSE OF LIMITED STUDIES,DOES NOT NECESSARILY MEAN ABSENCE OF RISK** Risk of antibiotics: Evidence should be sought from the last 25 years experience in the UK of giving an oral amoxicillin single dose, & other recommended antibiotic regimens for prophylaxis, & whether there are any reports of anaphylaxis or other serious adverse reactions while trying to prevent endocarditis. If so, which antibiotics, what route of administration & what were the previous history of allergy in the patients with anaphylaxis? **WE RECOMMEND THAT A REVIEW OF THE ABOVE EVIDENCE IS UNDERTAKEN.**	Thank you The evidence in this area will be reviewed and limitations/inadequacies of the studies will be noted The evidence on bacteraemia related to defined interventional procedures will be reviewed in this guideline. The lack of controlled clinical trials is acknowledged, other evidence, notably observational studies, will be reviewed. The absence of adequate evidence not equating to absence of risk is noted. This important point is noted. It is intended that economic modelling to be considered for identifying AB cost-effectiveness will consider the likely incidence of serious adverse events, including anaphylaxis.

				Mortality---morbidity is also important—some patients with viridians streptococcal endocarditis are cured by antibiotic treatment but subsequently have so much valve so much valve damage that congestive heart failure occurs & occasionally valve replacement may become necessary. ***[English T.A.,Ross J.K,Surgical Aspects of Bacterial Endocarditis,BMJ,1972,4,598-602] [Hatcher C.R.et al,Surgical management of complications of bacterial endocarditis,Ann Surg,1971,173,1045-1052]*** **WE RECOMMEND THAT THE SCOPE ADDRESSES MORBIDITY IN ADDITION MORTALITY RATES**	The scope will address morbidity as an outcome measure, and this has been added.
14.11	British Society for Antimicrobial Chemotherapy	4.5		The points made in section 4.4 above about a single antibiotic dose are relevant to cost. One of the most common cardiac abnormalities is mitral valve prolapse, which is usually benign/asymptomatic ***[Editorial: Mitral Valve Prolapse, mostly benign, BMJ, 306,943-4]*** The risk of death from endocarditis has been estimated to be 1 in 100,000 ***[Pollick, C, Wilansky,S ,Parker, S, Mitral valve prolapse: clinical & echocardiographic perspective. Canadian Medical Association Journal, 1986, 135,277-80*]**.** If only those patients with clear evidence of mitral valve regurgitation or thickened mitral valve leaflets are included, the numbers of cases needing prophylaxis would be reduced with an associated reduction in costs. Data on clinical efficacy of RECOMMENDED antibiotic prophylaxis is almost non-existent. It should be noted that here are no reports of fatal anaphylaxis associated with endocarditis prophylaxis, either in the USA during the last 50 years ***[American Heart Association, April 2007 guidelines on prevention of endocarditis]*** or in the UK	Thank you, the health economic implications will be reviewed in this guideline This has been noted
14.12	British Society for Antimicrobial Chemotherapy	6		Guidelines can not cover every circumstance. **WE RECOMMEND THAT THE GUIDELINES ALLOW FOR MEDICAL AND DENTAL PRACTIONERS TO BE ABLE TO OFFER PRPHYLAXIS IN ADDITION TO ANY RECOMMENDATIONS IF THERE ARE EXCEPTIONAL CIRCUMSTANCES WHERE THEY CONSIDER PROPHYLAXIS WOULD BE IN THE BES INTERNEST OF THE PATIENT.**	Thank you. It is correct that guidelines cannot cover every circumstance are intended to support, not replace, clinical judgement.
15	British Society of Disability and Oral Health	General		We are also concerned that if, after review of the available evidence, a significant change in the current protocol is recommended, it will be very difficult to explain to patients who may have had antibiotic cover by either method of administration for many years, that this may change. It would be very useful for all clinicians treating this group of patients, if an	Thank you, patient experience will be considered in the guideline process and recommendations will be considered As with all guidelines a quick reference

