National Institute for Health and Clinical Excellence

Headaches: scope consultation

Scope Consultation Table

13 August 2010 – 10 September 2010

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Airedale NHS Foundation Trust	1	General	The feeling at Airedale is that this scope is an appropriate basis for developing the guideline.	Thank you for your comment.
SH	Association of British Neurologist The National Hospital for Neurology and Neurosurgery	5	General	The scope document states that the guideline recommendations will fall within the licensed indications and only exceptionally will unlicensed treatments be recommended. This may pose difficulties as very few drugs used in headache disorders are specifically licensed for headaches.	Thank you for your comment. This statement is a standard statement included in NICE guidelines. However, if good evidence exists for unlicensed treatments these treatments will be included in the review of evidence.
SH	British Pain Society	1	General	The British Pain Society would like to welcome the selection of headache as a suitable topic for a guideline as it is a cause of significant morbidity.	Thank you for your comment.
SH	Department of Health	1	General	The Department of Health has no comments to make, regarding this consultation	Thank you for your comment.
NICE	NICE- Interventional Procedures	1	General	The NICE Interventional Procedures Programme have looked at this scope and do not see any apparent areas of overlap in this scope with the IP programme. For information, the IP Advisory Committee are currently considering the percutaneous closure of patent foramen ovale for recurrent	Thank you for your comment and information.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				migraine (IP812) and deep brain stimulation for intractable trigeminal autonomic cephalalgias (IP895). However, these do not appear to be covered in section 4.3.1 f) of the scope which lists the non-pharmacological interventions which this guideline will cover.	
SH	Pain Concern	2	General	In our experience this wording will cause problems with patients. It raises a suspicion that the doctors don't understand, and that something may have been overlooked. It may trigger the demand for needless investigations (privately if the NHS doesn't pay). There is all the worry and stress that this causes. It will cause embarrassment when explaining your condition to family and friends. Chronic pain has been recognised as a condition in its own right by the Scottish government and the chief medical officer's report "In Pain :Breaking through the Barrier" (Sir Liam Donaldson, 2009) also highlights the importance to patients and the health service of recognising chronic pain as a condition. SIGN used the term chronic daily headache which is acceptable to patients. I understand that NICE may not want to use this term but if another term is adopted it should be one that does not add to the stress of this distressing condition.	Thank you for your comment. We have removed the wording used in the draft scope to describe headaches that have characteristics of more than one headache type or are difficult to classify. We have not finalised the wording we will use but will work with the Guideline Development Group to finalise wording. We have included a narrative comment to say that we will include these patients. The feedback at the stakeholder workshop was that useful advice can be provided for these patients.
SH	Pain Concern	3	GENERAL	Headaches and migraine as a big problem so Pain Concern is delighted that NICE is developing guidance.	Thank you for your comment.
SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline. The draft scope seems comprehensive.	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Paediatrics and Child Health	1	General	This scope looks excellent. We are sure the guideline will be most useful and appreciated by clinicians at all levels.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	2	General	Anecdotal evidence supports that, due to time constraints, more and more patients are referred to secondary care clinic for opinion on one minor uncertainty. The guideline should consider, as an assessment option, phone discussion with a secondary care doctor which can resolve such minor issues by discussion rather than an appointment in secondary care out-patient clinic. This may take more time for primary and secondary care practitioners, but can save the patient time and the NHS money on a secondary care consultation.	Thank you for your comment. We hope that the guideline will increase the confidence of generalists in diagnosing headache and reduce unnecessary referral. The guideline will consider when referral to specialist is appropriate.
SH	Royal College of Paediatrics and Child Health	3	General	In general paediatrics (as well as for primary care doctors, and patients or parents), the crucial diagnostic dilemma is whether headaches are primary or secondary to a life threatening condition, particularly raised intracranial pressure due to a brain tumour. We think that the scope should give more emphasis on identification of warning symptoms and signs of an underlying condition and recommendations for imaging, with guidelines as to type of imaging and emergency time frame.	Thank you for your comment. We will signpost within point 4.3.1c characteristics of headaches that raise suspicion of serious underlying disease and require further investigation and referral. The detail of further investigation for secondary headache is not within the remit of the guideline.
SH	Royal College of Paediatrics and Child Health	4	General	We think the ways in which the sinister causes of headache (meningitis, subarachnoid hemorrhage, intracranial pressure) can be excluded should be covered; though the guideline concerns management of the primary non life threatening causes, this will be useful for the clinician.	Thank you for your comment. We will signpost characteristics of headaches that raise suspicion of serious underlying disease, however detail on investigations required are beyond the remit of this guideline.
