National Institute for Health and Clinical Excellence

Sedation in infants, children and young people: scope consultation

Scope Consultation Table

11 July 2008 – 8 August 2008

Type	Order No	Stakeholder	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	1	Advisory Committee for Community Dentistry in the Faculty of Dental Surgery	4.1.1 b)	ACCD agree that it is important to define different sedation recommendations for different age groups in the population	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	2	Advisory Committee for Community Dentistry in the Faculty of Dental Surgery	4.1.2 a)	ACCD consider it a pity that sedation before GA is planned to be excluded as many children prior to a dental GA may be given this, as may children with disabilities or behavioural problems. Anaesthetists vary as to what drugs and amounts they may use for pre GA sedation. This makes it difficult for Oral Surgeons and Dentists to give reliable guidance to parents and carers prior to their children's attendance. If this were included in the Guideline then there might be a more specific recommendations over what, when and how to use pre GA sedation making advice before the event more reliably possible.	Thank you for your comments, unfortunately this is outside of the original topic referral from the Department of Health.
SH	3	Advisory Committee for Community Dentistry in the Faculty of Dental Surgery	4.2 b)	ACCD agree that it is important to look at Healthcare settings but also thinks that the training of dentists and dental nurses is important too. This point came up in the discussion at the stakeholders meeting when discussion on the scope of the guideline was considered. Recommendations for this would be useful. ACCD consider it is also important, in fact essential, that the Guideline does not remove the opportunity for children to be acclimatised to dental treatment in a primary care setting by using Inhalation Sedation	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	1	Association of Catholic	general	This draft consultation makes no reference to neonates who should be	Thank you for your comments.

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		Nurses in England and Wales		included to ensure that they are provided with the same dignity and rights as other infants and children. The report of a study by Carbajal et al. on 'Neonates in Intensive Care Endure Painful Procedures, Mostly Without Analgesia 'released July 2008 available on http://www.sciencedaily.com/releases/2008/07/080701165057.htm informs us that 'repeated and prolonged exposure to pain alters a neonate's subsequent pain processing, long-term development, and □esponsib' . All traumatic experience in childhood affects long term psychological development and can contribute to later psychopathology producing relationship difficulties with others and poor ability to cope with stress within a range of other painful situations. Children are particularly vulnerable because they cannot effectively express their own needs or pain or discomfort particularly if they are unwell. No baby or child should be left suffering unnecessarily in terminal stages or in other therapeutic or diagnostic situations. However any decision to change or develop practice around administration of a general anaesthetic or sedation in babies ,infants , children and young people should be informed by current research studies. Malviya,Voepal-Lewis et al 1997 http://bja.oxfordjournals.org/cgi/content/abstract/84/6/743 have suggested general anaesthesia can produce better results than sedation .The more recent study by Machata et al. 2008 http://bja.oxfordjournals.org/cgi/content/abstract/101/2/239 informs us that there are improved results with Profonol based sedation. No form of sedation or anaesthesia is without some risk but there is also an ethical duty to prevent unnecessary pain and suffering in all babies children and young people as there is with adults, particularly vulnerable adults .Professionals have an additional ethical □esponsibility to ensure that they do not introduce or exacerbate existing pain through inadequate or inappropriate methods of anaesthesia or sedation.	The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.

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SH	1	Association of Paediatric Anaesthetists	general	In the discussion of the proposed scope of the guideline, I noted that it did not contain any reference to **training and credentialing**. This has been a major issue in the past and one which I think the guideline should address. The reason for this, as you explained, is that sedation is a spectrum going from anxiolysis through conscious sedation and deep sedation to full anaesthesia. When some intravenous agents are used (e.g. propofol) the boundary between deep sedation to anaesthesia is easily crossed resulting in accidental anaesthesia. Anaesthesia is a condition of deep unconsciousness in which protective airway and other reflexes are lost and there can be profound cardiovascular changes, notably hypotension. It is universally acknowledged that the management of anaesthesia requires specialist skills which most other physicians and surgeons would not normally have acquired in their training. It is necessary therefore to specify, as indicated in recent review of US sedation practice: a) which specialists can or cannot induce which levels of sedation; b) provide standardized and detailed requirements for specific drugs; c) define the minimum requirements for initial and ongoing credentialling.[1] I would be grateful if the GDG would consider these points when re-drafting the scope of the guideline.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	1	British Association for the Study of Community Dentistry	general	BASCD is a multi-faceted organisation with a wide membership from all countries in the United Kingdom and Ireland and provides a learning and research forum for all aspects of public health and oral health improvement. BASCD's work involves interaction and collaboration with other agencies and societies with similar aims: to improve oral health, address inequalities in oral health experience and improve the quality, safety and effectiveness of services. Although oral health has steadily improved in the UK many young children experience dental decay. The disease is most prevalent in	Thank you for your comments and willingness for continued engagement.

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				disadvantaged children reflecting deprivation and poor diets. The consequence of this is that many children experience pain and require treatment such as extraction and/or restoration of deciduous and permanent teeth. These procedures can, wherever possible, be provided using local anaesthesia but for many young children and young people anxiety and/or the complexity of procedure make the use of sedation a useful adjunct to dental care. While Members of BASCD and others continue to strive to prevent this disease it is imperative that an effective adjunct for clinical dentistry, such as sedation is delivered safely and effectively. We wish the Review Team well and would be willing, as an organisation, to contribute actively or comment further.	
SH	4	British Association for the Study of Community Dentistry	2 e)	We note in paragraph 2(e) the reference to 3 levels of sedation. In dentistry there is clear guidance that deep sedation should not be practised in a primary care setting. Even in a hospital setting our experience is that many anaesthetists opt for full anaesthesia rather than deep sedation.	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard definitions.
SH	5	British Association for the Study of Community Dentistry	3 b)	Sedation is cited as being "commonly used in dental practice where the use of general anaesthesia is now restricted to the hospital setting". Sedation was delivered in addition to procedures requiring a general anaesthetic prior to any restrictions and its use has increased in dentistry in primary care since.	Thank you for your comments.
SH	6	British Association for the Study of Community Dentistry	3 f)	With reference to inhalation sedation the issues of gas scavenging and health and safety issues related to inadvertent exposure of the operators should be addressed.	Thank you for your comments.
SH	7	British Association for the Study of Community Dentistry	3 h)	With reference to intravenous administration reference to uses of bolus versus continuously titrated administration should be included.	Thank you for your comments. The developers will review the evidence relating to/discuss both dosage of drugs and routes of administration.
SH	8	British Association for the Study of Community Dentistry	3 i)	One challenge in dentistry is the need for shared use of the airway. This may present risks, particularly in the case of deep sedation, which mean such practice, while safe in other areas of medical practice is	Thank you for your helpful comments. Adverse events and the safety of procedures

