**National Institute for Health and Clinical Excellence**

**Sedation in Children and Young People**
**Guideline Consultation Comments Table**
**17 May – 12 July 2010**

| Type | Stakeholder | Order No | Document | Page No | Line No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
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| SH | Alder Hey Children's NHS Foundation Trust | 1 | APPENDIX | GENERAL ALGORITHM | | I am surprised to see midazolam recommended for upper GI endoscopy and wonder if there is any evidence to indicate that this is safe. It has a morbidity and ?mortality attached to the practice in adults, so I'd be very surprised if this could be recommended without some indication of restrictions in a "shared airway" procedure | Thank you for your comment. The RCT midazolam safety data for gastroenterology supports the use of this drug. The observational data in the A&E setting and in the dental setting demonstrate adverse event rates which are extremely low. It was felt that this could be extrapolated to GI procedures. It was acknowledged by the GDG that GI procedures may inherently cause some adverse events, such as vomiting. |
| SH | Alder Hey Children's NHS Foundation Trust | 2 | FULL | 51 | 22 | These fasting guidelines seem excessive and will make elective procedures very difficult. Appreciate you have allowed for 'clinical exceptions' but still somewhat OTT, given evidence on fasting from other countries. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Alder Hey Children's NHS Foundation Trust | 3 | FULL | 54 | 23 | End tidal CO2 monitoring will only be possible with airway related devices. If the child is not Intubated is the guideline recommending transcutaneous CO2 monitors – expensive and not that widely used at the moment? | Thank you for your comment. End tidal CO2 can be monitored via nasal catheter of spontaneously breathing pts. |
| SH | Alder Hey Children's NHS Foundation Trust | 4 | FULL | GENERAL | | Generic paperwork would be very helpful to go along with this guideline and a national standard for recording of all essential items would be reinforcing. | Generic paperwork is outside of the scope of this guideline. The NICE Implementation team may pick this up. Quality Standards are being developed. |

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| SH | Alder Hey Children's NHS Foundation Trust | 5 | FULL | GENE RAL | | It would be sensible somewhere (in the title or preamble) to note that this is short term or procedural sedation to distinguish it from the sort of sedation that we'd be claiming to do on the ICU | Thank you, this is stated in the scope. |
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| SH | Alder Hey Children's NHS Foundation Trust | 6 | FULL | GENE RAL | | My only comment would be that using VISUAL and not only written and verbal methods of communication for children with Learning Difficulties, literacy problems and younger children is appropriate- and maybe developing materials/guidance for general use would be helpful. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We anticipate that the 'good practice' recommendations will help inform local policy and agree that developing such materials/guidance would be useful implementation tools. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 1 | FULL | GENE RAL | | The AAGBI welcomes this detailed and timely guidance relating to minimal, moderate and deep sedation for painful procedures, painless imaging, endoscopy and dental procedures for children and young people. | Thank you for your comment. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 2 | FULL | GENE RAL | | The guidance includes sedation services for infants, children and young people under-19 years of age. Specific comment regarding sedation (or not) for procedures in neonates and ex-premature neonates would be helpful. | Thank you for your comment. Special consideration has been given to neonates and infants in the recommendations on pre-sedation assessment. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 3 | FULL | GENE RAL | | The AAGBI has serious reservations about the description of training requirements for personnel delivering deep sedation with agents with a narrow margin of safety (propofol, sevoflurane or opioids combined with ketamine). The GDG has acknowledged that these agents frequently induce periods of anaesthesia rather than deep sedation and the guidance is not consistent with current UK practice. | Thank you for your comment. The developers believe the recommendations on personnel and training to be accurate. We have added in the glossary the definition of margin of safety and of specialist sedation techniques that use drugs with a narrow margin of safety. |

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| SH | Association of Anaesthetists of Great Britain and Ireland | 4 | FULL | GENE RAL | | In the absence of a nationally accredited course, the description of theoretical knowledge, practical experience and competencies for sedation is vague. Advanced life support skills relate to rescue from cardiac arrest, not anaesthesia/sedation skills. For deep sedation, the AAGBI would recommend achieving and maintaining a basic level of competence in anaesthesia practice. | This area was debated extensively by the group and the views you put forward were discussed. The group disagree with your suggestion but would like to thank you for raising it. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 5 | FULL | GENE RAL | | The term ‘healthcare professional’ is defined in the guideline as including doctor, dentist or nurse; for the purposes of deep sedation in the UK, the AAGBI would recommend that this individual achieve a basic level of competence in anaesthesia practice. | Thank you for your comment. Definition of “Healthcare professional trained in delivering anaesthetic agents” has been added to the glossary and used in the guideline, and used in the appropriate recommendation on personnel and training. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 6 | FULL | GENE RAL | | The AAGBI has concerns regarding ‘operator-sedationists’. For deep sedation, the guideline should specify that the person administering sedation should not be the same person who is carrying out the procedure. | Thank you for your comment. This is stated in the full guideline, paragraph 4.1.3 (GDG discussion, Factors to consider in assessment). |
| SH | Association of Anaesthetists of Great Britain and Ireland | 7 | FULL | GENE RAL | | The guidance relating to starvation for emergency procedures under deep sedation is inconsistent; patients who undergo deep sedation should be starved as for general anaesthesia. | Thank you. In general for fasting for deep sedation should be the same as for general anaesthesia. We note in the guideline where specific fasting is not required. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 8 | FULL | GENE RAL | | The guidance relating to monitoring is inconsistent; the GDG acknowledges that moderate sedation with midazolam for upper GI endoscopy may be associated with airway obstruction. Capnography | Thank you for your comment. The developers believe the recommendations on monitoring to be accurate. |

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| | | | | | | should be recommended as standard monitoring for moderate sedation for upper GI endoscopy, as for deep sedation. | |
| SH | Association of Anaesthetists of Great Britain and Ireland | 9 | FULL | GENE RAL | | The AAGBI welcomes the emphasis on psychological preparation for children and their parents, but there should be greater emphasis on non-pharmacological techniques for procedures such as painless imaging, for instance distraction techniques, the use of play specialists, or the technique of 'feed and wrap' for young infants. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. A full evidence review of non-pharmacological interventions was not prioritised when shaping the scope into key clinical questions for effectiveness reviews. We acknowledge that this additional work could potentially augment the guidance and we made a suggestion for a future research recommendation (See section 3.4.3). |
| SH | Association of Anaesthetists of Great Britain and Ireland | 10 | FULL | GENE RAL | | It would be helpful to list specific contraindications to sedation such as OSA, neuromuscular disorders, morbid obesity. | Thank you. The developers feel that this is too much detail for inclusion in the guideline. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 11 | FULL | GENE RAL | | It would be helpful if the GDG could develop more specific guidance on agents/doses for different procedures, rather than leaving individual Trusts to develop their own protocols. | Thank you. The developers feel that this is too much detail for inclusion in the guideline. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 12 | FULL | 29 | 1 | It would be helpful to include the full ASA definition of levels of sedation as important narrative relating to safety has been omitted, for instance partial or complete loss of airway reflexes in deep sedation, the requirement to respond to light tactile stimulation (not a sternal rub) in moderate sedation. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Association of | 13 | FULL | 36 | 15 | It is not clear if the guideline includes | Thank you for your comment. The |

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| | Anaesthetists of Great Britain and Ireland | | | ? | | recommendations for neonates or ex-premature infants. Specific reference would be helpful. | developers acknowledge that there are differences between infants and older children but this guideline can be applied to children of all ages. There is discussion about infants for painless imaging procedures in section 6.13.1.2, Evidence to recommendations for painless imaging. We have also added special consideration for neonates and infants to the recommendation on pre-sedation assessment. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 14 | FULL | 41 | 19 | Please clarify consensus method used. | Thank you for your comment.This is clear within the text of the full guideline which reports the use of nominal group technique. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 15 | FULL | 47 | 17 | Additional specialist advice should be sought for neonates or ex-premature infants. | Thank you, the recommendation has been amended accordingly. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 16 | FULL | 51 | 6 | For deep sedation, the individual delivering sedation should not be the same as the person undertaking the procedure. It is acknowledged that it is possible to take your 'eye off the ball' once sedation has been completed; this also holds if the same person is administering sedation and doing the procedure, and the GDG acknowledges that there is a narrow margin of safety for deep sedation. | Thank you for your comment. This is stated in the full guideline, paragraph 4.1.3 (GDG discussion, Factors to consider in assessment). |
| SH | Association of Anaesthetists of Great Britain and Ireland | 17 | FULL | 52 | 1 | Deep sedation may be associated with loss of protective airway reflexes; guidance for urgent procedures under deep sedation should include specific reference to fasting. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 18 | FULL | 52 | 24 | For the anxious child/child with a learning disability referral to a **psychologist/play specialist** may be **more appropriate than a mental health specialist.** | Thank you for your comments. This difference may exist in relation to local service delivery models. We have used the term to apply broadly. |

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| SH | Association of Anaesthetists of Great Britain and Ireland | 19 | FULL | 53 | 15 | Training in the use of anaesthetic agents should relate to specific competence in anaesthesia practice. | The GDG acknowledge that all training relating to sedation should have a competency focus for knowledge skills and attitudes. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 20 | FULL | 54 | 8 | Moderate sedation for upper GI endoscopy should include capnography. | Thank you. The developers believe this recommendation to be accurate. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 21 | FULL | 55 | 2 | Specific reference should be made to non-pharmacological techniques, particularly for neonates, ex-premature neonates and infants under 5kg. | Thank you for your comment. We have amended one recommendation on pre-sedation assessment and we recommend that for neonates and infants, specialist advice should be sought. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 22 | FULL | 63 | 21 | Mention should be made of lean body weight when administering sedation to obese children. | Thank you, we agree with your comment, we have amended the wording to include the ideal body weight. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 23 | FULL | 64 | 16 | The requirement to avoid the situation of 'operator-sedationist' for deep sedation should be explicit. | Thank you for your comment. This is stated in the full guideline, paragraph 4.1.3 (GDG discussion, Factors to consider in assessment). |
| SH | Association of Anaesthetists of Great Britain and Ireland | 24 | FULL | 80 81 | 14 | The GDG acknowledges that there is no consistency of training in sedation, and that training may be delivered by a number of providers. For deep sedation using anaesthesia agents the AAGBI has concerns that the responsibility to define appropriate training is to be devolved to individual Trusts. | Thank you, we acknowledge your comment; individual Trusts are mentioned as an example. The developers feel that this is too much detail for inclusion in this broad national guideline. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 25 | ALGORITHMS | | | The use of arrows may have greater visual impact in emphasising the continuum between different levels of sedation. | Thank you for your comment, the whole algorithm has been replaced. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 26 | FULL **NICE** | 13 | | Basic Life Support in hospital includes the use of bag, valve mask ventilation, not simply expired air resuscitation. | Thank you for your comment, the recommendation and glossary have been amended accordingly. |