				information sheet could be published explaining the recommended guidance, including the evidence for this, in order to pass this onto patients.	guide (QRG) will be produced for this guideline
15.1	British Society of Disability and Oral Health	4.3	d)	The British Society of Disability and Oral Health represents approximately 800 dental surgeons in the UK. Most, if not all, these practitioners, care for patients who have significant medical problems. As such we work regularly with current guidelines for the prevention of Infective Endocarditis. We are concerned that if NICE does not address the problems of 'route of administration of antibiotic prophylaxis' as mentioned in this section of the scoping document, this will lead to further confusion and delay a speedy resolution to the problem. We understand that other NICE guidelines contain no recommendations regarding route of administration, however we feel strongly that this is controversial area and that dental practitioners need some direction in order to expedite safe care. Whilst most general practitioners would prefer the oral route of administration, some, primarily hospital clinicians would still prefer the option of intravenous administration if it is felt appropriate. We would therefore urge NICE to consider this as a special case.	Thank you This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
16	British Society of Oral Medicine			This organisation was approached but did not respond	
17	British Society of Paediatric Dentistry	4.3		It would be helpful in this particular guideline if details of dosage, route of administration, timing and duration of antibiotics could be included in the guideline. For dental treatment the antibiotics will be prescribed and given by dental practitioners, many of whom will be in a primary care setting, and I think this will be essential information for them.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens

18	British Society of Periodontology			This organisation was approached but did not respond	
19	BUPA			This organisation responded and said that it has no comments to make	
20	CASPE Research			This organisation responded and said that it has no comments to make	
21	Cochrane Oral Health Group			This organisation was approached but did not respond	
22	Commission for Social Care Inspection			This organisation was approached but did not respond	
23	Connecting for Health			This organisation was approached but did not respond	
24	Department of Health			This organisation responded and said that it has no comments to make	
25	Dudley Group of Hospitals NHS Trust			This organisation was approached but did not respond	
26	East & North Herts PCT & West Herts PCT			This organisation was approached but did not respond	
27	Eastman Dental Hospital (Special Care Dentistry)	4.3	d)	Whilst I understand that other NICE Guidelines do not offer recommendations on the route of administration of antibiotics, this is probably the most contentious issue for Dental Surgeons. Current proposed guidelines (BCS/RCP) have suggested that some patients require IV antibiotics, as per existing BSAC guidelines. However new BSAC guidelines have done away with the need. Clarification needs to be given to Dental Surgeons, most of whom no longer possess IV skills. The practical ramifications are significant, if IV administration is recommended, this has an impact on secondary care and if they are not, then all patients currently being treated in secondary care can be referred back to their general dental practitioner. Again this has a significant impact. Is this situation not a “special case”? It is certainly an area where practitioners in either primary or secondary care are seeking guidance.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
28	Faculty of Dental Surgery			This organisation responded after the consultation period and we were unable to take their comments into account	
29	Faculty of General Dental Practice (UK)	General		The only area that is not included in the scope is that of dose of antibiotic and in our view this should be covered by the NICE guidelines.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline

					recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
30	Health Commission Wales			This organisation was approached but did not respond	
31	Healthcare Commission	General		Title - This relates to interventional procedures. What about the frequent questions one is posed re prophylaxis in relation to intercurrent infection? Particularly relevant to children but also those who are elderly with prosthetic valves. All of these would like guidance re the use of antibiotics when they have a temperature. Whilst I can understand that this will widen the scope, nevertheless these might actually be more helpful to those in primary care.	Thank you, your comments have been noted, however this is not within the remit of the scope, it is not possible to discuss this aspect within this guideline
31.1	Healthcare Commission	General		Regimes pre and post	Thank you ,the effectiveness of antibiotics for prophylaxis will be included in the GDG consideration, the scope remit does not include treatment for IE
31.2	Healthcare Commission	3.d		Is there controversy? I have never heard it suggested that those with structural defects should not take antibiotics, nor that the danger of taking these might outweigh the benefits. The American Heart Association and European equivalent guidelines all promote the use of antibiotics in any situation where dental treatment might cause gingival bleeding.	Thank you, the AHA guidelines and European and UK equivalents are now not consistent in their recommendations outside the area of dental treatment that might cause gingival bleeding
31.3	Healthcare Commission	4.1.1		Need to define what structural cardiac defect covers. Clearly it will encompass all congenital defects. However isolated atrial septal defects are know not to suffer from IE and are generally excluded from treatment. Coarctation of the aorta, which is not really a cardiac defect, is generally included. What about after treatment. At what point following successful surgery or interventional device placement does one come out from needing cover. One would include an abnormal valve and its treatment by a prosthetic valve, which will always need treatment. However, what about patients who have minimal amount of mitral regurgitation who might actually need prophylaxis. Following surgery to repair a valve lesion, will these need cover? Finally, with the placement of increasing numbers of stents in coronary arteries, should these require treatment?	Thank you, structural cardiac defects will be defined in the guideline following consideration of the evidence and the GDG assessment of which defects are considered to be risk factors for the development of IE
31.4	Healthcare Commission	4.3.b		Would suggest adding “any operation where the skin is cut or traumatised”. There is a belief that anyone undergoing “clean” surgery (e.g. joint surgery) should have antibiotics if they have a structural cardiac defect. This would include body piercing (the single most important question to teenagers living with a congenital condition)	Thank you. Your comments have been noted, however this is outside the remit of the scope, it will not be possible in this guideline to cover all procedures which have been connected with endocarditis