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				not appropriate to dentistry. We would expect that such clinical issues would be addressed in the final report.	recommended will feature in the development of guidance.
SH	9	British Association for the Study of Community Dentistry	4.1.1 a)	We welcome the intention to make the guidance age specific. For example in dentistry there is considerable debate as to when it is appropriate to offer intravenous sedation as an option in addition to inhalation sedation. It may be necessary to consider body mass in such guidance as well as the actual age of the child. We believe the scope should include guidance on appropriate routes of administration. This is particularly appropriate in the case of midazolam where we know that both intravenous, and mucosal routes, both nasal and intraoral, are used.	Thank you for your comments, routes of administration will also be considered.
SH	10	British Association for the Study of Community Dentistry	4.2 b)	Primary care including dental general practice settings, dental practice sitting in primary care should include Primary Care Trust Dental Services settings as the majority of vulnerable children and sedations are provided by a group of salaried dental clinicians. The scope of the health care setting should be expanded to include these directly provided Trust Dental Services.	Thank you for your comments. This is currently within the scope of this guideline.
SH	11	British Association for the Study of Community Dentistry	4.3 b)	It is important that any sedation is delivered as part of an overall care pathway, which includes preventive care. It is also to assess and reduce inequalities in access to care are considered as part of the guidelines. Need should encompass a risk assessment of the medical history, anxiety and complexity of procedure to be undertaken.	Thank you for your comments. The GDG will consider this.
SH	12	British Association for the Study of Community Dentistry	4.3 c)	With reference to equipment requirements, we would welcome recommendations regarding maintenance. We are aware for example in dentistry that different practice is operated by different companies regarding the same piece of inhalation sedation kit, neither of whom are the original suppliers.	Thank you for your comments. The GDG will consider this.
SH	14	British Association for the Study of Community Dentistry	4.3 e)	Include intra-nasal and oral Midazolam (off-license).	Thank you for your comments. The GDG will consider this.
SH	1	British Dental Association	3 e)	The BDA is concerned at the use of the American system of grading sedation into mild/moderate/deep and anaesthesia. By their definition alone, deep sedation is not conscious sedation and therefore is anaesthesia.	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are

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					widely accepted as the gold standard.
SH	2	British Dental Association	general and 4.3	Further to the points raised on stakeholders meeting on 25th of July in London, to make sedation in children in dentistry safer and more effective, the guideline should clearly cover the following areas: 1) What type of drugs and routes are effective (single/multi-drugs, inhalation/Intravenous/parental/rectal) in children of different ages and level of understanding. 2) Consideration should be given to the minimum training and support required for each type of sedation recommended in the guideline. 3) Detail minimum equipment, facilities, monitoring during and after the procedure, and number of staff required to carry out dental treatment on different ASA grades children and children with learning difficulties. 4) Any mention of the hospital environment or hospital setting should be clearly defined. 5) Basis of appropriate quality assurance, including regularity 6) Procedures for: Taking informed consent, fasting/no fasting, safe way of travelling back home, who should accompany the children – These should all be detailed. 7) Thousands of children (mainly ASA I and II) undergo dental treatment, mainly extraction of multiple deciduous teeth, under general anaesthesia. For these children, is there a suitable sedation procedure that is safer and more cost-effective than general anaesthesia? 8) What other non-pharmacological methods are effective that should be tried prior to, or used in conjunction with, sedation of children for dental treatment?	Thank you for your comments. All of the issues raised in this comment are covered within the scope.
SH	3	British Dental Association	4.3	Specifically, does this Guideline Development Group's remit include inhalational sedation using nitrous oxide/oxygen ?	Thank you for your comments. It is not usual to specify individual interventions within the scope but sedation techniques are covered

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					by section 4.3e) of the scope. [
SH	4	British Dental Association	4.3	Sedation and analgesia are two separate treatment modalities: Sedation is used to reduce anxiety. It is not a substitute for poor, or no, analgesia in the hope that the child will not remember the procedure.	Thank you for your comments. The scope covers sedation for painful and non-painful diagnostic and therapeutic procedures and the use of sedation in combination with analgesia is covered in section 4.3e).
SH	1	British Paediatric Neurology Association	3	The definition of sedation does not take account of non-sedating sleep induction, e.g. with Melatonin. It is important that the guideline defines sleep, awake anxiolysis, mild / conscious sedation, deep sedation, and also general anaesthesia (GA). Although deep sedation and GA can merge and patients can pass unintentionally from one to the other, a definition that makes them exclusive rather than overlapping terms would be an improvement on the current situation: e.g. define Deep Sedation as a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused, and is accompanied by 1) inability to respond purposefully to physical stimulation or verbal command, (GCS or Childs GCS 3-9/15), AND intact airway protective reflexes: retention of ability to maintain patent airway independently and continuously. Then GA becomes a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused, and is accompanied by 1) inability to respond purposefully to physical stimulation or verbal command, (GCS or Childs GCS 3-9/15), AND loss of airway protective reflexes: including loss of ability to maintain patent airway independently and continuously. Melatonin can help a patient go to sleep but is not sedative in that the EEG is without transformation just like normal sleep and any patient	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard definitions. Non-sedation sleep induction is outside of the scope of this guideline, which focuses on the use of sedation. The guideline will provide definitions as suggested.

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				who is safe in normal sleep will be safe in Melatonin sleep so no extra care to monitor for the patient slipping into DS or GA is needed. They need whatever they need for normal night-time sleep only. Melatonin has been useful and preferable to sleep deprivation for getting sleep EEGs (a procedure) and also is sometimes good for inducing sleep for keeping the child still for MRI (a procedure).	
SH	1	British Society of Paediatric Dentistry	3 e	The ASA definition of deep sedation does make deep sedation unsuitable for the delivery of dental treatment in a primary dental care setting. When the guideline is developed it would be helpful if only minimal and moderate sedation i.e. conscious sedation were considered suitable for the primary dental care environment.	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard definitions. The GDG will consider points raised.
SH	2	British Society of Paediatric Dentistry	general	As a lot of sedation does take place in primary dental care (e.g. nitrous oxide sedation, oral/intranasal/IV midazolam), it would be helpful if appropriate training and the equipment and monitoring required could be addressed by the GDG.	Thank you for your comments. It is anticipated that the developers will need to make training and equipment recommendations.
SH	3	British Society of Paediatric Dentistry	general	It would be helpful if the GDG would consider the types of sedation that were appropriate for children of different ages.	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	4	British Society of Paediatric Dentistry	3 h	It may be possible to over-emphasis the consequences of failed sedation. It is similar to losing the compliance of a child under local anaesthesia and an appropriately trained clinician should be able to manage the child and parent to avoid extreme distress. This really re-iterates the importance of appropriate training.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	5	British Society of Paediatric Dentistry	general	We would really like the guideline to help and encourage dental practitioners to carry out sedation for children in primary dental care. It would be very difficult if all sedation ended up in secondary care – the system could not cope with this.	Thank you for your comments. The guideline will be relevant to both primary and secondary care but will not make

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					recommendations on service delivery.
SH	6	British Society of Paediatric Dentistry	general	NICE is to be commended on developing a guideline in this area of practice that is very important to the safe care of children.	Thank you for your comments
SH	7	British Society of Paediatric Dentistry	general	The scope does not address the training or credentialing required for the individuals administering sedation. Although NICE guidelines do not usually address skill mix or staffing requirements, in the context of procedural sedation in children, a clear definition of who is able to administer the sedation, particularly deep sedation, is essential.	Thank you for your comments. It is anticipated that the developers will need to make training and equipment recommendations.
SH	8	British Society of Paediatric Dentistry	general	The scope does not address service configuration, particularly the role of anaesthesia services in the development of sedation services within a clinical setting. Although NICE guidelines do not usually address this issue, a consideration of service configuration is essential, for instance, if sedation services are to be developed in a hospital where young children are not anaesthetised as a routine.	Thank you for your comments. Whilst it is likely that the GDG will make recommendations about training, models of service delivery is outside the scope of this guideline.
SH	9	British Society of Paediatric Dentistry	4.1.1.b	Risks of anaesthesia and sedation are higher in younger children, particularly infants <1 year, even in expert hands. The scope suggests that the guideline development group would consider whether different recommendations are required for different age groups. Age specific guidelines are essential – the airway and respiratory reserve in an infant is very different from that of an adolescent.	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	10	British Society of Paediatric Dentistry	general	Sedation in General Dental Practice currently has a good safety profile as deep sedation is avoided – the scope of the guideline should make it clear that this should not change.	Thank you for your comments. Deep sedation is included within the scope of the guideline as guidance is required in this area.
SH	11	British Society of Paediatric Dentistry	general	Serious adverse events in sedation are rare but may be catastrophic – it would be useful if the scope of the guideline could address the issue of adverse event reporting.	Thank you for your comments. The GDG will consider this.