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| SH | Association of Anaesthetists of Great Britain and Ireland | 27 | FULL NICE | 18 | | The Resuscitation Council UK offers one-day training courses in Immediate (not Intermediate) Life Support; this does not involve training in the use of laryngeal mask airways. | Thank you for your comment. Guidance does not specify training for use of laryngeal mask. |
| SH | Association of Anaesthetists of Great Britain and Ireland | 28 | FULL | | | The guidance will need to be carefully proof read as there are a number of typing errors, for instance P2: line 19 is a statement not a question; P29 line 32L 'choose' not chose; P60 line 41: 'could' not caoul; P61 line 15 'sedation' not sedition. | Thank you for your comment. The guideline has been proofread. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 1 | FULL | GENERAL | | Given the size and scope of the document, comments may be limited. Some specific aspects, such as pharmacology and therapeutics, have not been considered in detail | Thank you. The developers feel that this is too much detail for inclusion in the guideline. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 2 | FULL | GENERAL | | The APA commends the importance placed on training and clinical standards and the need to develop standardised assessment tools. However, the GDG should provide more specific guidance on life support training, including considering recommending nationally recognized training courses for example, as provided by the Resuscitation Council and the Advanced Life Support Group. The category of sedationist provided could be linked to the level of life support course advocated | Thank you. We cannot brand a specific course; we can only identify the course content. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 3 | FULL | GENERAL | | Although the GDG do mention alternatives to sedation (for example, page 28 / lines 26 – 34; 32), the guidance would be improved by more detailed consideration of the role of sedation-sparing 32 / sedation-avoidance | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. A full evidence review of non- |

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| | | | | | | techniques including ambient environment; distraction techniques and guided imagery; 'feed and sleep'[1];play and the potential contributions of professionals such as hospital play specialists | pharmacological interventions was not prioritised when shaping the scope into key clinical questions for effectiveness reviews. Service delivery recommendations on healthcare professional team constituent membership such as 'play therapists' in relation to your point was not a guideline priority. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 4 | FULL | GENE RAL | | It may be useful to describe sedation within a hierarchy and we suggest that for any patient, clinicians should be encouraged to consider alternative techniques[2] before **actively choosing** to give sedation. If there is no published evidence or expert opinion in support of the alternatives[2], then this should be clearly stated | Thank you for your comments. Guideline recommendations do address this. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 5 | FULL | GENE RAL | | If supported either by published evidence or expert opinion, the use of analgesia (especially local anaesthetic drugs) as an adjunct to sedation should be stressed more forcibly | Thank you for your comment. We have amended the recommendations on painful procedures and added a footnote on local anaesthetic. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 6 | FULL | GENE RAL | | Except for intravenous propofol, the GDG do not consider the need (or otherwise) to obtain intravenous access. The guideline should include discussion on this potentially contentious point | Thank you for your comment. This has been discussed in section 6.4.4, GDG discussion of the evidence for Ketamine. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 7 | FULL | GENE RAL | | The efficacy of melatonin, which is advocated by some, should be reviewed | Thank you for your comment, but this was not considered a priority by the GDG. |
| SH | Association of Paediatric | 8 | FULL | GENE | | The guidance should include specific | Thank you for your comment. We have |

[1] *'Feed and sleep'* techniques are used in infants undergoing painless procedures such as magnetic resonance or computerised tomographic imaging. These are scheduled either after a short episode of sleep deprivation or at a normal sleep time and after a feed. The technique also involves sleep cues such as bathing, dimmed lighting during feeding etc.
[2] including ambient environment; distraction techniques and guided imagery; 'feed and sleep'[1]; and play and the potential contributions of professionals such as hospital play specialists

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| | Anaesthetists of Great Britain and Ireland | | | RAL | | recommendations on infants, especially those born prematurely | added special consideration for neonates and infants to the recommendation on pre-sedation assessment. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 9 | FULL | GENE RAL | | It would be useful for the guidance to include a list of medical / physical conditions associated with sensitivity to sedatives (for example, obstructive sleep apnoea, prematurity, myotonia) and to include a concise list of the side-effects of, and contra-indications to, all the recommended drugs | This has been discussed in general terms in sections 4.1.1, Clinical introduction to pre-sedation assessment, and 4.1.3, GDG discussion, factors to consider in assessment.<br>Other than the general discussion, this is too much detail. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 10 | FULL | GENE RAL | | 'Sedation' is frequently mis-spelled as 'sidition', for example, page 61 / line 15; page 338 / line 10 | Thank you for your comment. The issue has been addressed accordingly. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 11 | FULL | GENE RAL | | Ketamine is associated with laryngospasm. This does not mentioned | Thank you, this is stated in section "6.4.4, GDG discussion of the evidence for ketamine". |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 12 | FULL | 27 | | Wording in this section may need revision/clarification. For example:<br>• Lines 18 – 30: the GDG could make it clearer when sedation might be more appropriate than anaesthesia and vice versa?<br>• Line 27, anaesthesia *'may have resource implications'*: why qualify this, as anaesthesia **does have** resource implications and requires quite a different level of organization?<br>• Line 30: the emphasis here is on cost effectiveness when it ought to be on efficacy and safety | • These are general comments – specific comments are made in reference to specific procedures<br>• Many hospitals already have anaesthesia services in place<br>• We have assumed that the sedation techniques are effective and safe – therefore the cost effectiveness question is reasonable |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 13 | FULL | 28 | 15 – 23 | Please indicate which geographical area this data refers to (i.e. England only or England and Wales)? | Thank you for your comment. Page 28 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document |

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| | | | | | | | was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 14 | FULL | 28 | 24 – 25 | This is not the case in Wales, where the practice continues and has not been banned | Thank you for your comment. Page 28 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 15 | FULL | 30 | 28 | The guideline deals with children and young adults up to 19 years. The GDG should consider supplementing the BNFC with the BNF for adults | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 16 | FULL | 41 | | **2.5 Consensus**<br>Please explain why the nominal group technique was preferred | Thank you for your comments. Within development process, nominal group technique works effectively rather than other iterative methods such as Delphi. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 17 | FULL | 47 | 7 | Establishing suitability for sedation should additionally include evaluation of the potential efficacy of sedation-sparring / sedation-avoiding techniques[2] | Thank you, we agree with your comment; this is covered in chapter 5. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 18 | FULL | 47 | 17 | Specialist advice may also be indicated for infants, especially those born pre-term, and if the role of alternative techniques for any patient is unclear or the individual does not have the expertise to use these | Thank you, the recommendation has been amended accordingly. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 19 | FULL | 47 | 22 | The healthcare professional should additionally have an obligation to choose the most suitable technique (including sedation-avoiding techniques[2]) or hierarchy | Thank you for your comment, the suitability for sedation has been discussed in a previous recommendation on pre-sedation assessment. |

[2] including ambient environment; distraction techniques and guided imagery; 'feed and sleep'[2]; and play and the potential contributions of professionals such as hospital play specialists

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| | | | | | | of techniques, before opting for sedation. He / she should then consider sedation-sparring techniques and analgesia (especially local anaesthetics) as part of any sedation plan | The developers do not wish to change the wording as it was felt that the current wording is clear. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 20 | FULL | 48 | 10 | Healthcare professionals delivering sedation should additionally have knowledge and understanding of sedation-sparring / sedation-avoiding techniques[2], the role of local anaesthetics and the special considerations in infants | Thank you for your comment, the suitability for sedation has been discussed in a previous recommendation on pre-sedation assessment.<br>The developers do not wish to change the wording as it was felt that the current wording is clear. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 21 | FULL | 49 | 1 - 11 | Any healthcare professional delivering sedation should successfully complete an accredited course in paediatric life support (for example as provided by the Resuscitation Council or Advanced Life Support Group) and attend a refresher course / update annually (content and standard determined by the local Resuscitation Committee or equivalent). Additionally, sedations must maintain their clinical competence and be up to date, for example, in the current algorithms for resuscitation | Thank you for your comment, NICE guidance does not specify the training providers. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 22 | FULL | 50 | 8 AND 9 | Establishing suitability for sedation should additionally include evaluation of the potential efficacy of sedation-sparring / sedation-avoiding techniques[3] | Thank you for your comment. We have assessed this and found no evidence. |
| SH | Association of Paediatric Anaesthetists of Great | 23 | FULL | 50 | 20 - 22 | Specialist advice may also be indicated for infants, especially those born pre-term, and | Thank you for your comment, the recommendation has been amended |

[3] including ambient environment; distraction techniques and guided imagery; 'feed and sleep'[3]; and play and the potential contributions of professionals such as hospital play specialists

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| | Britain and Ireland | | | | | if the role of alternative techniques for any patient is unclear or the individual does not have the expertise to use these | accordingly. |
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| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 24 | FULL | 50 | 24 - 26 | The healthcare professional should additionally have an obligation to choose the most suitable technique (including sedation-avoiding techniques[2]) or hierarchy of techniques, before opting for sedation. He / she should then consider sedation-sparring techniques and analgesia (especially local anaesthetics) as part of any sedation plan | Thank you for your comment, the suitability for sedation has been discussed in a previous recommendation on pre-sedation assessment.<br>The developers do not wish to change the wording as it was felt that the current wording is clear. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 25 | FULL | 52 | 27 - 33 | Healthcare professionals delivering sedation should additionally have knowledge and understanding of sedation-sparring / sedation-avoiding techniques[2], the role of local anaesthetics and the special considerations in | Thank you for your comment, the suitability for sedation has been discussed in a previous recommendation on pre-sedation assessment.<br>The developers do not wish to change the wording as it was felt that the current wording is clear. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 26 | FULL | 52 | 20 - 22 | *'Offer parents and carers the opportunity to be present during sedation when appropriate. If a parent or carer decides to be present offer them advice about their role during the procedure'.* This recommendation reflects current accepted good practice but the conclusions reached after review of the literature (later in the document) on the benefits of parental presence (see also comments under page 99 / 5.1.9 / line 2 below) are negative, which may reflect the limitations of the studies rather than the validity of their findings. The GDG may be trying to reflect the *'pardigm shift to family centred care'* (page 108) whilst emphasising the paucity of evidence | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for practice. This approach is supportive of your point. |