SH	RPSGB	1	General	The RPSGB welcomes the development of these clinical guidelines.	Thank you for your comment .
SH	Society Of British Neurological Surgeons	2	General	The role of the GP in the management of Headaches is very important. However, indications for specialist referrals need	**Thank you for your comment. We will signpost characteristics of**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				to be clear. Also, the alerts for priority access to secondary and tertiary opinions are important. Likewise, access and indications for early imaging need to be defined clearly. There is an issue whether all headache syndromes should have brain imaging at least once however clear the clinical evidence indicates a primary headache cause.	**headaches that raise suspicion of serious underlying disease and require further investigation and referral.**We do expect the role of imaging in diagnosis of primary headache to be considered by the GDG.
SH	The Migraine Trust	3	General	There are existing headache guidelines such as SIGN or BASH	Thank you for your comment. We are aware of these existing guidelines and will consider them during guideline development. .
SH	Royal College of Nursing	2	1 and 2	Would it be better to have consistency with terminology? The age group is referred to as young people and then adolescents	Thank you for your comment. The term, adolescents was in the original remit from NICE and therefore cannot be changed in this statement. However, for the purposes of the rest of this guideline the term 'young people' was agreed as more appropriate for the age range covered.
SH	Royal College of Paediatrics and Child Health	5	1	The guideline is intended to address diagnosis and management of chronic headache, and we think this should be reflected in the title to avoid confusion with acute and transient headache.	Thank you for your comment. We agree and have received permission from the Department of Health to remove 'new onset' from the title. We will however still cover acute headaches in some circumstances.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	1	2	Our comments are as follows; if it is intended that the guideline should apply to medical generalists and non-specialists in headache, and not to specialists in headache	Thank you for your comment. The guidelines are intended to be used by both the generalist and specialist

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				management, this should be made explicit. We take the view that the guideline should be intended to apply to the management of headache in primary care and non-specialist settings.	settings. Whilst they may be most applicable to generalists, it is not expected that specialists would be working outside of NICE guidelines if the recommendations are appropriate for the patient and clinical problem.
SH	Headache Clinics UK	1	2	Our comments are as follows …The remit states 'new onset', this would appear to exclude any chronic problems that a patient may be presenting with for the first time. Should it perhaps say 'first time presentation' or similar to clarify scope?	Thank you for your comment. We agree and have received permission from the Department of Health to remove 'new onset' from the title.
SH	Allergan Ltd	1	3.1	The disability associated with a day of migraine has been recognised by the World Health Organization as being part of the same class of disability as active psychosis, dementia, and quadriplegia, and being more disabling than blindness, paraplegia, severe depression, or rheumatoid arthritis (Harwood RH et al. Bull World Health Org 2004;82:251–8). This would add additional background to the level of understanding with respect to the disability experienced during attacks by migraine patients.	Thank you for this additional information. The majority of this information will be within the main guideline introduction where this will be useful to include.
SH	Allergan Ltd	2	3.1	The current scope does not establish the prevalence of the different diagnoses of primary headaches which will be covered by the guideline (as presented in sections 4.3.1. a, b & c of the scope). This information should be provided to illustrate the size of the population relative to each of the primary headache diagnoses, and therefore guide healthcare professionals (specifically General Practitioners) of the likelihood of a patient presenting with a specific primary headache diagnosis.	Thank you for your comment. We agree that this would be useful information to include, however this would be most appropriate for the guideline introduction so that the scope remains brief.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Faculty of Occupational Medicine	1	3.1	One important aspect is fitness for work – particularly whilst investigations are being planned or are ongoing. Most patients should be fit, depending on the severity of the headache, its likelihood of causing distraction and thus safety issues, and the effects of the medication.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	6	3.1 b)	We think that more types of headaches that are commonly found in the community setting should be included, such as sinus headache, allergy headache, headache due to dental problems .	Thank you for your comment. Whilst we recognise the importance of these common headache types, we are unable to include their management as the focus is on management of primary headaches.
SH	Society Of British Neurological Surgeons	1	3.1 b)	Include intracranial haemorrhage as a cause of secondary headache	Thank you for your comment. The list included in 3.1 (b) is not intended to be comprehensive and are examples only.
SH	College of Optometrists	1	3.2 a-d	There is widespread ignorance about the incidence and epidemiology both of common primary headaches and also secondary headaches. It would be useful to put hard figures to the relative incidence of both to aid primary care practitioners (including optometrists) in making a diagnosis. If primary care practitioners can be made more confident in their diagnosis this would make referral to secondary care less common.	Thank you for your comment. We agree that this would be useful information to include, however this would be most appropriate for the guideline introduction so that the scope remains brief.