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SH	1	British Society of Paediatric Gastroenterology, Hepatology and Nutrition	general	There is a need for this particular guidance to include the views of children. Understand there are parent/carer representatives on the GDG but how will this guideline engage with children and take their views, concerns and expectations into consideration?	Thank you for your comments. The developers are working with other National Collaborating Centre colleagues to learn how they are facilitating this important aspect. We will also work closely with the Royal College of Nursing (who also have experience in this area) to see if we can effectively incorporate views, concerns and expectations of children.
SH	2	British Society of Paediatric Gastroenterology, Hepatology and Nutrition	4.1.1 b	Our view is that some recommendations will need to be age-group specific.	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	3	British Society of Paediatric Gastroenterology, Hepatology and Nutrition	4.3 d	Patient monitoring – can this be more clearly defined – what will this include?	Thank you for your comments. Monitoring of vital observations will be considered within the context of this guideline scope.
SH	4	British Society of Paediatric Gastroenterology, Hepatology and Nutrition	general	Very thorough and clearly thought through – looking forward to reading the guidance!	Thank you for your comments
SH	1	CLIC Sargent	general	This is an important guideline for infants, children and young people with cancer.	Thank you for your comments.
SH	2	CLIC Sargent	3	Sedation in children and young people is of particular importance in relation to imaging in oncology. There are different policies in different units regarding when sedation is acceptable or otherwise for patients undergoing radiological imaging such as MRI or CT scans. More consistency is needed in the delivery of sedation for children and young people with cancer.	Thank you for your comments, the guideline will apply to this population and will seek to address current variations in practice through evidence based clinical recommendations.
SH	1	Dental Sedation Teacher Group	3	Children and young adults with additional needs merit special consideration.	Thank you for your comments, the GDG will certainly be

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					considering this aspect.
SH	2	Dental Sedation Teacher Group	3 e) f) and general	Dentists acting as operator and □editionist must keep sedation at the level of anxiolysis or conscious sedation. Whilst sedation is a continuum, conscious sedation with midazolam, administered by a trained dentist working with a trained nurse, in an adequately assessed patient, carries an excellent margin of safety and dentists should never attempt to achieve a deeper level of sedation.	Thank you for your comments.
SH	3	Dental Sedation Teacher Group	3 i)	Sedation in dentistry is well regulated and dentists have recognised the need for training and guidance documents for many years. We think that there is very little variation within the field of dental sedation because of our frameworks for clinical governance, which includes guidance from the GDC.	Thank you for your comments.
SH	4	Dental Sedation Teacher Group	4.1.1	In dental sedation great emphasis is placed on the use of concurrent behavioural management techniques (including the ambience of the environment). It is not sensible to have absolute age limits for IV midazolam conscious sedation in the adolescents/young adults group as it can unnecessarily restrict management options. This is because the clinician has to assess the level of cooperation and understanding of the patient—maturity is much more important than age.	Thank you for your comments. The use of sedation in combination with non-pharmacological techniques is covered as detailed in 4.3 e). The developers will consider whether different recommendations are needed for different age groups but the guideline will also discuss the importance of taking into account the needs of the individual patient.
SH	5	Dental Sedation Teacher Group	4.4.1	DSTG hope that dentistry will be adequately represented on the membership of the GDG	Thank you for your comments. Dentistry is well represented on the GDG.

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SH	1	Guy's & St Thomas' NHS Foundation Trust	3 b) - last sentence	In dental practice, sedation is always used in combination with local anaesthesia.	Thank you for your comments, the GDG will take this into consideration during development.
SH	2	Guy's & St Thomas' NHS Foundation Trust	3 e)	The American concept of 'deep sedation' has led to much confusion and is probably unhelpful. Patients are either responsive to command (conscious sedation) or unresponsive to command (anaesthetised). If anaesthetised they should be under the care of an anaesthetist. UK guidance must be clear and unequivocal.	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard.
SH	3	Guy's & St Thomas' NHS Foundation Trust	3 f)	Consideration should also be given to the method of administration, particularly for IV drugs. Careful titration, observing the patient's response, to a recognised sedation end-point is appropriate for the vast majority of cases. Bolus intravenous doses often result in over-sedation.	Thank you for your comments. This will be addressed through evidence review and guideline recommendations.
SH	4	Guy's & St Thomas' NHS Foundation Trust	4.1.1 a)	In relation to dentistry, 16 would be a more appropriate upper age limit.	Thank you for your comments. The target population for this guideline is determined by the related NSF.
SH	5	Guy's & St Thomas' NHS Foundation Trust	4.1.2 a)	Important to define 'pre-medication' & 'night sedation'.	Thank you for your comments. Both will be defined within the guideline glossary.
SH	1	Liverpool University Dental Hospital	3 a	The older Child and young adults with additional needs merit special consideration as there is not equitable access to dental care for this group. In dentistry such patients can frequently be managed successfully with midazolam (conscious) sedation. One group of patients who sedate very successfully are those with cerebral palsy, treatment under midazolam sedation is usually safer as tremors and involuntary movements are attenuated. Whilst there is considerable clinical experience of safe practice, unfortunately there is not much of an evidence base. What is important for this older and often	Thank you for your comments. The scope is very clear regarding the target population age range for both development and implementation of the guidance. Children and young people who have special needs will be considered, and if necessary, focussed recommendations

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				disadvantaged group, is that sedation remains a possible treatment option. When sedation is not available and only general anaesthesia is on offer, dental treatment tends to be more radical, and often associated with the loss of more teeth. Dental procedures that require multiple visits (eg root canal treatment of an infected tooth) are not available and so teeth are often lost or procedures such as periradicular surgery undertaken that have a reduced outcome of success. A patient who is reliant on carers to clean their teeth would not get a 6 monthly general anaesthetic for a scale and polish. However, sedation enables this group of patients to receive regular 3 monthly professional cleaning which has a positive effect on the patients and those who care or live with them. We also frequently take blood tests for medical colleagues on our sedation sessions. Patients with profound learning disabilities who will not allow an examination to be undertaken, often present with the carers wanting to see if there is a dental problem, that could be responsible a recent behavioural change. Sedation can allow a clinical and radiographic examination to take place. This allows an informed decision to be made as to whether a general anaesthetic is required for treatment. Many patients receive an examination under GA just in case there is dental pain. It is worth mentioning that comprehensive care for dental treatment under GA is not easily available and those that exist have long waiting lists. The majority of general anaesthetics administered for dental procedures are for extractions and oral surgery in maxillofacial units. Equipment and staff are often not available for restorative (fillings) care.	made.
SH	2	Liverpool University Dental Hospital	3 e	Some fortunate dentists may work with an anaesthetist who may administer propofol sedation – in a hospital setting, and it is possible that CNS depression goes deeper than conscious sedation in order to carry out a procedure. This is fine when an anaesthetist is sedating but we feel that this should only be undertaken in a secondary care setting.	Thank you for your comments.