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| | | | | | | in the literature to support this. However, it may not be helpful to challenge what is now accepted good practice, at least in the UK. Some of the references are now quite old (notably references 87 (1993); 110 (1996); 122 and 202 (1998)) and the validity of these studies, does not seem to be questioned. | |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 27 | FULL | 52 | 24 AND 25 | For elective sedation in a child with severe anxiety or learning disability, is there evidence in support of referral to a mental health specialist? It is disappointing that this is not explored in the subsequent discussion on *'Psychological Preparation'* (page 74 onwards)<br><br>The APA questions whether the term *'mental health specialist'* can be applied in quite the same way to both anxious patients and those with a learning disability. Each deserves / warrants slightly different specialist input (psychotherapy, play therapy) and complex patients may need a multidisciplinary approach. The key here is obtaining the necessary financial investment<br><br>The guidance should additionally consider the roles of hospital play specialists, particularly in the care of severely anxious patients or those with learning disabilities. This should include their role as an adjunct or alternative to referral to a mental health specialist | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities.<br><br>Service delivery recommendations on healthcare professional team constituent membership was not a guideline priority.<br><br>We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. A full evidence review of non-pharmacological interventions was not prioritised when shaping the scope into key clinical questions for effectiveness reviews. We acknowledge that this additional work could potentially augment the guidance. |
| SH | Association of Paediatric Anaesthetists of Great | 28 | FULL | 53 | 7 AND | This point should also include practical experience in and knowledge of how normal | Thank you, we acknowledge your comment, however the developers believe this |

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| | Britain and Ireland | | | | 8 | physiological variables change with age | recommendation to be accurate. |
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| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 29 | FULL | 53 | 15 - 19 | *'....trained in delivering anaesthetic agents.........is available to administer the following sedatives: sevoflurane, propofol, opioids combined with ketamine'.* These are anaesthetic **not** sedative drugs, although with skill these can be administered in a manner that provides sedation. This point is not one of semantics; the perception that these drugs can be regarded as sedatives is potentially seriously misleading | Thank you we agree with your comment and we have changed the word 'sedatives' to 'drugs'. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 30 | FULL | 53 | 21 - 26 | Professionals should have documented evidence of competency, experience and training covering all the age-groups for which they will provide a service | Thank you, we acknowledge your comment, however the developers believe this recommendation to be accurate. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 31 | FULL | 53<br>54 | 7<br>28-29 | It would be useful to clearly define the terms 'coping' and 'distress' | Thank you for your comment. The GDG did not feel that there is a need to define these terms, they are commonly understood. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 32 | FULL | 54 | 7 - 29 | Mention should be made interpreting physiological variables and behaviour in relation to patients' ages | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 33 | FULL | 55 | 22 – 24 | The GDG should consider the role of local anaesthetic techniques (topical agents; infiltration) in conjunction with sedation and advocate their use if supported by evidence / expert opinion | Thank you for your comment. A footnote has been added to the recommendation. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 34 | FULL | 55 | | **Table**<br>As configured, this table states that nitrous oxide is given alone; the supplementary information about oxygen appears over the page. Care should be taken to ensure that | Thank you for your comment. The table is now contained within one page. |

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| | | | | | | this table does not spread this table over two pages. (In a well-publicised critical incident a few years ago, $N_2O$ without oxygen was delivered to a patient attending an emergency department) | |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 37 | FULL | 58 | 2 - 16 | The APA commends the recommendation for research to develop a tool for assessing which patients would be appropriate for behavioural therapy, who would require sedation and who will need anaesthesia | Thank you for your comment.This is implicit in the research recommendation 3.4.1 |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 38 | FULL | 61 | 18 - 20 | The APA commends the Guideline Development Group's (GDG) recommendation to establish a national registry, although practically this may be difficult to achieve | Thank you for your comment. This is a future research recommendation. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 39 | FULL | 63 | 21 | Drug doses need to take account of co-existing disease, especially obesity and conditions associated with drug sensitivity (such as obstructive sleep apnoea, prematurity, myotonia), in addition to weight. Body mass index and lean body mass are important factors in determining dose | Thank you, we have amended the wording to include the ideal body weight. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 40 | FULL | 63 | 35 - 41 | For elective sedation in a child with severe anxiety or learning disability, is there evidence in support of referral to a mental health specialist? It is disappointing that this is not explored in the subsequent discussion on *'Psychological Preparation'* (page 74 onwards)<br><br>The APA questions whether the term *'mental health specialist'* can be applied in quite the same way to both anxious patients | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities. |

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| | | | | | | and those with a learning disability. Each deserves / warrants slightly different specialist input (psychotherapy, play therapy) and complex patients may need a multidisciplinary approach. The key here is obtaining the necessary financial investment<br><br>The guidance should additionally consider the roles of hospital play specialists, particularly in the care of severely anxious patients or those with learning disabilities. This should include their role as an adjunct or alternative to referral to a mental health specialist | |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 41 | FULL | 63 | 41 | The British Society of Disability and Oral Health and the British Institute of Learning Disability have published a guide on restraint (see www.bsdh.org.uk) | Thank you for your comment. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 42 | FULL | 65 | 26 | Add a requirement to document any need for physical restraint | Thank you for your comment, this was not one of our clinical questions. This is determined usually by local policy and reference to other guidance such as RCN (http://www.rcn.org.uk/__data/assets/pdf_file/0016/312613/003573.pdf ) and www.bsdh.org.uk may be helpful, as briefly discussed in Section 4.1.3, GDG discussion, Factors to consider in assessment. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 43 | FULL | 67 | | **Recommendation 5**<br>For clarity, consider stating here explicitly that the practice of a sole-sedationist / operator is unacceptable. Consider also emphasizing the team-approach in the care of children and young people | Thank you for your comment. This is stated in the full guideline, paragraph 4.1.3 (GDG discussion, Factors to consider in assessment). |

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| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 44 | FULL | 74 – 76 | | **'Psychological Preparation'**<br>Distraction techniques and the ambient environment should be included here in addition. Techniques might include a warm environment, music, visual stimulation (in all), feeding (*'feed and sleep'*), swaddling and sucrose (in babies). See general comments above | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. A full evidence review of non-pharmacological interventions was not prioritised when shaping the scope into key clinical questions for effectiveness reviews. |
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| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 45 | FULL | 80 | 3 | *'Offer parents and carers the opportunity to be present during sedation when appropriate. If a parent or carer decides to be present offer them advice about their role during the procedure'*. This recommendation reflects current accepted good practice but the conclusions reached after review of the literature (later in the document) on the benefits of parental presence (see also comments under page 99 / 5.1.9 / line 2 below) are negative, which may reflect the limitations of the studies rather than the validity of their findings. The GDG may be trying to reflect the *'pardigm shift to family centred care'* (page 108) whilst emphasising the paucity of evidence in the literature to support this. However, it may not be helpful to challenge what is now accepted good practice, at least in the UK. Some of the references are now quite old (notably references 87 (1993); 110 (1996); 122 and 202 (1998)) and the validity of these studies, does not seem to be questioned. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We anticipate that the 'good practice' recommendations will help inform local policy and agree that developing such materials/guidance would be useful implementation tools. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 46 | FULL | 80 | 4 | For elective sedation in a child with severe anxiety or learning disability, is there evidence in support of referral to a mental health specialist? It is disappointing that | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services |

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| | | | | | | this is not explored in the subsequent discussion on *'Psychological Preparation'* (page 74 onwards)<br><br>The APA questions whether the term *'mental health specialist'* can be applied in quite the same way to both anxious patients and those with a learning disability. Each deserves / warrants slightly different specialist input (psychotherapy, play therapy) and complex patients may need a multidisciplinary approach. The key here is obtaining the necessary financial investment<br><br>The guidance should additionally consider the roles of hospital play specialists, particularly in the care of severely anxious patients or those with learning disabilities. This should include their role as an adjunct or alternative to referral to a mental health specialist | as this is where expert advice can be sought in relation to learning disabilities. Service delivery recommendations on healthcare professional team constituent membership such as 'play therapists' in relation to your point was not a guideline priority. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 47 | FULL | 81 – 83 | | **4.4 'Personnel and Training'**<br>This section should also consider communication skills with children, which are integral to success of sedation techniques | Thank you for your comment, we acknowledge the importance of effective communication skills, We have explained the principles of effective communications in section 4.1.3, GDG discussion, particularly in the "Information and consent" sub-paragraph. |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 48 | FULL | 82 – 83 | 29 / 2 | Specifically, certificated □editionists should successfully complete an accredited course and be competent in resuscitation (including vascular access and advanced airway skills) in children and young people of all ages | Thank you for your comment, healthcare professionals are required to work within their scope of practice determined by training and competency. The guideline establishes this in the Section 4.4, Personnel and training. |
| SH | Association of Paediatric Anaesthetists of Great | 49 | FULL | 84 | 1 | **Recommendation 19**<br>*'....trained in delivering anaesthetic* | Thank you for your comment. We have changed the word 'sedatives' to 'drugs' |