SH	The Migraine Trust	1	3.2 c	Patients managing chronic headaches want an explanation from their doctor and not 'just' treatment	Thank you for your comment. We agree that this is important and will be included within the provision of information and support for patients and carers in 4.3.1g
SH	Joint Royal Colleges Ambulance	1	4.1	JRCALC welcomes guidance for children 12 years and over	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Liaison Committee (JRCALC)			as current national guidance on headaches (SIGN 107) makes no mention of management in this group.	
SH	British Paediatric Neurology Association	1	4.1.1	Need for guideline to include children 5-11 as well, or a separate guideline: still common in this age group	Thank you for your comment. NICE guideline for headaches in children will be developed separately. Information will appear on the NICE website when available.
SH	Children's Brain tumour Research Centre, university of Nottingham	1	4.1.1	Adolescent boys are a group that are particularly poor at accessing health care. Whilst primary headache is less common in this population I think they do merit consideration as to how to support their engagement with health care where appropriate. Brain tumours, whilst a rare secondary cause of headache for the whole population, are an important cause of persistent headache in adolescent males and therefore they should be encouraged to attend health care if symptomatic.	Thank you for your comment. We do agree that adolescent boys are an important population. We hope the guideline will raise awareness of headache but we are unable to address the issue of prompting groups to attend health care.
SH	College of Optometrists	2	4.1.1	It is not uncommon for teenagers and young girls in particular to attend for eye examinations with symptoms of headache. We recognise that these may be due to other factors, but they may also be due to minor refractive or ocular problems which are exaggerated by school work. Some guidance on how to manage these patients would be helpful.	Thank you for your comment. We recognise that this is an NHS setting in which headache patients are seen and the guidelines will help optometrists recognise primary headache and alert them to symptoms suggestive of underlying disorders.
SH	College of Optometrists	3	4.2 a)	It is quite common for patients to present to their optometrist complaining of headaches, often at the request of their General Practitioner. It is assumed that – as the scope says that 'all settings in which NHS care is received' will be covered, this will cover optometric practice.	Thank you for your comment. We recognise that this is an NHS setting in which headache patients are seen and the guidelines will be applicable in these settings as well.
SH	Faculty of Pain Medicine of	2	4.2	Our comments are as follows; the healthcare settings	Thank you for your comment. The

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	the Royal College of Anaesthetists		a)	covered should exclude specialist headache clinics.	guidelines are intended to be used by both the generalist and specialist settings. Whilst they may be most applicable to generalists, it is not expected that specialists would be working outside of NICE guidelines if the recommendations are appropriate for the patient and clinical problem.
SH	Headache Clinics UK	2	4.1.1 a	Our comments are as follows ..puberty rather than 12 years	Thank you for your comment. We recognise that puberty is an important factor in development of headache. NICE prefer a specific age rather than a term which could vary between individuals. We will include in the guideline consideration that young people of 12 may or may not have reached puberty.
SH	Headache Clinics UK	3	4.1.1 b	Our comments are as follows ….Why the particular consideration for women and girls? This already implies this is a target group and thus will limit critical thinking and research. We are all aware of the migraine issue in this group but this study is not simply about migraine. Surely the final guidelines based on research will identify the appropriate groups?	Thank you for your comment. The full population (aged 12 and over) will also be considered in this guideline. The guideline process requires groups which require specific consideration to be identified at the start of guideline development. The scoping process seeks to identify these groups. Women and girls are included within a separate subgroup as well due to the specific clinical needs of this population including treatment strategies during pregnancy, menstrual related migraines,

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					as well as the need for consideration when choosing contraceptive.
SH	Walton Centre NHS Foundation Trust	1	4.1.1	Why age 12? Would 16 be better as this is adult / paediatric cut off? I assume this is to include post menarche girls?	Thank you for your comment. Age 12 was decided as the most appropriate age to include post menarche girls as you suggest. However we recognise that people of 12 may or may not have reached puberty.
SH	British Paediatric Neurology Association	2	4.1.2	Need for guideline to include children 5-11 as well, or a separate guideline: still common in this age group	Thank you for your comment. A NICE guideline for headaches in children will be developed separately. Information will be available on the NICE website when available.
SH	Headache Clinics UK	4	4.1.2	Our comments are as follows ….See 3	Thank you for your comment, we have responded above.