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				Dentists, under guidance from the GDC would class this form of sedation as a general anaesthetic (because it is not conscious sedation). When the operator is undertaking sedation it is important that the patient remains within the realms of conscious sedation.	
SH	3	Liverpool University Dental Hospital	3 e and general	The culture in around sedation in dentistry is one of conscious sedation. Dentists are not concerned about pain control with respect to the sedation, as good local analgesia can be obtained; therefore our objectives/goals are different to some other sedationists.	Thank you for your comments.
SH	4	Liverpool University Dental Hospital	4.3	Patients with special needs often have transmucosal midazolam prescribed and this is off-license use. The application of intranasal midazolam (20mg/0.5ml ampoules from Guys and St Thomas's pharmacy) may be the only way you can access a patient in the first instance.	Thank you for your comments. The GDG will consider this.
SH	1	Luton and Dunstable NHS Trust	3 b	Specific mention of sedation used in children having CT scans or MRI scans	Thank you for your comments. This is covered by the scope and will feature within the guideline.
SH	2	Luton and Dunstable NHS Trust	4.1.1	Define youngest age and lowest weight that sedation can be safely given	Thank you for your comments.
SH	3	Luton and Dunstable NHS Trust	4.3	Define groups of children where sedation should not be given or given cautiously	Thank you for your comments. The GDG will consider this.
SH	4	Luton and Dunstable NHS Trust	4.3	Can sedation be safely repeated	Thank you for your comments. The GDG will consider this
SH	5	Luton and Dunstable NHS Trust	4.3	Use of reversal agents if oversedated	Thank you for your comments. The GDG will consider this.
SH	1	National Public Health Service for Wales	general and 4.3	It should be commended that this guideline will also cover sedation in children for dental treatment. Further to the points raised on stakeholders meeting on 25th of July in London, to make sedation in children in dentistry safer and more effective, the guideline should clearly cover following areas. 9) What type of drugs and routes are effective (single/multi-drugs, inhalation/Intravenous/parental/rectal) in children of	Thank you for your comments. All of the issues raised are covered within the scope.

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				different ages and level of understanding. 10) Training required, minimum equipment, facilities, monitoring during and after the procedure, and number of staff required to carry out dental treatment on different ASA grades children and children with learning difficulties. If the word 'hospital environment' is used, it should be clearly defined. 11) How should the quality assurance be carried out in periodic basis? 12) Procedure of taking informed consent, fasting/no fasting, safe way of travelling back home, who should accompany the children? 13) Thousands of children (mainly ASA I and II) undergo dental treatment, mainly extraction of multiple deciduous teeth, under general anaesthesia. For these children, is there a suitable sedation procedure that is safer and more cost-effective than general anaesthesia? 14) What other non-pharmacological methods are effective that should be tried prior to or used in conjunction with sedation of children for dental treatment?	
SH	1	Royal College of Anaesthetists	3 e	Depth of Sedation. The intended depth of sedation required of a technique is important. This target state will determine the skill mix required of the practitioner administering the sedative drug or drugs. The level of monitoring, and support a patient requires, increases as the level of sedation deepens, as does the potential for morbidity and mortality. Therefore the technique and depth of sedation should be safe, appropriate to the procedure, and no deeper than is necessary. Previous guidance [1,2,3,4,5] has placed great emphasis on defining a safe target state, i.e. conscious sedation, *"a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which*	Thank you for your helpful comments. Adverse events and the safety of procedures recommended will feature in the development of guidance.

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				verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation…..should carry a margin of safety wide enough to render loss of consciousness unlikely". In dentistry rigid enforcement of this definition has resulted in an exemplary safety record, and is the target state recommended for other areas of adult sedation practice [(1)]. However, conscious sedation may be inadequate for performing more difficult procedures, particularly in young children. Deep sedation describes a state in which the level of consciousness in significantly depressed, potentially bordering on general anaesthesia. The margin of safety is therefore considerably narrowed and complications, including loss of airway, respiratory depression, hypoxia and aspiration, can have very serious consequences, e.g. hypoxic brain injury, aspiration of gastric contents or even cardiac arrest and death. In the United Kingdom a level of sedation deeper than that defined as conscious sedation is deemed to require the same level of care as would a patient undergoing general anaesthesia [(1,2,4,5)]. We would like to make the following comments:- **1. Deep sedation is more likely to be associated with adverse events and requires a level of care identical to that for general anaesthesia. The skills of the individual concerned are therefore of great importance and must be defined.** **2. Deep sedation should only be used where there is a clear clinical indication and perhaps careful consideration should be given to the potential advantages of a controlled general anaesthetic in some circumstances, which may present fewer risks to the child.**	

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				3. Careful consideration must be given to what constitutes an appropriate environment, where complications can be managed quickly and competently.	
SH	2	Royal College of Anaesthetists	3 f	<u>Margin of Safety.</u> Implicit in any sedation technique are two features:- 1. Drugs must be titrated carefully to effect. 2. The drugs and techniques used …*should carry a margin of safety wide enough to render loss of consciousness unlikely*. The use of single drug techniques in dentistry, e.g. inhaled nitrous oxide/oxygen and intravenous midazolam, carefully titrated to effect, has resulted in an enviable safety record. It is a concern however, that despite the success and safety of these standard techniques alternative multiple drug techniques, with narrower margins of safety, are now seemingly being encouraged [(6)], in the absence of any established defined training programmes. The use of multiple drug techniques and anaesthetic drugs, used as boluses or infusions, is associated with narrowed margins of safety. Different drugs can have different speeds of onset, potency and duration of effect and in combination commonly have synergistic effects. Titrating multiple drugs can therefore be difficult and unpredictable, and evidence suggests that adverse events are more common using such techniques [(7,8)]. We would like to make the following comments:- **1. The simplest most appropriate technique, with the widest margin of safety, that will enable the proposed treatment to**	Thank you for your comments. All three points will be considered by the guideline development group in producing this clinical guideline.

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				be carried out satisfactorily, should be used. **2. Multiple drug techniques and those using anaesthetic drugs have narrower margins of safety and are therefore more likely to be associated with adverse events. Such techniques require the same level of monitoring and care as would be expected of general anaesthesia and should only be performed by practitioners who have been appropriately trained in their use, and have demonstrable competence in the management of potential complications.** **3. It is important to define the environment in which techniques with a narrower margin of safety, and increased risk of complications, should be used, i.e. one where skilled paediatric resuscitation and general anaesthetic facilities are immediately at hand.**	
SH	3	Royal College of Anaesthetists	4.3	<u>Role of the operator □editionist.</u> It remains common practice in many specialties for both the sedation and the diagnostic or therapeutic procedure to be undertaken by the same individual, monitoring of the patient sometimes being delegated to another member of the team. The safe administration of sedative drugs and subsequent monitoring of the patient requires dedicated training and continued vigilance, especially when using deep sedation or techniques with narrow margins of safety. **Is it still appropriate for a practitioner to take responsibility for both the sedation and what might be a complex therapeutic or diagnostic procedure? Should we instead be advocating the use of a dedicated □editionist?**	Thank you for your comments. The GDG will consider this.