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| | Britain and Ireland | | | | | *agents.........is available to administer the following sedatives: sevoflurane, propofol, opioids combined with ketamine'*. These are anaesthetic **not** sedative drugs, although with skill these can be administered in a manner that provides sedation. This point is not one of semantics; the perception that these drugs can be regarded as sedatives is potentially seriously misleading | |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 50 | FULL | 86 | 28 - 34 | **'When should the monitoring stop?'** Suggest advocating and reinforcing a formal handover to trained recovery staff in an appropriate facility with appropriate monitoring here | All staff involved with delivery of sedation are trained, including recovery staff |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 51 | FULL | 99 | 2 | *'Permitting parental presence during anaesthesia induction varies widely between and within hospitals and countries and is surrounded by controversy'.* On the contrary, this practice is **not** *'surrounded by controversy'* in the UK.,<br>As reference 110confirms in its comparison of practice in Great Britain,where parental presence was widely supported, with the United States, where it generally was not. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for practice. This approach is supportive of your point |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 52 | FULL | 106 | 14 - 16 | *'Taken in conclusion the results of the above randomised studies point that current evidence shows no apparent benefit of parental presence during anaesthesia induction in relation to decreasing parents' and children's anxiety'.* There would seem to be no critical appraisal discussion in relation to the validity of these studies | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for |

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| | | | | | | | practice. This approach is supportive of your point |
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| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 53 | FULL | 106 | 26 - 43 | This paragraph has omitted the concluding discussion of the systematic review referenced (Piira et al [181] ) *'Although parental presence may not have a clear, direct influence on child distress and behavioural outcomes, there are potential advantages for parents. It seems appropriate that clinicians provide parents with the opportunity to be present during their child's painful procedure.'* | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for practice. This approach is supportive of your point |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 54 | FULL | 108 | 3 - 5 | *'For parents there is inconclusive evidence indicating whether parents should be encouraged or discouraged to be present at their child's induction. The offer to be present is therefore to be based on negotiation with the care team'.* Is this a recommendation? If so it is retrogressive and if it is a statement about current practice (in the UK, it is inaccurate and contrary to current good practice guidance, which places the emphasis on promoting parental presence (other than in exceptional circumstances) rather than expecting parents to 'negotiate' | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for practice. This approach is supportive of your point |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 55 | FULL | 330 | 4 | *'Since 2002, anaesthesia has been prohibited in the non-hospital setting'.* This is not the case in Wales, where the practice continues | Thank you for your comment. We have now specified "in England". |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 56 | FULL | 336 | 11 | After consultation with colleagues undertaking dental sedation, the APA is surprised at the need to use up to 70% $N_2O$. Colleagues reported that this concentration | Thank you, we agree with your comment. 70% N2O is the max concentration that can be used in dentistry. |

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|  |  |  |  |  |  | is very rarely needed |  |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 57 | FULL | 337 | 14 - 20 | Whilst research into 'value for money' is important, this should not be viewed in isolation. In comparing anaesthesia with sedation, the GDG should additionally include safety (critical incidents) and outcome (failure rates; recovery; adverse effects) | Thank you. We have changed the recommendation as follows:<br>For children and young people under the age of 19 undergoing diagnostic or therapeutic procedures, are procedures carried out under sedation more safe, effective and cost effective than those carried out under general anaesthesia? |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 58 | FULL | 338 | 12 - 15 | The APA commends the Guideline Development Group's (GDG) recommendation to establish a national registry, although practically this may be difficult to achieve | Thank you for your comment |
| SH | Association of Paediatric Anaesthetists of Great Britain and Ireland | 59 | FULL | ALGO RITHM 48672 |  | **Algorithm 48672**<br>This advises contacting a consultant anaesthetist for certain categories of patients, if sedation fails. Whilst general anaesthesia may well be the most appropriate secondary plan, immediate direct contact, as described, may prove onerous for anaesthetic services. It may be better to advocate *'arrange(ing) /discuss(ing) anaesthesia support in a timely manner. Involve(ing) senior personnel'* instead | Thank you for your comments, following consultation we have decided not to present the guideline as a separate algorithm which is different to the NICE Quick Reference Guide produced by NICE prior to publication. |
| SH | British Society of Gastroenterology | 1 | FULL | GENE RAL |  | We are happy with the document as it relates to gastrointestinal endoscopy in young people | Thank you for your comment. |
| SH | College of Emergency Medicine | 1 | FULL | 249 | 25 | The correct reference for the 3.9% rate of vomiting with 50% nitrous oxide is ref 21 (Babl Pediatrics 2008) | Thank you, the reference has been changed |
| SH | College of Emergency Medicine | 2 | FULL | 249 | 26 | The reference for the reporting saturations is <90% in patients using 70% is ref 21 | Thank you, teference changed. The correct statistic is actually 0.1% of 548 patients who |

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| | | | | | | (Babl Pediatrics 2008). The correct statistic is 0.18% (i.e. 1 patient) of patients using 70% nitrous oxide had a saturation of <90%, not 3.9%. | received 70% nitrous oxide. |
| SH | College of Emergency Medicine | 3 | FULL | 244 | TABL E 62 | The Babl reference is 21 not 20 for this information | Thank you, the reference has been changed |
| SH | College of Emergency Medicine | 4 | FULL | 242 | TABL E 61 | The Babl reference is 21 not 20 | Thank you, the reference has been changed |
| SH | College of Mental health Pharmacy | 1 | FULL NICE | 15 | 13 | Please include route for propofol | Thank you for your comment. Where a route of delivery is not highlighted in the guideline, administration route is down to the clinical choice. |
| SH | College of Mental health Pharmacy | 2 | FULL NICE | 15 | 14 | Please include route for Sevoflurane | Thank you for your comment. Where a route of delivery is not highlighted in the guideline, administration route is down to the clinical choice. |
| SH | College of Mental health Pharmacy | 3 | FULL NICE | 15 | 18 | Please include route for fentanyl | Thank you for your comment. Where a route of delivery is not highlighted in the guideline, administration route is down to the clinical choice. |
| SH | College of Mental health Pharmacy | 4 | FULL NICE | 16 | 7 | Please include route for midazolam | Where a route of delivery is not highlighted in the guideline, administration route is down to the clinical choice. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 1 | FULL NICE | 21 | 20 | There was no Consultant or Specialist in Paediatric Dentistry within the Group and no Consultant or Specialist in Special Care Dentistry representing patients over the age of16 and under the age of 19. | Thank you for your suggestion. The developers are mindful of the need for ensuring that a broad range of experience and knowledge is represented on the group. This has to be balanced with the need to ensure that the GDG is a workable size and as such enables individuals to contribute effectively. When convening the guideline development group the developers have followed the principles outlined in the NICE guidelines manual. |

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| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 2 | FULL | 2 | 28 | As above, although there was a Professor and Consultant in Conscious Sedation and a very experienced General Dental Practitioner in the Guideline group.<br>The guidance uses dental extractions as the common scenario in Dentistry and states that the guidance can be applied to '90% of scenarios'. Our experience in the Paediatric group is that the larger proportion of sedation is to facilitate restorative procedures rather than extractions. The guideline does not cover restorative dentistry which may give different outcomes, also in the age range of 16 and under the age of 19. | Thank you for your comment; we use 'Dental procedures' throughout the guideline to include all dental interventions. |
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| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 3 | FULL | 29 | 28 | The premise is 'if sedation is unsuccessful…' Treatment planning is important as in line 33-34 if there is a need for repeated procedure such as a filling in different quadrants of the mouth then this could not be undertaken with repeated GA. This could lead to more extractions being planned and may be important in treatment planning and care in the transitional years. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 4 | FULL | 30 | 28 | The BNF for adults should be added to include prescribing for patients over 16 years old. | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 5 | FULL | 52 | 24 | There will need to be substantial investment in services to allow 'referral to a mental health specialist for children who are severely anxious or those who have a learning disability'<br>The approach is evidence based, appropriate and aspirational as a number of | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities. |

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| | | | | | | complex patients require this approach; however, this is not being achieved at present as there is not enough funding. | |
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| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 6 | FULL | 61 | | National Registry for Paediatric Sedation – It would be useful to link this to electronic clinical records and national data set. | Thank you for your comment. This is a future research recommendation. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 7 | FULL | 63 | 21 | The comment' dose of all drugs except vapours and gases must be calculated or adjusted according to the body weight'.<br>In Dentistry, the drugs nitrous oxide and midazolam are titrated to the individual patient's response. For obese patients, dose is based on weight and will be influenced by ASA grading; however, careful titration to response should bear in mind lean body mass. | Thank you, we agree with your comment, we have amended the wording to include the ideal body weight. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 8 | FULL | 63 | 41 | British Society of Disability and Oral Health and British Institute of Learning Disability have published a guideline on Clinical Holding and Physical Intervention for patients with Learning Disability www.bsdh.org.uk<br>This could be referenced here as an appropriate guideline for inclusion. | Thank you for your comment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 9 | FULL | 65 | 26 | The decision to use 'clinical holding' should be discussed and documented. | Thank you for your comment, this was not one of our clinical questions. This is determined usually by local policy and reference to other guidance such as RCN (http://www.rcn.org.uk/__data/assets/pdf_file/0016/312613/003573.pdf ) and www.bsdh.org.uk may be helpful, as briefly discussed in Section 4.1.3, GDG discussion, Factors to consider in |

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|  |  |  |  |  |  |  | assessment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 10 | FULL | 79 | 26 | HCP involved in sedation patients do provide psychological support but there is a definite need at times to include trained Mental Health Specialists for preparation of patients.<br>Funding will be necessary.<br>Recommendation 15 agree | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 11 | FULL | 81 | 14 | Training: The Diploma and MSc courses in Conscious Sedation in the UK and Ireland are subject to validation panels in the Universities with External assessors with expertise in the field. This includes Workplace assessments as well as summative and formative assessment. | Thank you, we acknowledge your comment; individual Trusts are mentioned as an example. The developers feel that this is too much detail for inclusion in this broad national guideline. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 12 | FULL | 82 | 19 | Agree that HCP need to undergo competency based assessment upon completion of training.<br>The organisation and funding of this will have to be determined and carefully planned. | Your concerns have been forwarded to the NICE implementation and costing teams for this guideline. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 13 | FULL | 82 | 29-42 | This will cause problems in relation to existing staff. It will also need to be built into training programmes at all levels.<br>'Grandparenting' arrangements will need to be considered for existing practitioners<br>Agree that HCP should have documented evidence of competency and should maintain CPD in subject. | Your concerns have been forwarded to the NICE implementation team for this guideline. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental | 14 | FULL | 83 | 1 | Recommendations 16-20<br>Agree- Maintain documentary evidence of clinical activity and CPD in sedation and that Trusts and Health Boards will need to ensure this is undertaken and funded. | Thank you for your comment. |