SH	Royal College of Paediatrics and Child Health	7	4.1.2	The College notes that the covered age range (from age 12 years) is wide and potentially includes pre- to post- pubertal ages. It is important, where different approaches are needed for different ages, that this is identified in the guidance. If this guidance is principally adult-based, we suggest it be from age 14 years. We would like clarification on whether there is to be a separate guideline for headache management in children. (The College submitted a topic suggestion for this in 2009.) The needs of this group are different, but just as important, and a guideline would assist clinicians in the management of this group. It is important to demystify headache in young children and a guideline will make GPs and general	**Thank you for your comment. Age 12 was decided as the most appropriate age to include post menarche girls. However we recognise some will have reached puberty at a younger age, and some not yet reached puberty and will be aware of this when considering the evidence.**A NICE guideline for headaches in children will be developed separately.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				paediatricians at ease when treating younger children with headache.	
SH	RCGP	1	4.2	Health care setting NHS care is received in a number of health care settings and these should be specified i.e. primary care, secondary care and schools. NHS school nurses form the core of health care in the latter setting where the unmet need in this area is considerable.	Thank you for your comment. The intention is to cover the full variety of healthcare settings due to the wide prevalence of headaches amongst the population.
SH	College of Optometrists	4	4.3	It is quite common for patients to present to their optometrist complaining of headaches, often at the request of their General Practitioner. If GPs wish to use optometrists as a means of eliminating any ocular cause for headache then it would be helpful for them to have guidelines as to when the headaches may have an ocular cause. In these cases the patient should be advised to first consult their optometrist who can then advise or refer on to the GP. This would save at least one GP appointment for each patient.	Thank you for your comment. The GDG will provide guidance on diagnosis of primary headache and when investigation of secondary headaches should be considered.
SH	Allergan Ltd	3	4.3.1 b	The diagnosis of medication overuse headache (MOH) is a diagnosis of exclusion following a withdrawal strategy of acute medications. The scope should ensure that strategies for withdrawal management are an output of the guideline and cover whether the withdrawal/reduction should be abrupt and unassisted or facilitated by concurrent prophylaxis. Management of patients who have failed on withdrawal of acute medications and who thus require a change in diagnosis and management plan from the provisional	Thank you for your comment. We agree this is important and intend to focus on the management of medication overuse headache within 4.3.1h which we expect to include withdrawal strategies.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				diagnosis of MOH should also be encapsulated in the scope.	
SH	Allergan Ltd	4	4.3.1 e	BOTOX® is the only evidence-based botulinum toxin type A specifically licensed for prophylaxis of headaches in adults with Chronic Migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). It is important to note that Botulinum toxin units are not interchangeable from one product to another as per the Summary of Product Characteristics of all botulinum toxins.	Botulinum toxin is going through the NICE technology appraisals selection process and therefore will no longer be included within this scope
SH	Allergan Ltd	5	4.3.1 h	please refer to point 3 - section 4.3.1. b.	Thank you for your comment. We have responded where listed.
SH	Association of British Neurologist The National Hospital for Neurology and Neurosurgery	1	4.3.1 (a)	Consider changing "migraine with and without aura" to "EPISODIC migraine with and without aura" to distinguish these disorders from chronic migraine	Thank you for your comment. We agree this may be a useful way of distinguishing chronic headaches, however we are using the classifications provided by the International Classification of Headache Disorders
SH	Association of British Neurologist The National Hospital for Neurology and Neurosurgery	2	4.3.1 (a)	Consider removing chronic unclassifiable. The vast majority of chronic daily headache is classifiable. However, to consider unclassifiable, NICE will have to define the classifiable groups (eg paroxysmal hemicrania, SUNCT, hypnic headache, new daily persistent headache etc). This will inadvertently lead to extension of the scope to numerous rare syndromes	Thank you for your comment. We have removed the last two bullet points in 4.3.1a and reworded to clarify this point.
SH	Association of British Neurologist	3	4.3.1	Consider removing mixed headaches. There are several problems with the issue of "mixed headaches".	Thank you for your comment. We have removed the last two bullet points in

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	The National Hospital for Neurology and Neurosurgery		(a)	Firstly, it can refer to any combination of headaches (eg cluster headache and migraine) as the term is ambiguous. Secondly, while it is commonly used to refer to a combination of migraine and tension-type headache, there is controversy about this issue. Patients with a migrainous biology can have headaches that are phenotypically consistent with migraine and tension-type headache (tension type headache in this case being a mild variant of the usual migraine); there is evidence from epidemiology, biomarkers and treatments responses (eg to triptans) to back up this view. Thirdly, almost all the literature on "mixed headaches" is old without clear definitions of what was being studied and therefore will be difficult to assess. Finally, the vast majority of these patients need to be managed as having chronic migraine (which is much more disabling than tension-type headache) especially since the treatment options for tension-type headache are very limited; the treatments that are available for tension type headache are also effective for migraine. NICE looking at "mixed headaches" will generate a lot of work for little return in value.	4.3.1a and reworded to clarify this point. We will ask the Guideline Development Group to consider patients who have headaches with characteristics of more than one type and will finalise the wording using the expertise of the Guideline Group.