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SH	4	Royal College of Anaesthetists	general	Training and Assessment. Sedation techniques can, if undertaken appropriately, enable a potentially unpleasant procedure to be successfully carried out and improve the experience for the child, hopefully avoiding any long term physical or psychological sequelae. Sedation is currently administered by healthcare professionals from widely differing specialties. Techniques used should be appropriate, effective and safe (safer than a well administered general anaesthetic). It is an unfortunate reality that the practice of sedation is occasionally accompanied by unexpected morbidity, and even deaths. Inappropriate practice is a frequent cause and deficiencies in respect of training and competency are consistently identified in all specialties. Adverse events have continued to occur in spite of sensible guidelines already having been published [1,2,3,4,5]. The cause lies in failure to implement this guidance and specifically, failure to address the issue of training of those individuals who administer sedative and analgesic drugs for procedures. Training should be defined and validated for all involved, irrespective of specialty background, be relevant to the techniques being used, and appropriate to the clinical environment in which they are being practised. The College is aware of the need for developing specific competencies for the safe administration of sedation for diagnostic and therapeutic procedures and is currently developing a curriculum for trainee anaesthetists for the use of conscious sedation techniques for dentistry.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations. Scope amended (new section 4.4).

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				We would like to make the following comments:- **Education and training are the principal issues to address.** **It is a reasonable expectation that practitioners of such techniques should possess the competencies required to administer sedative and analgesic drugs appropriately and safely, and crucially, have the skills to manage complications of such techniques, e.g. formally assessed airway skills to enable safe management of the inadvertently anaesthetised patient.** **Defined formal training and assessment is pivotal to improved safety in the provision of sedation for children and young people, and the success of this guideline.** **We would strongly encourage the inclusion of training and assessment in the use of sedation techniques within the scope of this guideline.** **<u>References:</u>** 1. Implementing and ensuring Safe Sedation Practice for healthcare procedures in adults. Report of an Intercollegiate Working Party chaired by The Royal College of Anaesthetists. AoMRC 2001. 2. Conscious Sedation in the Provision of Dental Care. SDAC DoH 2003. 3. Standards for Dental Professionals. GDC. 4. A Conscious Decision – A review of the use of general anaesthesia and conscious sedation in primary dental care. DoH July 2000.	

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				5. Recommendations for Standards of Monitoring During Anaesthesia and Recovery. AAGBI 2007. 6. *Department of Health/Faculty of General Dental Practice (UK).* Guidelines for the Appointment of Dentists with a Special Interest (DwSI) in Conscious Sedation. Gateway ref: 9102 7. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Anesthesiology 2002; 96:1004-17. ▪ Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update. American Academy of Pediatrics. Pediatrics Volume118, No 6, December 2006.	
SH	1	Royal College of Nursing	general	The scope will address the key issues and the guideline will be able to guide and inform practice ensuring some consistency and standard in care.	Thank you for your comments.
SH	2	Royal College of Nursing	general	Perhaps it is self evident but we would like greater emphasis on the accompanying analgesic and local anaesthetics to be administered to aid and facilitate the procedure as this would mean that less sedation would probably be required.	Thank you for your comments. The use of sedation in combination with analgesia is covered in the scope under section 4.3 e).
SH	3	Royal College of Nursing	2 b	As the children's NSF is quite generic in nature, it would be helpful to be more specific here.	Thank you for your comments, this is standard text that the developers are asked to use.
SH	4	Royal College of Nursing	general	The stakeholder information meeting was every well attended	Thank you for your comments.

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			and 3	reflecting how important nurses, anaesthetists, dentists and paediatricians view this issue. However the scope refers to children and young people, ***INFANTS*** need to be specifically mentioned if this clinical guideline is to be applied to them. Perhaps what is required is a tiered guideline: • one for infants under one year and the ex-premature survivor, perhaps up to 15/18 months • another for the young child from one year to mid school age • another which is appropriate for the young person	The guideline is relevant to all ages covered by the NSF for children and young people which includes the three age groups you have specified. The GDG will consider whether different recommendations are required for different age groups in the population
SH	5	Royal College of Nursing	3 a	"procedure too frightening" review choice of words here - might be better to state as "child's perception of the procedure is that it is frightening"	Thank you for your comments. We note that to be frightened is in proportion to the infant's/child's perceptions. The GDG will consider this as an important aspect of development.
SH	6	Royal College of Nursing	3 a	A large amount of sedation techniques are used for diagnostic procedures (CT/MRI) to ensure the child is motionless, although this is mentioned in 3d – motionless needs also to be highlighted in this section.	Thank you for your comments. We feel this is covered within the scope as it stands.
SH	7	Royal College of Nursing	3 b	Also a large amount of sedation techniques are used for diagnostic procedures (CT/MRI) and although there are probably no details as to the numbers – this needs to be highlighted in this section.	Thank you for your comments.
SH	9	Royal College of Nursing	3 b	Further, the range of areas where children may need some sedation is vast. Although these guidelines are intended for the NHS, the increasing number of independent providers might also be encouraged to use these. Comprehensive assessment of the infant, child or young person is critical to avoid adverse incidents if the practice is to be adopted in a ward side room, an outpatients or a GP surgery.	Thank you for your comments. NICE guidance applies to the NHS, but we appreciate it is has a wider context for implementation. Assessment will feature within the guidance and is covered by the scope.

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SH	10	Royal College of Nursing	3 c, d and e	Although NICE usually stops short of dosage recommendations and making recommendation regarding training and education requirements, this is one guideline which might like to step outside the usual framework and give more detail as appropriate. A comprehensive guidance and alerts as to the risks of polypharmacy perhaps include the BNF advisory notes on the therapeutic agents to be used. In addition recommendations as to the level of training, preparation, experience personnel administering "soft" sedation is required to have would be useful. The primary importance is the safety of the infant and child.	Thank you for your comments. It is anticipated that the developers will need to make dosage (and where appropriate titrating doses) and training recommendations.
SH	11	Royal College of Nursing	3 f. g and h	As there is such a fine line between soft sedation and deepening unconsciousness, we would like to see algorithms with various stop off points emphasised where the professional could call a halt to the process and the procedure and seek more expert help.	Thank you for your comments. The use of algorithms is normal within guideline development, and it is the intention of the developers to adopt this approach.
SH	12	Royal College of Nursing	3 f, g and h	There is a resource implication here and the minimum equipment and personnel required for safe sedation ought to be considered and included. These are High Dependency Children and the BPAM nursing criteria should be considered as a minimum.	Thank you for your comments. This will be addressed through evidence review and guideline recommendations.
SH	13	Royal College of Nursing	3 f, g and h	As failed sedation has the potential to be highly traumatic, the advice of mental health experts ought to be sought and a strategy of support for traumatised children identified.	Thank you for your comments. The Guideline Development Group does have this expertise within it and these aspects will feature within the guidance.
SH	14	Royal College of Nursing	3 i	Sadly there is a considerable variation and this is an opportunity to make this less so. Consensus and dissemination will go some way to standardising practice but until such policies become mandatory to safeguard the child, adherents to current variable standards of practice is likely to continue.	Thank you for your comments.