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| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 15 | FULL | 97 | 4 | American Academy of Paediatric Dentistry reference 14 –<br>Why not from the UK Paediatric literature? | Thank you for your comment. Guideline searches apply to the world's literature. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 16 | FULL | 170 | 10 | Agree : 'the use of midazolam alone in dental procedures in adolescents is common and there is some evidence on the effectiveness and safety of using MDZ alone'-<br>This practice is not the case in all Dental Schools and sedation services. | Thank you for your comment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 17 | FULL | 250 | 15 | There is no note of the use of topical LA which reduces the discomfort of LA . | Thank you for your comment. The use of topical LA was outside of our remit for the sedation guideline. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 18 | FULL | 250 | 27-40 | Agree with: 'the GDG considers nitrous oxide to be safe, short acting and highly effective in selected patient groups '<br>This is also the case for restorative dentistry as well. | Thank you for your comment |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 18 | FULL | 250 | 36 | Agree with GDG that 'patients must be assessed and that practitioners must be trained to use nitrous oxide safely'.<br>There is a requirement for clear definition of 'training' . | Thank you for your comment. We have specified as far as able – detail would be too great for all drugs in the guideline |
| SH | Dental Services Division, Cardiff and Vale | 19 | FULL | 251 | 3 | Noted and Agree: 'only specially trained dental sedation teams should use | Thank you for your comment. |

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| | University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | | | | | combinations of sedation drugs to achieve sedation...' | |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 20 | FULL | 251 | 10-13 | Noted that nitrous oxide and other drugs in this section have some evidence that they are safe and effective; however; they are not commonly used in Dental Schools and sedation services at present and would require dental teams to have additional training.<br><br>The generalisability of this model has to be questioned. | Thank you for your comment. The GDG felt that the guidance is realistic. Your comment will be forwarded to the NICE implementation team for this guideline. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 21 | FULL | 263 | 9 | Noted and agreed 'the GDG agreed that sevoflurane should only be used by specially trained sedation' teams. | Thank you for your comment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 22 | FULL | 335 | 6 | Noted and agreed ' moderate sedation with intravenous midazolam is considered to be effective for selected children and young people who are cooperative and younger children who can tolerate a nasal mask can be managed with nitrous oxide' | Thank you for your comment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 23 | FULL | 335 | 16 | Noted 'GDG agreed potential important economic advantages of avoiding hospital based anaesthetic services. The training of dental sedation teams was regarded as crucial.'<br><br>The model is based on extractions but the economics of multiple sedations to facilitate full mouth rehabilitation has not been | Thank you. The GDG felt that this wasn't a common enough scenario to require detailed HE analysis. |

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| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 24 | FULL | 335 | 37 | Noted The GDG 'states we found that sedation is clearly cost saving compared to GA in cases where the operating dentist/or a nurse is able to administer sedation without the addition of a sedationist dentist.'<br><br>At the present time, we are unaware that Dental Nurses are allowed to administer the sedation in many of the Dental Schools, Trusts and Health Boards. | Thank you. We have removed this sensitivity analysis from our write-up. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 25 | FULL | 336 | 5 | Noted and agreed 'GDG reported that very high rates of success (above 95%) are achievable with all techniques if patients are selected carefully.<br><br>The dental treatment must also be of an appropriate standard / level to compliment this high success rate.<br>' | Thank you for your comment. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 26 | FULL | 336 | 11 | Recommendation 33 is noted 'to achieve moderate sedation with nitrous oxide and oxygen (titrated to child's needs and using maximum of 70% Nitrous oxide).<br><br>The level of 70% nitrous oxide would rarely be used without specialist training.<br><br>If these are not suitable or effective, consider referring to a specialist team for other sedation techniques (e.g. MDZ in combination with N2O).'<br>Further investment in sedation services will be necessary to achieve this. | Thank you, we agree with your comment. 70% N2O is the max concentration that can be used in dentistry.<br><br>The definition of specialist team has been added to the glossary. |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental | 27 | FULL | 336<br><br>-338 | 13-27 | The research recommendations were noted and agreed.<br><br>Further research must also reflect | Thank you but this area was not prioritised by the GDG for a research recommendation. |

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| | Services Group, Cardiff University Dental Hospital) | | | | | restorative options including treatment planning and multi-visit options for care. | |
| SH | Dental Services Division, Cardiff and Vale University Health Board (previous name Dental Services Group, Cardiff University Dental Hospital) | 28 | FULL | 338 | 10-14 | Noted and agreed that 'a National Registry for Paediatric Sedation is established for the purpose of creating a database with sufficient data.'<br>This must be compatible with national data sets and be subject to Clinical Governance issues such as Data Protection. | Thank you for your comment |
| SH | Department of Health | 1 | NICE | GENERAL | | Our main concern is that the medicines recommended do not appear to be in line with the advice in the British National Formulary for Children (BNFC) 2009. We are currently unable to check whether the content of the 2010/11 edition differs from that for 2009.<br><br>In the recent constipation guideline, you have specifically commented on where the advice on dosage differs from the BNFC.<br><br>The biggest difference from the BNFC appears to relate to propofol. We are aware that this is widely used by anaesthetists in children but it is not licensed for those under 3 years of age, and it is contra-indicated for sedation of ventilated children in intensive care under 17 years Doses under 17 are given in the BNFC for anaesthesia, and not for sedation<br><br>Ketamine doses in the BNFC are for anaesthesia.<br>Therefore, if the evidence underpinning this guideline supports safe sedation with these agents (which we must assume it does), we feel that the differences from the BNFC | Thank you for your comment. An appendix and footnotes were added to both the NICE and full guideline to clarify the licensing of sedation drugs. |

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| | | | | | | should be addressed in order to ensure safe prescribing, particularly by non anaesthetists, as the skills and competencies of the sedation team described in the guideline appear to fall short of those of an anaesthetist trained in children's anaesthesia. | |
| SH | Faculty of Dental Surgery | 1 | FULL | 29 | 9-10 | This definition is not consistent with the definition of conscious sedation as used in the field of dentistry and deep sedation is not advocated. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Faculty of Dental Surgery | 2 | FULL | 49 | 1 | A table is presented with headings of different levels of<br>Sedation, however no definition has been provided of these sedation levels at this stage. The term Deep Sedation is referred to and in the field of dental sedation this term is generally equated with general anaesthesia. This needs to be clearly explained. | Thank you for your comment. Definitions of minimal, moderate, conscious, deep sedation and general anaesthesia are provided in the Glossary of terms |
| SH | Faculty of Dental Surgery | 3 | FULL | 51 | 22 | Fasting: Having read the evidence to support the issue of fasting thee appears to be limited support for the need for fasting and yet a blanket recommendation for the 2,4,6, rule has been recommended, with the exception of nitrous oxide sedation. For dental patients fasting children can have detrimental effects. The child already anxious, if starved can become more upset and agitated leading to adverse events.<br><br>In dental practice only conscious sedation is practised. All patients must be able to maintain their own airways and vital | Thank you for your comment. The recommendations on fasting have been amended following consultation. |

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| | | | | | | reflexes, the risk of aspiration is therefore negligible. We would welcome separate guidance for dental patients with regard to fasting. | |
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| SH | Faculty of Dental Surgery | 4 | FULL | 52 | 27 | We believe that all team members involved in the provision of sedation should have knowledge and understanding of the topics stated. Both clinician and assistant must have a broad knowledge of the techniques used.<br><br>We would welcome the addition that those assisting within the team also have knowledge and understanding | Thank you. This recommendation pertains to the healthcare professional delivering sedation. Support staff may need differing levels of training according to the area that they are providing support. |
| SH | Faculty of Dental Surgery | 5 | FULL | 53 | 11 | We believe that all team members delivering moderate sedation must be ILS trained | Thank you, we cannot recommend branded training. |
| SH | Faculty of Dental Surgery | 6 | FULL | 53 | 15 | We welcome the recommendation that anaesthetic agents should only be delivered by appropriately trained health care professionals. However we would like this statement to clearly state that the individual should be a specialist anaesthetist, to ensure they have an appropriate level of anaesthetic training. | Thank you for your suggestion. We do not name professionals / state the specialist group within recommendations. |
| SH | Faculty of Dental Surgery | 7 | FULL | 53 | 21 | We would like to recommend that all the team involved in the delivery of sedation have documented evidence of competency in their specific tasks within the team | The GDG acknowledge that all training relating to sedation should have a competency focus for knowledge skills and attitudes. |
| SH | Faculty of Dental Surgery | 8 | FULL | 54 | 8 | For moderate sedation we believe that Blood Pressure must also be monitored continuously. | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this. |
| SH | Faculty of Dental Surgery | 9 | FULL | 55 | 22 | At this stage the document refers to specific areas of care, however this is not clear. The section of Painful Procedures in the mind of the dental profession might also include dental procedures, however this is not | Thank you for your comment. This chapter (Summary of Recommendations) is a list of all the recommendations included in the full guideline. For more explanation on the various clinical settings, please refer to |

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| | | | | | | covered in this section.<br><br>We would like to recommend that this is summarised at this stage before talking about the individual disciplines. | chapter 6 (paragraph 6.12). |
| SH | Faculty of Dental Surgery | 10 | FULL | 56 | 25 | Reference is made to the use of midazolam for achieving moderate sedation for dental procedures.<br><br>Clarification is needed as to the most appropriate route of administration here in this section as different routes can produce varying levels of sedation. For example oral and transmucosal sedation are very unpredictable and can lead to over sedation. | Clinicians involved in paediatric sedation are able to make local decisions in relation to this. This is why the guideline is not prescriptive about the route that midazolam is administered. The principle is that the technique employed is matched to the patient. The unpredictability of non IV administration needs to be taken into account with regard to training and experience of the sedation team along with the possibility of a reduced marging of safety with regard to the intended target level of sedation. |
| SH | Faculty of Dental Surgery | 11 | FULL | 58 | 37 | We note that the GDG suggest a standard teaching method and assessment tool be developed in the field of sedation.<br><br>We would like to advise that within the dental profession there are many teaching programmes already established with sound assessment procedures. Also the National Examining Board for Dental Nurses runs a Certificate in Dental Sedation Nursing which is a nationally recognised course.<br><br>We believe that the dental courses currently running could be modified to form a template for training in all medical fields. | Thank you for your comment. The research recommendation is aimed to cover all clinical settings. |
| SH | Faculty of Dental Surgery | 12 | FULL<br>**NICE** | 19 | 6 | We would welcome clarification regarding a "National Registry". How would this work and who would qualify to be on it. | This is a research recommendation. |