					Body piercing is not included in the interventional procedures as it is not an NHS procedure, the scope does include information needs and advice regarding body piercing and tattooing that involves damage to mucosal tissue
31.5	Healthcare Commission	4.3.d		I can understand not wanting to specify duration, but I suspect most dentists, GP's, patients and parents would like clear guidance or whether a single shot is sufficient or whether there should be a second treatment after the intervention.	This is noted. However, the guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s). The developers recognise the need for national prescribing guidance on this topic to address these areas and will therefore be liaising with the British National Formulary (BNF) to ensure that it uses the guideline recommendations as the basis for its own detailed recommendations on the route of administration, timing and duration of antibiotic and antibiotic regimens for prophylaxis against infective endocarditis. It is intended that this is progressed so that BNF 55, which is published in March 2008, offers these up-to-date regimens
31.6	Healthcare Commission	4.4		Consider adding "treatment of IE necessitating hospital admission", "requirement for open heart surgery" and possibly "stroke or other embolic event".	The scope will address morbidity as an outcome measure, and this has been added.
32	Heatherwood and Wexham Park Hospitals Trust			This organisation was approached but did not respond	
33	Home Office			This organisation was approached but did not respond	
34	Institute of Biomedical Science			This organisation was approached but did not respond	
35	Medicines and Healthcare Products Regulatory Agency (MHRA)			This organisation was approached but did not respond	
36	Mid Essex Hospitals NHS Trust			This organisation was approached but did not respond	
37	National Patients Safety Agency			This organisation was approached but did not respond	
38	National Public Health Service – Wales			This organisation was approached but did not respond	

39	National Treatment Agency for Substance Misuse			This organisation was approached but did not respond	
40	Neonatal & Paediatric Pharmacists Group (NPPG)			This organisation was approached but did not respond	
41	Newcastle Upon Tyne Hospitals NHS Foundation Trust			This organisation was approached but did not respond	
42	NHS Health and Social Care Information Centre			This organisation was approached but did not respond	
43	NHS Plus			This organisation was approached but did not respond	
44	NHS Quality Improvement Scotland			This organisation was approached but did not respond	
45	OCD Today			This organisation was approached but did not respond	
46	Papworth Hospital NHS Trust			This organisation was approached but did not respond	
47	PERIGON Healthcare Ltd			This organisation was approached but did not respond	
48	Phoenix Partnership			This organisation was approached but did not respond	
49	Regional Public Health			This organisation was approached but did not respond	
50	Royal College of Nursing	General		With a membership of over 395,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The Royal College of Nursing welcomes proposals to develop this guidance.	Thank you
51	Royal Brompton and Harefield NHS Trust	General		Our current practice is to advise antibiotic prophylaxis given at the time of the following procedures for most children with congenital or acquired heart disease including those who have had 'corrective' surgery or 'curative' therapeutic cardiac catheterisation: • Dental extractions or other extensive dental work. • Endoscopic procedures. • Any surgery involving suturing or manipulation of the mouth and pharynx • Piercings (but without ever having seen a case of endocarditis resulting from piercing). • Patients at risk who have boils, infected eczema, impetigo or other	Thank you for this information