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SH	15	Royal College of Nursing	4.1.1	Either add in neonates or make clear neonates are excluded	Thank you for your comments. The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.
SH	16	Royal College of Nursing	4.1.1 b	To include different recommendations depending upon the length of sedation required.	Thank you for your comments
SH	17	Royal College of Nursing	4.1.1 b	As stated earlier, it is important that the different age ranges are represented because methods will vary considerably from 0-18. Also the range of drugs that can be used in a neonate for example will be very limited compared to an older child.	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	18	Royal College of Nursing	4.1.2	Can not establish whether these groups are covered or not because of the way the paragraph reads. Suggest rephrasing.	They are groups that will not be covered, as the heading suggests
SH	19	Royal College of Nursing	4.1.2 a & b	Agreed with the cohorts included and excluded – no comment regarding special consideration for the ex premature. This is a potentially serious omission.	Thank you for your comments. The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.
SH	20	Royal College of Nursing	4.2 a & b	The use of procedural sedation in the GP surgery and in the community setting needs to be considered with great care to ensure that the right people with the right skills and preparation follow agreed protocols to minimise the risks to infants and children.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	21	Royal College of Nursing	4.3	Clinical management section is excellent.	Thank you for your comments.
SH	22	Royal College of Nursing	4.3	Does not mention training/education/experience/knowledge of staff supporting children having sedation.	Thank you for your comments. It is anticipated that the developers will need to make training

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				Staff training is a big issue and ideally, although not the norm, there is a need to consider training and levels of competence for – person designated responsibility for child, the person prescribing drugs, to nursing staff who implement and manage care, and those carrying out procedures.	recommendations.
SH	23	Royal College of Nursing	4.3 a	The development of protocols for the assessment of infants and children suitable for sedation needs to be rigorous; body maps and airway maintenance/management tools could be developed. Clearly developed consensus on documentation would be useful.	Thank you for your comments. The GDG will consider this.
SH	24	Royal College of Nursing	4.3 a	This should include the 'suitability on referral for a procedure as well as suitable / fitness on the day of procedure'	Thank you for your comments. The GDG will consider this.
SH	25	Royal College of Nursing	4.3 b	There are implications for informed consent in this patient group, guidelines as to Gillick/Fraser competence needs to be clear. Therefore, suggest that this section should specify that consent will be included. Procedural sedation currently is undertaken with written consent in some departments.	Thank you for your comments. The GDG will consider this. Scope amended
SH	26	Royal College of Nursing	4.3 c	The resource and equipment requirement has already been considered. A practical checklist would make a good appendix to the final guidance.	Thank you for your comments. The GDG will consider this.
SH	27	Royal College of Nursing	4.3 d	There should be clear guidance for infant and child care following discharge post procedure. Parent information leaflets detailing the post procedural care would need to be comprehensive and clearly indicate where to go for support if the family were concerned about their child. Possible resource implications for 24/7 cover.	Thank you for your comments. The GDG will consider this.
SH	28	Royal College of Nursing	4.3 e	As above and also there may be a place for these BNF summaries to be INCLUDED in this document.	Thank you for your comments. It is not usual practice to reproduce material from the BNF within

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					NICE guidance.
SH	29	Royal College of Nursing	4.3 e	It is inevitable especially in the neonatal population that drugs may be required that are not licensed for use in their age group. A lot of neonatal units also use the Neonatal Formulary, so this should be taken into account	Thank you for your comments. The GDG will consider this.
SH	30	Royal College of Nursing	4.3 e	In clinical practice we have found that therapuetic doses of chloral hydrate for effective sedation for MRI or BSER are double that summarised within the BNF for Children. Some trusts use local policy to guide prescribers. Will the guideline address these issues?	Thank you for your comments. Guideline recommendations will normally fall within licensed indications. Where clearly supported by evidence, use outside a licensed indication may be recommended
SH	31	Royal College of Nursing	4.3 f	The role of "physician's assistants", advanced practice nurses such as ANNPs, other specialist nurses in procedural sedation needs to be clarified. Clearly specialist nurses cost a lot less than anaesthetists and this should not be seen as a cost cutting opportunity. Nurses of course have the capacity to learn the same prescribing and professional skills as anaesthetists but would be unlikely to want to function in this role. This is after all guidance for the minimal use of sedation to facilitate a procedure and not for prolonged use. Additionally nurses would not have the automatic licence to practice in this sphere guidance/advice of the Nursing and Midwifery Council (NMC) would have to be sought. However from a neonatal perspective. ANNPs already perform skills on infants which should attract exactly the humanitarian and sensitive ethos this scope alludes to. This includes procedures such as LPs, difficult IV cannulations and long line insertion.	Thank you for your comments. The GDG will consider this.

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				In addition this could support the ophthalmologist by using a minimal sedation policy making routine ROP examinations less distressing for the infants.	
SH	32	Royal College of Nursing	4.3 f)	The second statement appears quite ambiguous – could it be made clearer?	Thank you for your comments. Scope amended
SH	33	Royal College of Nursing	general	Following a recent report of a study by Carbajal et al. on 'Neonates in Intensive Care Endure Painful Procedures, Mostly Without Analgesia 'released July 2008 available on http://www.sciencedaily.com/releases/2008/07/080701165057.htm should the guidelines extend their scope to neonates to ensure they are treated with the same respect?	Thank you for your comments. The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.
SH	34	Royal College of Nursing	general	Will this guideline cover advice on regulation of sedation, i.e. on who can sedate, where and what emergency procedures need to be in place? This will guide some GPs who privately carry out circumcision in their surgeries.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations. The guideline will cover primary care settings within the NHS.
SH	1	Royal College of Paediatrics and Child Health	3i	SIGN has specifically reported that ketamine should not be used in sedation of children in emergency departments, but this is now quite common practice, safe, accepted, and well published	Thank you for your comments. Drugs in current use will feature in evidence reviews. Both efficacy and safety will be considered.
SH	1	Royal College of Paediatrics and Child Health	general	No mention is made in the scope about guidance on which drugs should/could be used and at what doses – clinicians would find this most helpful.	Thank you for your comments. It is anticipated that the guideline will provide guidance on these issues.
SH	1	Royal College of Paediatrics and Child Health	general	No mention is made in the scope about guidance on which drugs should/could be used and at what doses – clinicians would find this most helpful.	Thank you for your comments. It is anticipated that the developers will need to make dosage and training recommendations.

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SH	2	Royal College of Paediatrics and Child Health	4.3.e	Alder Hey emergency department has as yet unpublished data on use of s-ketamine for sedation in children. The data may be published by the time of literature review, but will certainly have been submitted. This has been fully supported by lead for medicines for children, chief pharmacist and anaesthetists S-Ketamine (Ketanest) is unlicensed, and has a better profile the ketamine (Ketalar)	Thank you for your comments and for bringing this to our attention. The GDG will consider this.
SH	2	Royal College of Paediatrics and Child Health	general	No mention is made of the taking of informed consent prior to sedation – again, it would be useful to include this.	Thank you for your comments. Section 4.3 (b) has been amended to cover consent prior to sedation.
SH	2	Royal College of Paediatrics and Child Health	general	No mention is made of the taking of informed consent prior to sedation – again, it would be useful to include this.	Thank you for your comments. The GDG will consider this and the scope amended.
SH	3	Royal College of Paediatrics and Child Health	4.2	Even within hospital settings it will be important to consider the environment, facilities for resuscitation, recovery, and the pre-sedation state of the child – an emergency may need to be dealt with differently to an elective case in familiar surroundings	Thank you for your comments. The clinical environment is covered under section 4.3c).
SH	3	Royal College of Paediatrics and Child Health	general	It is important to stress the need for a collaborative approach with Anaesthetic teams.	Thank you for your comment.
SH	3	Royal College of Paediatrics and Child Health	general	It is important to stress the need for a collaborative approach with Anaesthetic teams.	Thank you for your comments. The GDG will consider this.
SH	4	Royal College of Paediatrics and Child Health	general	Standardisation of training and competency based assessments in this area would be most useful and the RCPCH would endorse the importance of this.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	4	Royal College of Paediatrics and Child Health	general	Standardisation of training and competency based assessments in this area would be most useful and the RCPCH would endorse the importance of this.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	4	Royal College of Paediatrics and Child Health	General	This is a comprehensive scoping document	Thank you for your comments
SH	5	Royal College of Paediatrics	4.1.b	I suggest that neonates and infants are both treated separately	Thank you for your comments.