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| SH | Faculty of Dental Surgery | 13 | FULL | GENE RAL | | The document appears to support the use of “Deep Sedation”. This is not in line with other UK guidance on sedation particularly within the field of dentistry. The term “conscious Sedation” is advocated as the safest form of sedation particularly for children. | Thank you for your comment. The introduction to the dentistry section has been modified. “Conscious sedation” is now used in the recommendation and defined in the glossary. It remains the target state for dentistry. |
| SH | Faculty of Dental Surgery | 14 | FULL | GENE RAL | | Dental Sedation for ASA grade 3 or greater should not be carried out in a primary care setting. The higher end of ASA 2 should be treated with caution in primary care. | Thank you for your comment. The guideline is non-setting specific |
| SH | Faculty of Dental Surgery | 15 | FULL | 47 | | The dentist should seek further specialist advice before delivering sedation if either : 20 there is concern about a potential airway or breathing problem, or 21 the child or young person is assessed as ASA grade 3 or greater. | Thank you for your comment. |
| SH | Faculty of Dental Surgery | 16 | FULL | 49 | | “*Moderate sedation: All members have basic life support skills and at least one team member should have intermediate life support skills in airway management using mask ventilation and use of defibrillator*”<br>Comments: All members should have intermediate life support validated annually<br>“*Deep sedation: All members have basic life support skills and at least one team member should have advanced life support skills including advanced airway skills and cardiac arrest management*”<br>Comments: All members should have advanced life support validated annually | Thank you for your comments, training curricula have been recommended, recertification of skills and competencies are guided by local governance policies. |
| SH | Faculty of Dental Surgery | 17 | FULL | GENE RAL | | A comprehensive document but should have more definition in relation to sedation in Dentistry. | Thank you for your comment. Definitions of: Moderate sedation, Conscious sedation, Standard sedation techniques, Specialist sedation techniques have been added to the glossary. They apply to all settings, including dentistry. |

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| SH | Faculty of Dental Surgery | 18 | FULL | GENE RAL | 39 | Glossary/definitions: we assume that the nurse relates to RGN, and would like this expanded to include dental nurse for dental sedation provision. | Thank you for your comment. All references to nurse relate to registered general nurses. We acknowledge that dental nurses may be involved in sedation care but this is a local service delivery decision. |
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| SH | Faculty of Dental Surgery | 19 | FULL | 82 | | Training /personnel- the registered Dental Nurse should have also completed a recognised course e.g. the NEBDN post qualification in Conscious Sedation | Thank you for your comment. The suggested training for dental nurses helps them to demonstrate sufficient competency. As the guideline is non-setting specific, similar training pathways exist for other members of the multi-disciplinary team. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 1 | FULL | GENE RAL | | There appears to be a lack of appreciation of the definition of conscious sedation as used in dentistry for which it is of fundamental importance that the level of sedation must be such that the patient remains conscious, and is able to both understand and respond to verbal commands (if a patient is unable to respond to verbal contact when fully conscious, the normal method of communicating with them must be maintained).<br><br>The American terminology of minimal, moderate and deep sedation is unhelpful to dentists and is inconsistent with other UK guidance. The definition of minimal + moderate sedation appears to be generally compatable with ***conscious sedation*** which is the preferred terminology. This terminology makes the distinction between 'sedation' and general anaesthesia clear.<br><br>The term *conscious sedation* is well defined, understood and accepted within the dental community. The term *Deep Sedation* in the field of dental sedation is equated with general anaesthesia, and is | Thank you for your comment. The introduction to the dentistry section has been modified. "Conscious sedation" is now used in the recommendation and defined in the glossary. It remains the target state for dentistry |

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| | | | | | | likely to be continued to be viewed as such by the General Dental Council.<br><br>There are two relevant Cochrane Reviews that have not been included in the development of the guideline:<br>Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment. Cochrane Database of Systematic Reviews 2006, Issue 1. Art. No.: CD003877. DOI: 10.1002/14651858.CD003877.pub3.<br>Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year olds. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD006334. DOI: 10.1002/14651858.CD006334.pub2.<br><br>**It is not clear why nine trials that were cited within the above Cochrane Reviews have not been included the guideline.** | These Cochrane reviews were evaluated during the scoping process.<br>All studies within *Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment* which met the inclusion criteria for this guideline were reviewed. The Cochrane review<br>*Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year old* found no RCTs comparing general anaesthesia to sedation for the provision of dental care in children. |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 2 | FULL | GENE RAL | | This document seems to endorse the provision of deep sedation without intravenous access – particularly in children in whom venous access is difficult – this seems to be out of keeping with other guidance.<br><br>As a minimum standard, securing venous access should be strongly recommended prior to the surgical procedure being attempted. | Thank you for your comment. This has been discussed in section 6.4.4, GDG discussion of the evidence for Ketamine. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 4 | FULL | 29 | 9-10 | This definition is not conscious sedation as understood in Dentistry. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would |

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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 5 | FULL | 30 | 6-8 | There is little information about what should be undertaken in primary care and in specialist facilities outside of the hospital environment. Non-hospital secondary care is omitted e.g. Community/Salaried Dental Service | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 6 | FULL | 50 | 15 | It is not usual for dentists to weigh patients for inhalation sedation. Young people who do not appear to be under or overweight are not routinely weighed<br>prior to IV sedation with midazolam. Your recommendations suggest that all should be weighed. | The term 'weight' here is used in reference to standard approaches in healthcare, where healthcare professionals will measure or estimate weight and height in conjunction with accepted tools such as the Broselow Tape, enabling correct dosage of drugs and choice (sizing) of equipment. Weight in relation to growth assessment is not always a sensitive marker, and therefore is only one aspect of the assessment process. The GDG acknowledge the comment that it is not routine practice to weigh children and young people undergoing dental sedation, which is why we have qualified this in the recommendation by bracketing 'growth assessment', an estimate made by the sedation team which may or may not record the child or young person's weight. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 7 | FULL | 43 | 7-8 | Choice of technique may also depend on patient factors such as their level of anxiety | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 8 | FULL | 43 | 21 | Should this read ‘non-pharmacological’ rather than ‘pharmacological’? | Yes. Thank you for spotting this typo. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 9 | FULL | 47 | 22 | Anxiety levels and other patient factors such as level of cooperation and understanding should be included. | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and |

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| | | | | | | | Consent. |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 10 | FULL | 48 | 5,6 | The term *delivering sedation* is not helpful and is too specific. In dentistry the sedation team usually consists of a trained operator/sedationist assisted by a trained health care worker-usually a sedation trained dental nurse. The dental nurse however, **does not administer** sedation. Therefore we do not have a team who are "all" trained in the "delivery" of sedation. Perhaps the sentence could be phrased with greater clarity to prevent ambiguity and confusion. | Thank you for your comment. Definitions of Administration of sedation, Delivery of sedation and Sedation team have been included in the glossary for clarity. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 11 | FULL | 48 | 1 | For GA in dentistry, patient preference is not an indication and neither is patient preference an indication for sedation. Why is this included?<br>Anxiety level should be included.<br>Operator opinion informed by patient assessment should be included | Thank you for your comment. The GDG felt that patient preference should be taken into account. Psychological and developmental status (which include anxiety) are indeed included in the pre-sedation assessment recommendations. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 12 | FULL | 48 | 7 | Monitoring and resuscitation are together. They should be separate and add equipment and drugs used for sedation complications prior to resuscitation are readily available. | Thank you for your comment. The developers do not wish to change the wording as it was felt the current wording is clear. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 13 | FULL | 48 | 21 - 22 | Few complications are encountered in dentistry. Therefore, to obtain practical experience would require simulation which we believe should be acceptable. | Thank you for your comment. The training recommendations apply to all settings. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 14 | FULL | 49 | 1 | 1. Definition minimal + moderate should be conscious sedation according to Dental Definition.<br>2. The resuscitation skills required for minimal and moderate sedation should be the same.<br>3. Not in line with current dental guidance, but supports 2006 Resuscitation Council report (with respect to the | 1. Definitions of minimal, moderate and conscious sedation have been added to the glossary.<br>2. The recommendations on training and monitoring apply to all clinical settings;<br>3. Thank you for your observation. The GDG supports recommendation made by the Resuscitation Council report 2006 for managing emergencies in dental practice |

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| | | | | | | requirement for practices to have a defibrillator)<br>4. Concern about this and other recommendations of up to 50% $N_2O$. If titrated there is no need to limit beyond what IS machines can deliver. | 4. The recommendations on monitoring apply to all cases of moderate sedation. In one recommendation about personnel and training we specify that for sedation with nitrous oxide alone (up to 50% in oxygen) the sedation team should have the same skills as for minimal sedation. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 15 | FULL | 49 | L5-12 | For minimal and moderate sedation, there should be a recommendation about how monitoring is carried out. | Thank you for your comment. The GDG did not feel it was necessary to specify monitoring for minimal sedation. This is local clinical choice.<br>There is a recommendation about monitoring for moderate sedation. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 16 | FULL | 50 | 20 | As there are no recognised sedation specialists, we suggest replacing “specialist” with “further” (i.e. seek advice from a more experienced colleague) | Thank you, we disagree with your suggestion because further is too vague. We have defined “specialist in sedation” in the glossary. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 17 | FULL | 50 | 24 | This list needs to include relevant patient factors such as anxiety levels and level of cooperation and understanding should be included (to cover patients with additional needs). | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent.<br><br>Psychological and developmental status (which include anxiety) are also included in the pre-sedation assessment recommendations. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 18 | FULL | 51 | 22 | Fasting - the evidence to support the need for fasting appears to be limited and yet a blanket recommendation for the 2,4,6, rule has been recommended (with the exception of nitrous oxide sedation).<br><br>This recommendation is contrary to current dental guidance (SDAC: reference 206, SDCEP: reference 198). Fasting is not needed for minimal / moderate sedation.<br><br>For dental patients fasting in children can | Thank you for your comment. The recommendations on fasting have been amended following consultation. |