SH	Association of British Neurologist The National Hospital for Neurology and Neurosurgery	4	4.3.1 (d)	Could consider ergots in this section though they have largely fallen out of use and therefore reasonable to omit	Thank you for your comment. We will agree with the GDG whether ergot should be used as a comparator when assessing evidence for pharmacological treatments.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	British Paediatric Neurology Association	3	4.3.1 c	Specifically, when to request prompt neuroimaging (MRI) and urgent neuroimaging (CT) for tumours / pathology needing neurosurgical advice	Thank you for comment. We agree this is important. However, details on what investigations to undertake for secondary headaches are beyond the scope of this guideline.
SH	British Paediatric Neurology Association	4	4.3.1 e	Specify to include propranolol, and pizotifen	Thank you for your comment. The list of treatments in 4.3.1e has been modified to include these as specific examples.
SH	British Pain Society	2	4.3.1 A General	We would like to welcome the inclusion of a number of suggestions that we have put forward in forming the Scope. In particular we welcome the inclusion of mixed type headaches which has the potential to widen the scope of the guidelines.	Thank you for your comment. We have changed the wording in the scope as some stakeholders felt the term 'mixed headache' was not correct but have indicated that we will include patients whose headache have characteristics of more than one type.
SH	British Pain Society	3	4.3.1 A General	One of the problems with headache for clinicians is the myriad sub-varieties. The scope mentions three separate types of migraine all termed primary headache. Should the evidence suggest that they all require their own dedicated treatment algorithm this would make this a very complex guideline for practitioners to follow.	Thank you for your comment. We will work with NICE editors to make the guideline as clear as possible.
SH	British Pain Society	4	4.3.1 a	Does 'diagnosis' include recommendations about appropriate investigations when primary headache is being considered?	Thank you for your comment. Yes, diagnosis will include appropriate investigation.
SH	British Pain Society	5	4.1.3 f	We welcome the inclusion of a range of treatment approaches in addition to pharmacological interventions. We feel this is important as most successful treatment plans for headache will be muliti-dimensional	Thank you for your comment

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	College of Optometrists	5	4.3.1 a)	Does NICE also want to include headache caused by ocular problems (such as ocular muscle imbalance), uncorrected refractive error or the onset of presbyopia?	Thank you for your comment. The main focus of the guideline is the diagnosis and management of primary headache syndromes and not secondary headache. The appropriate diagnosis of primary headaches is included and the GDG may wish to refer to ocular headache.
SH	College of Optometrists	6	4.3.1 f)	Headaches caused by ocular muscle imbalance, uncorrected refractive error and presbyopia can be effectively managed by refractive means (either with prescription or prismatic correction in spectacles).	Thank you for your comment. However, as we will not be including management of secondary headache, we will not be including refractive management strategies.
SH	Faculty of Occupational Medicine	2	4.3.1	One important aspect is fitness for work – particularly whilst investigations are being planned or are ongoing. Most patients should be fit, depending on the severity of the headache, its likelihood of causing distraction and thus safety issues, and the effects of the medication.	Thank you for your comment.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	3	4.3.1 a)	Our comments are as follows; the term 'chronic daily headache' gives no indication of headache phenotype aside from frequency and does not inform management, and should not be included in the diagnosis list.	Thank you for your comment, however they relate to an earlier version of the scope. The term chronic daily headache was not included in the draft scope for consultation.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	4	4.3.1 a)	Our comments are as follows: the diagnosis of cervicogenic headache is not straightforward and it is almost certainly over-diagnosed. Clear diagnostic criteria are lacking.	Thank you for your comment. However, it appears to relate to an earlier version of the scope. Cervicogenic headache was not included in the draft scope for consultation
SH	Faculty of Pain Medicine of	5	4.3.1	Our comments are as follows; in ruling out other secondary	Thank you for your comment. We agree

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	the Royal College of Anaesthetists		a)	headaches, emphasis should be placed on diagnosis of secondary headache due to serious disease (e.g. intracranial space-occupying lesion).	that emphasis will be on characteristics that raise suspicion of serious disease.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	6	4.3.1 b)	Our comments are as follows; 'chronic daily headache' should be omitted for the reason previously given.	Thank you for your comment. However, it appears to relate to an earlier version of the scope. The term chronic daily headache was not included in the draft scope for consultation.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	7	4.3.1 b)	Our comments are as follows: the use of verapamil is prophylactic and it should be omitted from this list.	Thank you for your comment. However, it appears to relate to an earlier version of the draft scope. Verapamil was not included within acute treatments in the draft scope for consultation.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	8	4.3.1 c)	Our comments are as follows; 'chronic daily headache' should be omitted.	Thank you for your comment, however they relate to an earlier version of the scope. The term chronic daily headache was not included in the draft scope for consultation.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	9	4.3.1 c)	Our comments are as follows; we consider that the list of drugs is too broad for the non-specialist (methysergide and botulinum toxin, and arguably the anti-epileptics, should be used under the guidance of a specialist) and too restrictive for the specialist.	Thank you for your comment. However, it appears to relate to an earlier version of the draft scope.