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		and Child Health			
SH	5	Royal College of Paediatrics and Child Health	general	A method of data collection about adverse events as well as recommended documentation of monitoring during sedation would improve the evidence base in the future.	Thank you for your comments. The GDG will consider this.
SH	5	Royal College of Paediatrics and Child Health	general	A method of data collection about adverse events as well as recommended documentation of monitoring during sedation would improve the evidence base in the future.	Thank you for your comments. The GDG will consider this.
SH	6	Royal College of Paediatrics and Child Health	general	It should be stated somewhere that sedation should be done by those who are trained and competent in this area, which will hopefully avoid the junior member of a clinical team being sent to offer sedation on an ad hoc basis.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	6	Royal College of Paediatrics and Child Health	general	It should be stated somewhere that sedation should be done by those who are trained and competent in this area, which will hopefully avoid the junior member of a clinical team being sent to offer sedation on an ad hoc basis.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	7	Royal College of Paediatrics and Child Health	general	For the avoidance of doubt there should be an explicit declaration as to whether the scope includes or excludes neonates under the age of 28 days.	Thank you for your comments. The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.
SH	7	Royal College of Paediatrics and Child Health	general	For the avoidance of doubt there should be an explicit declaration as to whether the scope includes or excludes neonates under the age of 28 days.	Thank you for your comments. The developers have intentionally avoided the term neonate, as this is not consistently interpreted. The guideline will focus on all infants from birth; this by definition includes those born pre term.
SH	1	Royal College of Pathologists	general	The guideline should seek to define sedation more closely, and to differentiate it from other (possibly useful) approaches: e.g.,	Thank you for your comments. The GDG will consider this.

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				neurolepsis, neuroleptanalgesia, neuromuscular blockade.	
SH	2	Royal College of Pathologists	general	Clinical guidance should address: dosimetry problems in the young, for example due to immaturity, ethnicity; resources, training, needed to address concomitant conditions such as shock, mechanical issues such as airway obstruction; drug-drug interactions, especially when use of combination products (e.g., sedative / analgesic) is considered.	Thank you for your comments. The GDG will consider this.
SH	1	Royal Liverpool Children's NHS Trust	general	NICE guidelines do not routinely outline educational, competencies that might be required. Following on from the stakeholders meeting the education and training of healthcare professionals undertaking sedation practice should be mandatory and include the level of competency that must be achieved and the time-frame for updating practices and knowledge. Must also be trained in rescue methods where these are needed.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	2	Royal Liverpool Children's NHS Trust	general	There is a lot of work already carried out in the USA and Scotland in this area. Would it be a possibility to look at these when developing the guideline.	Thank you for your comments. The GDG will consider this.
SH	3	Royal Liverpool Children's NHS Trust	3 e	Terminology is important and the Americans have recognised that the wording 'conscious sedation' is taken out – this should be carefully reviewed.	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard definitions.
SH	4	Royal Liverpool Children's NHS Trust	general	The terms 'sedation' and 'pain' appear many times and seem to be used interchangeable which they are not. This leads to a lot of confusion when healthcare professionals are planning interventions for non-painful versus painful procedures. The guideline should highlight that sedation drugs **do not provide analgesia**. (Pain memory)	Thank you for your comments. The guideline will cover the effectiveness, safety and limitations of sedation techniques including the use of sedation in combination with analgesia as described in section 4.3 e).
SH	5	Royal Liverpool Children's NHS Trust	general	Play specialists and pharmacists are a vital component of providing successful outcomes when managing a procedure. Are they	Thank you for your comments. The GDG will consider this.

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				represented on the group?	
SH	6	Royal Liverpool Children's NHS Trust	general	The paediatric psychology network has produced an extremely valuable document – evidence based guidelines for the management of invasive and / or distressing procedures with children. Is this group represented?	Thank you for your comments. This specialist area is represented on the GDG.
SH	7	Royal Liverpool Children's NHS Trust	3 h	If sedation is unsuccessful – plans should be in place **and** agreed by the child (if old enough), the parent/carer and the medical staff **before** the procedure commences. E.g. abandon and re-schedule and time for re-scheduling 1hr, 6 hrs or 24 hrs – all determined by the child's condition and implications of the results of the procedure.	Thank you for your comments. It is anticipated that the GDG will address this point.
SH	8	Royal Liverpool Children's NHS Trust	3 i	'Deep' sedation is a situation which may easily become 'anaesthesia' and should be left to members of the anaesthetic team exclusively.	Thank you for your comments.
SH	9	Royal Liverpool Children's NHS Trust	4.1.1 a) & b)	Age groups – under 1 year children should be sedated by anaesthetists. Age groups not the only thing to consider but also the child's health status and medical history. The ASA classification lends itself very well to this situation e.g. ASA I and II – all 'sedation' trained and competent healthcare professionals. ASA III – anaesthetists OR senior medical staff trained and deemed competent e.g. A & E consultants. ASA IV and V – anaesthetists only	Thank you for your comments. The GDG will consider whether different recommendations are required for particular subgroups of the population covered by the guideline.
SH	10	Royal Liverpool Children's NHS Trust	4.3 a	Assessment – include: individual patient focus for the sedation considered, their previous experiences and potential need for psychological input beforehand	Thank you for your comments. The GDG will consider this.
SH	11	Royal Liverpool Children's NHS Trust	4.3 b	Preparation – information **and consent** including the "abandonment plan"	Thank you for your comments. The GDG will consider this.
SH	12	Royal Liverpool Children's NHS Trust	4.3 c	Environment – 'known' clinical area i.e. not in an office etc where the emergency team if required would have difficulty locating. Presence of suction. Oxygen and emergency drugs.	Thank you for your comments. The GDG will consider this.
SH	13	Royal Liverpool Children's NHS Trust	4.3 d	Monitoring – designated 'sedation practitioner' monitors child continuously and records observations at agreed times e.g. 5 mins. Continued until 'pre-sedation' state achieved.	Thank you for your comments. The GDG will consider this.
SH	14	Royal Liverpool Children's NHS Trust	4.4 e	Consider 'patient first' principle i.e. safety, agreement, understanding as well as cost effective use of resources	Thank you for your comments. The GDG will consider this.

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SH	1	Sheffield Children's NHS Foundation Trust	3 g	The scope recognises the serious adverse events that may, and do, occur when deeper levels of sedation are not managed appropriately. Untoward incidents involving sedation are reported occasionally in this Trust, which has a paediatric acute and procedural pain service and sedation guidelines. These incidents usually involve relatively inexperienced staff. If deeper levels of sedation are to be managed safely, appropriately trained staff are required, working in an organisational structure that provides assessment of competence and supervision.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	2	Sheffield Children's NHS Foundation Trust	3 i	The guideline intends to provide recommendations to improve the effectiveness and safety of all types of procedural sedation and to reduce current variations in standards of care. For deeper levels of sedation, effectiveness and safety depend on competent trained individuals supervising the child undergoing a procedure. The human resource to provide this service is not usually available in Trusts, including our own. We believe that the guideline must address the issue of competency and supervision of individuals involved in sedation in order to improve effectiveness and safety. We agree the competencies should be defined for managing different levels of sedation rather than covering them with job titles.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	3	Sheffield Children's NHS Foundation Trust	4.1.2.a	Pre-medication is specifically excluded. A large body of evidence exists in this area that can be directly extrapolated to other procedures. Indeed, in children, pre-medication is usually prescribed to enable Intravenous cannulation or restraint with minimal distress. These procedures occur commonly in other areas of the hospital. This evidence should be considered, even if recommendations are not made with regard to pre-medication.	Thank you for your comments. Pre-medication is outside of the current scope but the GDG will consider whether evidence from this area can be used as indirect evidence for this guideline.
SH	4	Sheffield Children's NHS Foundation Trust	general	It should be recognised that there are classes of drugs which are only used for general anaesthesia and classes which are used for sedation but can be used to achieve general anaesthesia in sufficiently large doses. The temptation to assign whole classes of drugs to the category "anaesthetic use only" should be resisted. [see SIGN Guidelines where Ketamine, an agent widely, and successfully used for sedation, is designated as an "anaesthetic agent to be used by	Thank you for your comments. The GDG will consider this.