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| | | | | | | have detrimental effects. The child and young adult patient, if starved can become more upset and agitated leading to adverse events. This is also very traumatic for the patient with learning disabilities and behavioural problems.<br><br>Fasting is not required for minimal and moderate conscious sedation and there is no evidence to support otherwise.<br><br>In dental practice only conscious sedation is practised. All patients must be able to maintain their own airways and vital reflexes, the risk of aspiration is therefore negligible.<br><br>We would welcome separate guidance for dental patients or for conscious sedation with regard to fasting.Refer to McKenna et al. Prim Dent Care. 2010 Jan;17(1):5-11). | |
|---|---|---|---|---|---|---|---|
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 19 | FULL | 52 | 27 | We believe that all team members involved in the provision of sedation should have knowledge and understanding of the topics stated. Both clinician and assistant must have a broad knowledge of the techniques used.<br><br>We would welcome the addition that those assisting within the team also have knowledge and understanding | Thank you. This recommendation pertains to the healthcare professional delivering sedation. Support staff may need differing levels of training according to the area that they are providing support. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 20 | FULL | 54 | 8-12 | Monitoring does not required heart rate and $SaO_2$ for $N_2O$ and oxygen inhalation sedation. | Thank you for your comment. We agree with your comment but the recommendation applies to moderate sedation in general. In a previous recommendation on personnel and training, sedation with nitrous oxide alone (up to 50% in oxygen) is compared to minimal sedation. |

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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 21 | FULL | 54 | 7-16 | Blood pressure measurement is not mentioned as part of assessment - this is standard is in dentistry | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this. |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 22 | FULL | 55 | 1 | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 23 | FULL | 55 | 8 | 1. We believe that return to a level of consciousness suitable for care by a non-healthcare qualified escort is acceptable.<br>2. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | Thank you, we agree with your comment. The recommendation has been amended. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 24 | FULL | 55 | 13 AND FOO TNO TE | States that vital signs that usually include blood pressure should return to normal, but it is not recommended to measure blood pressure earlier in the guideline. | Thank you but we disagree with your comment.<br>The guideline is non setting specific, and assessment will invariably differ across a range of settings where different target levels of sedation are aimed for by the sedation team. Blood pressure can only be used as a marker for discharge criteria if it has been recorded as part of the initial assessment, this is routine practice in hospital settings and especially where moderate to deep sedation is the target level. The nature of the non-setting specific recommendations reflect the diverse populations that the guideline addresses, and it is not necessary for example within dental settings when mild sedation is the target level for a blood pressure to be routinely recorded. |
| SH | Intercollegiate Advisory | 25 | FULL | 55 | 14- | 1. We believe that return to level of | Thank you, we agree with your comment. |

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| | Committee for Sedation in Dentistry IACSD | | | | 15 | responsiveness and orientation suitable for care by a non-healthcare qualified escort is acceptable.<br>2. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | The recommendation on discharge criteria has been amended. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 26 | FULL | 55-56 | 24 -1 | 1. All techniques are grouped together for conscious sedation. We are concerned about the inclusion of oral midazolam within minimal sedation. It is not clear why a lower level of training is recommended for oral midazolam compared to IV midazolam – this is contrary to dental guidance.<br>2. Oral and Transmucosal sedation should be listed as techniques that can be used to produce 'moderate sedation' | Thank you. We agree with your comment and the recommendations on dentistry and painful procedures have been amended accordingly. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 28 | FULL | 56 | 27 - 28 | We do not think it is equitable to mention one technique that is only available in one centre in the UK. | Thank you for your comment. The term "Alternative techniques" has been introduced and defined for dentistry. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 29 | FULL | 58 | 23-30 | We think it is inappropriate for the guideline to be so prescriptive on fasting when this is included a research recommendation. Fasting increases the likelihood of fainting in adolescents. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 30 | FULL | 59 | 2-10 | Training for conscious sedation in dentistry for standard techniques is well established and so we do not think this needs to be the subject of a research recommendation. | Thank you for your comment. The research recommendation is aimed to cover all clinical setting. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 31 | FULL | 61 | 15-20 | We have concerns about how this would be accomplished especially in primary or non hospital secondary care. | Thank you for your comment. This is a future research recommendation. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 32 | FULL | 62 | 15-16 | Conscious sedation correct here - should be in the rest of the guideline. | Thank you for your comment. "Conscious sedation" has been added to the recommendations in the dental setting and defined in the glossary. |

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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 33 | FULL | 64 | 22-23 | The recommendation that only one of 2 professionals can be involved in the procedure is contrary to current dental guidance. Both members of the dental team involved in the procedure can be trained in sedation. This would have a significant impact on the provision of sedation for dentistry. | Thank you for your comments. The GDG felt that this was important when delivering moderate or deep sedation. |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 34 | FULL | 65 | 1-26 | Need to acknowledge that consent varies in different parts of the UK | Thank you for your comment. This has been acknowledged in the guideline. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 35 | FULL | 68 | 7- 14 | The paucity of evidence of the benefits of fasting, the results of Keidon 2004 (page 71), and the clinical experience that fainting is more likely in fasted patients brings into question the justification for the fasting recommendations. | Thank you for your comment. The recommendations on fasting have been amended following consultation |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 36 | FULL | 73 | 10-12 | Patients with learning difficulties may require increased care (including overnight) pre-treatment if there is a requirement to fast. | Thank you. We think an overnight stay is unlikely to be necessary except in rare circumstances. We do not think it necessary to raise this issue in the guideline. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 37 | FULL | 87 | 2 | Oxygen saturation monitoring is not required for $N_2O$ and oxygen inhalation sedation | Thank you, the recommendations has been amended accordingly |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 38 | FULL | 88 | 1 (REC 24) | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 39 | FULL | 88 | 1 (REC 24) | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient.<br><br>Continuous recording of monitoring is not necessary for minimal to moderate sedation. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |

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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 40 | FULL | 88 | 2 (REC 25) | We agree with the recommendation except for return to baseline level of consciousness. | Thank you for your comment, the recommendation has been amended accordingly |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 41 | FULL | 90 | 10 (REC 26) | We agree with the recommendation except for return to baseline level of consciousness. | Thank you for your comment, the recommendation has been amended accordingly |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 42 | FULL | 161 | 16 - 17 | Does not make sense with the stem line 17 | Thank you for your comment. It has been amended accordingly. |
| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 43 | FULL | 27-280 | | We have concerns about the requirement for the ability to intubate when using propofol.<br><br>We believe that for older children (>10 years), conscious sedation for dentistry with propofol can be provided safely and reliably by a trained non-anaesthetist. This is common practice in several clinical settings,.<br><br>The implication of the proposed recommendations is that only trained anaesthetists can provide sedation using propofol.<br><br>Implementing this recommendation would have a significant impact on the provision of patient care and access to dental services.<br><br>Much of the evidence quoted appears to refer to deep sedation and not conscious sedation as used in dentistry.<br><br>We suggest that the evidence and this recommendation are reconsidered and make reference to the use of propofol in *conscious sedation.* | Thank you this has been addressed in the guidance. The guidance advocates further training for more complex or alternative techniques. |
| SH | Intercollegiate Advisory | 44 | FULL | 336 | 11 | It is not equitable to mention a technique | Thank you, we agree with your comment. |

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| | Committee for Sedation in Dentistry IACSD | | | | | which is only available in 1 centre in the UK. | The recommendation has been amended, |
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| SH | Intercollegiate Advisory Committee for Sedation in Dentistry IACSD | 45 | NICE | GENE RAL | | We are concerned about the implication within the final paragraph of the introduction which appears to imply that GA is better and safer and the only reasons for not using it are economic. | Thank you for your comment. We do not believe that the summary asserts this at all. It simply recognises that general anaesthesia is the definitive choice when sedation fails. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 1 | FULL | 56 | 26-28 | I have been providing paediatric Conscious Sedation for a while now (since 1999) and earlier this week my personal audit reached the 8000 mark as operator - sedationist.(Lately about 1000 children a year). Over the past 8 years I have used a range of techniques and drugs, but I have found that the safest and most reliable Alternative Sedation Technique involves the Intravenous titrated technique in children often using ketamine + midazolam or ketamine +propofol.<br>At Leagrave Dental Sedation Clinic there are separate sedationists who sedate children. They treat about 2500 children a year using ketamine and midazolam and one sedationist is using propofol as well.<br><br>I have assessed many practices in the South-East of England-about 10 practices providing Alternative sedation techniques and most of them are using ketamine and or propofol for paediatric conscious sedation.<br><br>For a SAAD presentation at the annual symposium in 2008 I contacted about 40 practices involved with NHS sedation in the South-East and those that are providing paediatric sedation are using similar techniques - and I worked out that about 50 000 children were being sedated using | Thank you for your comment. The term “Alternative techniques” has been introduced and defined for dentistry. |

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| | | | | | | these techniques annually.<br><br>I have not heard of any recent (last 5 years) adverse reactions or emergencies regarding these techniques in children.<br><br>I feel that it is not the drug which should be classified as dangerous or put in a higher category of vigilance as we are all meeting the definition of conscious sedation.<br><br>My fear is that patient access to dental services will be adversely affected as patients will either be unsuccessfully sedated with midazolam only (creating dental phobics) and many will be referred for GA and put the patient through additional trauma when these techniques have proved to be safe, efficient and they have a high success and low side effect rate- when used by sedationists with the appropriate training and experience.<br><br>From a financial perspective this technique is far less expensive to carry out in the primary care setting than GA in hospital.<br>I hope that you will seriously consider these factors in placing these drugs in the category of 'DEEP Sedation' drugs and all the additional requirements needed as there is no evidence from the stats that this is needed. | |
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| SH | LEAGRAVE DENTAL SEDATION CLINIC | 2 | FULL | 59 | 23-24 | Clinical monitoring and being in constant contact with the patient is crucial. I have done trials with BIS monitors in practice. This demonstrated that the level of sedation was between 80 and 90. This proved too | Thank you for your comment. |