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	11	4.3.1 e)	Our comments are as follows; craniofacial local anaesthetic nerve blocks should be evaluated in addition to the other listed non-pharmacological management options.	Thank you for your suggestion. We have not added craniofacial nerve blocks to the scope as these will not be delivered by a generalist or in a generalist setting which is the focus of the guideline.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	General Chiropractic Council	1	4.3.1 a	This does not include cervicogenic headache and we do not oppose this.	Thank you for your comment.
SH	General Chiropractic Council	2	4.3.1 a	Psychosocial factors are also a key clinical issue	Thank you for your comments. These will be included within 4.3.1f
SH	General Chiropractic Council	3	4.3.1 f	Manual therapies are included in the nonpharmaceutical therapies for assessment and we support this. There are good quality trials and well structured systematic reviews available.	Thank you for your comment.
SH	Headache Clinics UK	5	4.3.1	Our comments are as follows …Use of term 'mixed type? This is too broad and not in the ICHD list. Correct diagnosis would highlight the main headache type and the 'mix' if it exists. Inclusion of cervicogenic headache (but note in comments from workshop, management to limited to a 'specialist'. His needs defining as a manipulative specialist to avoid confusion) The inclusion of chronic conditions would appear to conflict with new onset. See 1 above	Thank you for your comment. We have changed the terminology and removed 'mixed type'. We agree and have received approval from the Department of Health to remove 'new onset' from the remit.
SH	Headache Clinics UK	6	4.3.1 d	Our comments are as follows ….Oxygen should be removed	Thank you for your comment. We do not agree that oxygen should be removed as it is used as an acute treatment for cluster headaches and guidance is required.
SH	Headache Clinics UK	7	4.3.1 f	Our comments are as follows …. Why is the title not the same in 4.3.1 (d), (e) and (f) ? Is this study biased towards medication? The title 4.3.1 (f) should be as in (d) and (e). I.e. 'treatment of headache types specified in 4.3.1a with:….	Thank you for pointing this out. Apologies for this inconsistency in sub-titles. The wording of 4.3.1f has been updated to remain consistent with the

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Imaging should probably be placed in diagnosis section and not non pharmacological management Note: Oxygen seems to have moved from 4.3.1 (d) to 4.3.1 (e) which should be (f) to be consistent with scoping document.	pharmacological treatment wording. There is some evidence to suggest that imaging can reduce anxiety and healthcare use in chronic headaches which is why this is included within management. However, we do expect that it will also be considered within diagnosis. Oxygen is intended to be considered as an acute treatment strategy for cluster headaches. It is within the pharmacological treatment section as it is prescribed.
SH	Joint Royal Colleges Ambulance Liaison Committee (JRCALC)	2	4.3.1	JRCALC would welcome further guidance on the approach to triage and transfer to ED for secondary HA for children/young people.	Thank you for your comment.
SH	Pain Concern	1	4.3.1 A	Heachaches unclassifiable	Thank you for your comment. Unclassifiable headaches have been removed from the list in 4.3.1a and this reworded to clarify.
SH	Royal College of Nursing	3	4.3.1 f	Within the non-pharmacological management options, imaging is listed, is it in the right place?	Thank you for your comment. There is some evidence to suggest that imaging can reduce anxiety and healthcare use in chronic headaches which is why this is included within management. However, we do expect that it will also be considered within diagnosis.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Nursing	4	4.3.1 f	Should early psychological triggers be included? Lifestyle could include identifying early trauma or learned behaviour	Thank you for your comment. We expect that early psychological triggers may be included in psychological interventions.
SH	Royal College of Nursing	5	4.3.1 f	Could include CBT	Thank you for your comment. It was intended that CBT will be covered within psychological therapies, we have added it as an example in the scope.