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				anaesthetists only".] Our view is that if an individual is trained to use a drug, understands the side effects and can manage them, then they should be able to use them. The emphasis should move from what the drug is, to how it is used. ****,**** and **** **The Lancaster experience of 2.0 to 2.5 mg/kg intramuscular ketamine for paediatric sedation: 501 cases and analysis** Emerg. Med. J., May 2004; 21: 290 - 295.	
SH	1	Society and College of Radiographers	general	The Society and College of Radiographers (SCoR) welcomes the development of guidance in sedation of children and that best practice can be developed for implementation	Thank you for your comments
SH	2	Society and College of Radiographers	2	The SCoR welcomes the inclusion of patients and where appropriate, their carers or families making informed decisions about their care and treatment, which includes realistic option regarding sedation.	Thank you for your comments.
SH	3	Society and College of Radiographers	3 e	The SCoR recognises and welcomes the statement regarding the ease of transition from one state of consciousness level to another and that appropriate monitoring must be maintained	Thank you for your comments.
SH	4	Society and College of Radiographers	3 h	The SCoR strongly supports this statement. Every effort is needed to try and get sedation/pain relief for children right first time	Thank you for your comments.
SH	5	Society and College of Radiographers	4.1.2	Agree	Thank you for your comments.
SH	6	Society and College of Radiographers	4.3 c	The SCoR supports guidance for appropriate environments, levels of equipment and staff. Staffing levels and competences would be helpful	Thank you for your comments. Whilst it is likely that the GDG will make recommendations about training, models of service delivery is outside the scope of this guideline.
SH	7	Society and College of Radiographers	4.3 e	In MRI some success has been reported with Neurolinguistic Programming to help overcome nervousness and claustrophobia	Thank you for your comments. Non-pharmacological techniques are included in the scope when used in combination with sedation and they may be included in the

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					evidence reviews as comparators to sedation techniques.
SH	8	Society and College of Radiographers	general	The SCoR is aware that there are specific safety issues with regard to MR scanning and sedation. We would suggest that the GDG refer specifically to MHRA guidelines on safety training and authorisation for entering the MR control area. There must be overall control of the area by the MR authorised person, and this must be established for each case/session. They have authority for controlling all staff and equipment entering the MR controlled area	Thank you for your comments. The GDG will consider this.
SH	9	Society and College of Radiographers	general	The SCoR is aware that the European Union has allowed a 4 year derogation of the Physical Agents (EMF) Directive 2004. However, there is strong pressure from certain groups in Europe, that no exceptions should be made for MR scanning. Despite the efforts of the Alliance for MR, of which the SCoR is a member, there is concern that in 2012 the Directive will be adopted. This will have a devastating effect on MR. It will not be possible for staff to be in the MR room during scanning, or while undertaking biopsies. This effectively rules out any paediatric work until patients are able to be left in the room unattended. The SCoR think it would be wise for the GDG to be fully informed about the proposed changes, and would suggest asking ****, or his nominee to contribute on this subject.	Thank you for your comments. The GDG will consider this information regarding the specific clinical environment within MR scanning facilities.
SH	1	Society for the Advancement of Anaesthesia in Dentistry (SAAD)	6	I am unhappy with the concept of "Deep Sedation". Patients are either conscious (verbal responses) or they are unconscious (no verbal response i.e. anaesthetic). NICE should either: a. Abandon the concept of Deep Sedation or call it something else that does not use the word "Sedation" (light anaesthesia?) b. Define the point at which Conscious Sedation becomes anaesthesia	Thank you for your comments. For the purpose of this guideline, the developers will be using the ASA definitions as these are widely accepted as the gold standard definitions
SH	2	Society for the Advancement of Anaesthesia in Dentistry (SAAD)	6	There was much discussion about training. This should go even further and define the appropriate environment, suitable techniques and suitable patients. Of course, one should not, in the process, prevent the development of new techniques and drugs.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.

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SH	3	Society for the Advancement of Anaesthesia in Dentistry (SAAD)	general	Psychological support is an important part of anxiolysis and conscious sedation. Can we take that for granted and not spend too much time debating and prescribing this?	Thank you for your comment. Clinical guidelines help address current variations in practice, and psychological support will be considered as it is a key area.
SH	1	South Tees NHS Hospitals Trust	general	Successful sedation requires a skilled practitioner – most problems arise because of inadequate training, experience and support. I agree entirely with the thoughts expressed by many of my colleagues at the meeting on 25 July 2008.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	2	South Tees NHS Hospitals Trust	3 e/f/g	The continuum of sedation/anaesthesia is the biggest risk factor in the sedation of children. Deep anaesthesia is not safe unless given by someone with the skills to provide anaesthesia. There is no guarantee that a particular dose will provide the expected level of sedation.	Thank you for your comments.
SH	3	South Tees NHS Hospitals Trust	3 e	There was discussion at the Stakeholders meeting about the training required and a suggestion that APLS would be a suitable requirement. Whilst I believe the APLS course is a good introduction to the care of the ill child, practising airway management on a minikin and repeating the procedure until you can achieve air entry on the one manikin, does not provide sufficient experience to care for the airway of every child you meet.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.
SH	4	South Tees NHS Hospitals Trust	4.1.1	It would be useful to divide the children in to age bands as children respond very differently to procedures and medications at different ages.	Thank you for your comments. It is anticipated that recommendations will be age specific.
SH	5	South Tees NHS Hospitals Trust	4.2.c/d	Minimum requirements for equipment/monitoring is an important area.	Thank you for your comments. Thee areas are covered within 4.3c) and d).
SH	6	South Tees NHS Hospitals Trust	general	Should the sedation be provided by a single operator? Or should a separate person be observing the sedation level of the child to the person performing the LP for example? There is always a risk when doing two things simultaneously of failing to recognise a change in the	Thank you for your comments. The GDG will consider this.

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				level of sedation.	
SH	1	STEPS	general	There was a lot of discussion that centred around the issue of training. The comments were made exclusively by anaesthetists or doctors who were keen to ensure that there was some guidance as to what constitutes adequate training for certain procedures. I just wanted to add a lay perspective to this. As a parent of a 2-year old child who has now had 4 general anaesthetics and endured many diagnostic tests and countless procedures I have asked a million questions about the procedures, expected outcomes etc. As a pharmacologist by training I like to think that I am as well informed as possible. However, I have never asked if the personnel performing the procedures or giving the drugs are trained in certain techniques or life-saving (eg airway clearance) skills. As a parent you put your trust and the life of your child in the hands of those who are treating her. It is my view that the very least one can expect is that the personnel are adequately trained to perform the suggested procedures and to deal with the consequences of that technique should there be any adverse or unexpected reactions. I therefore agree strongly with the other stakeholders that in the case of child sedation there should be some directive with regard to training.	Thank you for your comments. It is anticipated that the developers will need to make training recommendations.