				severe bacterial skin infection. The exceptions are the following malformations and conditions: • Isolated pulmonary stenosis (infundibular,valvar,supravalve and peripheral) • Secundum ASD, sinus venosus ASD, coronary sinus ASD (but NOT primum ASD) • Followind surgical or transcatheter closure of PDA and ASD (excluding primum defects) • Following surgical repair of isolated total anomalous pulmonary venous drainage • Dilated cardiomyopthy without mitral regurgitation • Kawasaki disease It may be possible to refine this list and certainly it is much more productive to have a list of those conditions and situations where endocarditis prophylaxis is not required. Hope this is helpful. The guidelines of the American Heart Association are very good and an excellent basis for discussion. The paediatric BNF seems to have dealt with the topic appallingly unless I failed to find the relevant section some months ago.	
51.1	Royal Brompton and Harefield NHS Trust	4.3a		Lesions with increased risk of IE: ventricular septal defect, aortic stenosis (including valvar, subvalvar and supravalvar), tetralogy of Fallot and variants, any single ventricle physiology, Ebstein's malformation of the tricuspid valve, persistent arterial duct, congenital mitral stenosis, any rheumatic heart disease, any left sided valvar regurgitation, coronary artery fistula, any patient after valve replacement, any patient after intracardiac surgical repair but not atrial septal defect, any patient after insertion systemic to pulmonary artery shunt, any patient after insertion conduit, transposition of the great arteries post repair.	Thank you for this information, the evidence related to cardiac defects and increased risk of IE will be reviewed for this guideline
51.2	Royal Brompton and Harefield NHS Trust	4.3b		Interventional procedures: dental procedures leading to gingival bleeding, genitourinary procedures, upper and lower GI tract surgery, insertion devices including pacing wires into the heart and great vessels.	Thank you for this information, the evidence related to interventional procedures and increased risk of IE will be reviewed for this guideline. It is, however, not possible for this guideline to address all groups of interventional procedures. The sites covered include all those important groups for which AB prophylaxis should be considered, including: dental procedures leading to gingival bleeding, genitourinary procedures, upper and lower GI tract surgery
51.3	Royal Brompton and Harefield NHS Trust	4.3c		As per current BNF regimen.	Thank you

52	Royal College of Midwives	4.1.1 a)		Please could this section make explicit that the guideline covers pregnant and childbearing women.	Thank you, this guideline covers adults with known underlying cardiac defects, which includes women of childbearing age.
52.1	Royal College of Midwives	4.3 b)		The College is glad to see that the clinical management of childbirth will be included in the scope of this guideline.	Thank you, childbirth will be considered as an obstetric procedure in relation to prophylaxis for IE, specifically the clinical management of childbirth will not be included
52.2	Royal College of Midwives	General		The College welcomes the development of this guideline as women experience contradictory advice from dentists and cardiologists on the use of prophylaxis for infective endocarditis.	Thank you
53	Royal College of Paediatrics and Child Health			This organisation was approached but did not respond	
54	Royal College of Pathologists			This organisation was approached but did not respond	
55	Royal College of Physicians of London			This organisation was approached but did not respond	
56	Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond	
57	Sheffield PCT			This organisation was approached but did not respond	
58	Sheffield Teaching Hospitals NHS Foundation Trust			This organisation was approached but did not respond	
59	Social Care Institute for Excellence (SCIE)			This organisation was approached but did not respond	
60	Specialist Advisory Committee on Antimicrobial Resistance (SACAR)			This organisation was approached but did not respond	
61	UK Clinical Pharmacy Association			This organisation was approached but did not respond	
62	University Hospital Birmingham			This organisation was approached but did not respond	
63	University Hospital Birmingham NHS Trust			This organisation was approached but did not respond	
64	University of North Tees and Hartlepool NHS Trust			This organisation was approached but did not respond	
65	Welsh Assembly Government			This organisation responded and said that it has no comments to make	
66	Welsh Scientific Advisory Committee (WSAC)			This organisation was approached but did not respond	

67	Western Cheshire PCT			This organisation was approached but did not respond	
68	York NHS Trust			This organisation was approached but did not respond	