SH	Royal College of Paediatrics and Child Health	8	4.3.1	We think this should include recommendation to maintain a diary for recurrent headaches; a record of the type and duration of headache will help the patient as well as the clinician.	Thank you for your comment. We agree diaries may play a role in headache diagnosis and may be considered within this section. The GDG members will decide how to incorporate this.
SH	RCGP	2	4.3.1 a	Clinical issues - diagnosis of the following primary headaches. This list lacks rigor. For example, why just chose hemicrania continua and exclude paroxysmal hemicrania? Chronic and classifiable headache does not fit into this schema and is not a recognised headache classification.	Thank you for your comments. We have removed hemicrania continue from the scope. Unclassifiable headache has also been removed and this point clarified. The other headache types stated are all within the International Classification of Headache Disorders.
SH	Royal College of Paediatrics and Child Health	9	4.3.1 c)	The scope looks at characteristics of secondary headaches but 4.3.2 b) says guidance will not cover "investigation and management of secondary headache…". We would like clarification on what detail will be provided about secondary headaches in the guideline. We suggest it cover 'red flag' symptoms or signs for which different action needed (e.g. referral to secondary care) and also indicate urgency for this (if symptom suspicious of brain tumour then urgent referral needed).	Thank you for your comment. The guidance will signpost characteristics of headaches that raise suspicion of serious underlying disease and require further investigation and referral.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	RCGP	3	4.3.1 e	Angiotensin II receptor antagonists should be included if ACE inhibitors are to be considered. For example, Candesartan is widely used on the Continent.	Thank you for your comment. We have added Angiotensin II receptor antagonists to point 4.3.1e
SH	Royal College of Paediatrics and Child Health	10	4.3.1 f)	We think that BP measurement could be included here. It will be of immense value as clinicians will not then miss hypertension as the cause of headache; it will also help in screening for hypertension.	Thank you for your comment. We do not wish to specify at this stage the detail of assessment that health care professionals will perform to diagnose primary headache and exclude secondary headache.
SH	RCGP	4	4.3.2 f	Imaging is defined as a non-pharmacological management of primary headache and use as a treatment is inferred. Imaging is not a treatment for headache and should be removed from this section and considered under 4.3.1c - characteristics of secondary headaches that require specific investigation and management. It would also be useful to consider whether MRI or CT is the modality of choice.	Thank you for your comment. There is some evidence to suggest that imaging can reduce anxiety and healthcare use in chronic headaches which is why this is included within management. However, it will also be considered within diagnosis.
SH	The Migraine Trust	2	4.3.1	The list of headaches seems arbitrary – for example hemicrania continua is a rare primary headache	Thank you for your comment. We have removed hemicrania continue from the scope.
SH	Walton Centre NHS Foundation Trust	2	4.3.1 a	I am not sure what "mixed" headaches are. I would definitely include "new persistent daily headache" including low CSF pressure headache as this is a regular cause of undiagnosed chronic daily headaches. NDPH is a very difficult management area.	Thank you for your comment. We have removed the term 'mixed' headache. The headaches we have listed are those where diagnosis and management is possible in generalist setting. We will indicate if patients require more

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					specialist advice.
SH	Walton Centre NHS Foundation Trust	3	4.3.1 e	I would include bo tox as it will be highly contentious.	Thank you for your comment. However, botulinum toxin is now going through the NICE technology appraisals selection process and will therefore not be included in this scope.
SH	College of Emergency Medicine	1	4.3.2 b)	It is important that patients presenting with secondary headache due to serious underlying pathology requiring urgent investigation and treatment eg. subarachnoid haemorrhage, meningitis, are not missed and the scope should define 'red flag' symptoms and which immediate investigations are recommended e.g. CT brain, LP etc. Therefore I would suggest that this section should be 'investigation of secondary headache other than medication overuse headache ***and headaches with 'red flag' features requiring urgent investigation'.***	Thank you for your comment. The management of secondary headaches is beyond the remit of the guideline. Signposting of those that may be related to serious underlying disease and require specific investigations will be covered within 4.3.1c.
SH	Allergan Ltd	6	4.4 b	Indirect costs (including productivity costs) represents a large part of the costs associated with migraine attacks. The All-Party Parliamentary Group on Primary Headache Disorders (APPGPHD) established that migraine leads to 100,000 people missing work or school every working day, a huge loss of time and productivity (Headache Disorders -not respected, not resourced – report of the APPGPHD, 2010). "Days lost from usual activity" should cover days lost from work (productivity losses). Productivity in the Workplace is often assessed using the Migraine Disability Assessment Questionnaire (MIDAS) which is a 7-item measure of headache-related disability in the previous 3 months (Stewart	Thank you for your comments. The Migraine Disability Assessment test is included as one of our stated possible outcomes and therefore this will be covered as suggested. Specific questionnaires to be used within the outcomes will be decided by the GDG members.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				et al. 2001, Stewart et al. 1999a, Stewart et al. 1999b, Fragoso 2002). Using this questionnaire, appropriate data on productivity will be assessed and thus should be included in the list of outcome measures relevant for this population.	
SH	Allergan Ltd	7	4.4 c	Disease-specific patient reported outcome measures should be added to the generic HRQoL questionnaires, as they are more sensitive to change in HRQoL and disability due to migraine / headaches. The Migraine Specific Questionnaire (MSQ v2.1) measures how migraines affect and/or limit daily performance (Jhingran et al. 1998). The MSQ has provided valid and reliable evidence in a wide range of migraine patients, including both episodic migraine and chronic daily headache patients (Jhingran et al. 1998b, Pathak et al. 1998, Martin et al. 2000, Cole et al. 2007). The Headache Impact Test (HIT-6) is widely used to measure disability amongst various headache diagnoses and is used for screening and monitoring patients in clinical research and practice (Kosinski et al., 2003).	Thank you for this helpful information. The outcomes listed are examples suggested for questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review. The guideline development group will finalise the list and we will include these in the options that we will consider.
SH	Allergan Ltd	8	4.4 e	"Medication overuse headache" is a diagnosis as opposed to an outcome. This section needs to be clarified to list the type of outcomes relevant to MOH management. The goal of managing MOH is not only to detoxify the patients and stop the chronic headache but also to improve responsiveness to acute or prophylactic drugs. In this context the following	Thank you for your comment. The intention is to seek information on the onset / prevalence / reduction etc. of medication overuse headache as relevant depending on whether the question relates to MOH or another

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				outcomes need to be considered: reduction in headache days , reduction in acute medication consumption and days on which acute medication is used. (Evers et al, The lancet Neurology 2010).	headache type.
SH	Allergan Ltd	9	4.4 f	Resource use outcomes should include GP consultations, Specialist visits (Neurologist and other Headache specialist), A&E attendance, diagnostic tests (conducted either in primary or secondary setting), hospitalisations (including length of stay), and any treatment specifically used for headache (both over the counter and prescription medications).	Thank you for your comment. It is intended that resource use will cover all NHS resources used.
SH	Royal College of Paediatrics and Child Health	11	4.4	The scope seems mainly to assess subjective relief from pain and cost effectiveness of medical treatment of primary headache. We think that the outcomes should include related morbidity and mortality possibly due to missed or late diagnosis of secondary headache.	Thank you for your comment. The outcomes listed are those that are suggested for questions that we expect the guideline to answer. The list is not exhaustive and the Guideline Development Group will have the opportunity to amend the list.
SH	Headache Clinics UK	8	4.4	Our comments are as follows ….Priority B, A, C, D , G, E, F (from notes)	Thank you for your comments. We have responded to each individually.
SH	Children's Brain tumour Research Centre, university of Nottingham	2	4.4	This guidance should have two aims: 1: to avoid unnecessary investigation and ensure appropriate treatment in people with primary headache AND 2: to ensure people with a secondary headache are recognised and treated promptly. Both these outcomes need to be measured in order to determine the efficacy of the guideline. Outcomes measures therefore should include the numbers of young people and adults who	Thank you for your comment. The outcomes listed are those that are suggested for questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review. The outcomes listed are not those that will be required to

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				are recognised to have a secondary cause of headache and are appropriately investigated and the numbers who are inappropriately diagnosed with a primary headache and therefore experience a delay in the diagnosis of their secondary headache.	assess the efficacy of the guideline.
SH	Headache Clinics UK	9	4.5	Our comments are as follows ….Unnecessary secondary care referrals contribute a large cost and thus approaches to reduce these should be explored The study should examine the current NHS pathways and increase appropriate low cost – high effectiveness approaches	Thank your for your comment. The Guideline group will be required to prioritise the questions for health economic analysis. We do expect that costs of referral and investigation are likely to be included in health economic analysis.
SH	Royal College of Paediatrics and Child Health	12	4.5	We note that economic costing may also include hidden costs for parents losing time off work to collect children with headache from school or stay with them at home over a period of time. Educational loss may also influence future earning potential for the child with headache.	Thank you for your comments. Whilst we note this as an important personal cost, these guidelines will be from the NHS perspective and therefore only costs borne by the NHS will be formally included in the guideline.
SH	RPSGB	2	5.2	The RPSGB would wish to include the management of minor ailments in this section in addition to 'Over-the-counter drug usage'	Thank you for your comment. We do not think the addition of management of minor ailments is appropriate in this section.