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| | | | | | | expensive to do this for every patient but gave us a correlation between level of sedation between the BIS monitor and clinical evaluation of consciousness levels. | |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 3 | FULL | 59 | 34-36 | Subanaesthetic doses of Ketamine (0,25-0,5mg/kg) have proven to be potent analgesics and are respiratory stimulants rather than depressant at these doses. The combination of ketamine with either midazolam or propofol will help protect respiratory function in conscious sedation and are beneficial in children with asthma. | Thank you for your comment. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 4 | FULL | 59 | 38 | Subanaesthetic doses of ketamine has an incredibly safe safety profile and is used in our clinic for oral, IV, IM and nasal use. This reduces the 'paradoxical effect' sometimes seen with midazolam. | Thank you for your comment. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 5 | FULL | 60 | 9-11 | 0,5mg/kg propofol is added to 0,25mg/kg ketamine and has proved to have ketamine-sparing effect and also has reduced PONV considerably in our audit of nearly 2000 children having IV sedation for dental treatment. The most dominant factor determining PONV is pre-op anxiety. | Thank you for your comment. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 6 | FULL | 60 | 13-17 | See comments in previous paragraphs | |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 7 | FULL | 60 | 19-21 | We provide 5000 sedations a year for NHS dental contract most for paediatric sedation and are paid £55 per sedation. How much lower could GA be provided for the same service-I think not. It is time that a national tariff be a agreed to help promote safe sedation. | Thank you. We have passed your comment on to the NICE implementation team. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 8 | FULL | 61 | 2-4 | Ketamine is safer as it has a wider therapeutic range and safety profile – I have never had a case of desaturations when using ketamine on its own for CS in | Thank you for your comment. |

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| | | | | | | paediatric CS. It has been used in combination with propofol in >2000 cases as operator- sedationist in kids without any desaturations. | |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 9 | FULL | 82 | 12-16 | When trained and experienced in using anaesthetic agents for conscious sedation – titration of small increments will allow a wider therapeutic range without desaturations. The technique is important and not the drugs. We have not experienced apnoea and only a few cases with desaturations in the tens of thousands of cases managed at the clinic. We do not use opioids in children< 50kg. | Thank you, we acknowledge your comment, however the developers feel the statement to be accurate. The part regarding personnel and training applies to all clinical settings. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 10 | FULL | 169 | 34-36 | When midazolam is combined with ketamine the mixture may result in deep sedation if excessive amounts (boluses) of each drug is given –this can happen with any of the drugs. If the target is conscious sedation, small increments need to be titrated and you will be able to manage the child with conscious sedation long before the child becomes unresponsive | Thank you. We agree. |
| SH | LEAGRAVE DENTAL SEDATION CLINIC | 11 | FULL | 251 | 11-12 | IV Ketamine is used 100x much more widely in dental clinics than sevoflurane. I am aware of only one clinic using this effective inhalational technique. | Thank you for your comment. The paragraph in questions regards the discussion of the evidence for nitrous oxide. The recommendation on dental procedures has been amended and it does no longer mentions sevoflurane. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 1. | FULL | GENERAL | | The American terminology of minimal, moderate and deep is unhelpful to dentists. It is also inconsistent with other UK guidance.<br><br>Dentists will keep using the term *conscious sedation* as this is well defined, accepted and understood. It has clarity of meaning. The term Deep Sedation in the field of | Thank you for your comment. “Conscious sedation” is now used in the recommendation in the dentistry setting. “Conscious sedation” is also defined in the glossary. |

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| | | | | | | dental sedation is equated with general anaesthesia and is viewed as such by the General Dental Council. We advocate the use of the term "conscious Sedation" as this is the safest form of sedation for non-anaesthetists. | |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 2. | FULL | GENE RAL | | This document seems to endorse the provision of deep sedation without intravenous access – particularly in children in whom venous access is difficult – this seems to be out of keeping with other guidance. As a minimum, securing venous access should be strongly recommended prior to the surgical procedure being attempted. | Thank you for your comment. This has been discussed in section 6.4.4, GDG discussion of the evidence for Ketamine. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 3. | FULL | GENE RAL | | There is little information about what should be undertaken in primary care and in specialist facilities. | Thank you for your comment. The guideline is non-setting specific |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 4. | FULL | GENE RAL | | The remit for this guidance is too wide with no differentiation between babies and young people. It would be beneficial to provide recommendations specific to under 2s, pre-cooperative, under 12 and adolescent. | Thank you for your comment. The developers acknowledge that there are differences between infants and older children but this guideline can be applied to children of all ages. There is discussion about infants for painless imaging procedures in section 6.12.1.3, Evidence to recommendations for painless imaging. We have also added special consideration for neonates and infants to the recommendation on pre-sedation assessment. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 5. | FULL | 27-280 | | Re intubation and propofol. It would be helpful to have the following breakdown of clinical scenarios regarding the need for this training:<br>1. age defined criteria | Thank you for your comment, but intubation is not part of the sedation care. We have specified the training needed for different level of sedation. |

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| | | | | | | 2. to differentiate on the different sedation target states | |
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| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 6. | FULL | 29 | 9-10 | This definition is not conscious sedation as used in Dentistry and adopted by other medical specialties. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 7. | FULL | 30 | 6-8 | Specialist or secondary care facilities outside of a hospital environment is omitted e.g. Salaried Dental Service | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 8. | FULL | 30 | 15 | It is not usual for dentists to weigh patients for inhalation sedation. Young people who do not appear to be under/over weight are not routinely weighed<br>prior to IV sedation with midazolam. Your recommendations suggest that all should be weighed. | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 9. | FULL | 37<br>317 | TABL E | This table could imply that the agents used in “minimal sedation” are less potent than those listed under moderates and deep sedation. Intranasal and oral midazolam is listed under minimal sedation, these techniques cannot be titrated against patient response and are therefore capable of causing moderate sedation. | Thank you for your comment. The recommendation on painful procedures has been amended accordingly. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 10. | FULL | 37<br>? | 87 | Oxygen saturation monitoring is not required for $N_2O$ inhalation sedation with oxygen | The recommendations on monitoring apply to all cases of moderate sedation. Sedation with nitrous oxide is regarded as minimal sedation. |
| SH | Liverpool University Dental Hospital and | 11. | FULL | 47 | 22 | Anxiety levels and other patient factors such as level of cooperation and understanding | Thank you, we agree with your comment. This is stated in the existing text in Section |

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| | Dental Sedation Teachers Group | | | | | should be included. | 4.1.3, GDG discussion, Information and Consent. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 12. | FULL | 48 | 7 | It is not helpful to have monitoring and resuscitation equipment on the same bullet point-their roles are different. | Thank you for your comment. The developers do not wish to change the wording as it was felt the current wording is clear. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 13. | FULL | 48 | 5,6 | The term *delivering sedation* is not helpful and is too specific.<br>In dentistry the sedation team usually consists of a trained operator/sedationist assisted by a trained health care worker-usually a sedation trained dental nurse. The dental nurse however, **does not administer** sedation. Therefore we do not have a team who are “all“ trained in the “delivery” of sedation.<br>Perhaps the sentence could be phrased with greater clarity to prevent ambiguity and confusion. | Thank you for your comment. Definitions of Administration of sedation, Delivery of sedation and Sedation team have been included in the glossary for clarity. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 14. | FULL | 49 | 14-15 | For minimal and moderate sedation, there should be a recommendation about how monitoring is carried out.<br>It is still possible to oversedate patients, especially with non-titrateable techniques such as oral and transmucosal administration. Guidance should be given for monitoring. | Thank you for your comment. The GDG did not feel it was necessary to specify monitoring for minimal sedation. This is local clinical choice.<br>There is a recommendation about monitoring for moderate sedation. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 1. | FULL | 49 | 1 | The resuscitation skills required for minimal and moderate sedation should be the same.<br><br>This guidance is not in line with current dental guidance (but supports 2006 Resuscitation Council report with respect to the requirement for practices to have a defibrillator).<br><br>The reference to max 50% $N_2O$ is confusing. If a drug is titrated there is no | Thank you for your comment. The recommendations on monitoring apply to all cases of moderate sedation. In one recommendation about personnel and training we specify that for sedation with nitrous oxide alone (up to 50% in oxygen) the sedation team should have the same skills as for minimal sedation. |

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| | | | | | | need to limit beyond what IS machines can deliver, these machines have an excellent safety record. | |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 2. | FULL | 50 | 24 | This list needs to include relevant patient factors such as anxiety levels and level of cooperation and understanding (to cover patients with additional needs). | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent.<br><br>Psychological and developmental status (which include anxiety) are also included in the pre-sedation assessment recommendations. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 3. | FULL | 51 | 22 | Fasting: The evidence for fasting prior to dental procedures under conscious sedation does not support the blanket recommendation for the 2,4,6, rule (with the exception of nitrous oxide sedation).<br><br>This recommendation is contrary to current dental guidance (SDAC: reference 206, SDCEP: reference 198). Fasting is not needed for minimal / moderate sedation.<br>For dental patients fasting children can have detrimental effects. The child and young adult patient, if starved can become more upset and agitated leading to adverse events. This is also very traumatic for the patient with learning disabilities and behavioural problems. We feel that for conscious sedation (minimal and moderate sedation) fasting is not required; there is no evidence to support otherwise.<br><br>In dental practice only conscious sedation is practised. All patients must be able to maintain their own airways and vital reflexes, the risk of aspiration is therefore negligible. We would welcome separate | Thank you for your comment. The recommendations on fasting have been amended following consultation. |

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| | | | | | | guidance for dental patients or for conscious sedation with regard to fasting. Refer to McKenna et al. Prim Dent Care. 2010 Jan;17(1):5-11). | |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 4. | FULL | 52 | 27 | We believe that all team members involved in the provision of sedation should have knowledge and understanding of the topics stated. Both clinician and assistant must have a broad knowledge of the techniques used.<br><br>We would welcome the addition that those assisting within the team also have knowledge and understanding | Thank you. This recommendation pertains to the healthcare professional delivering sedation. Support staff may need differing levels of training according to the area that they are providing support. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 5. | FULL | 54 | 7-16 | Blood pressure measurement is not mentioned as part of assessment - this is standard practice in dentistry | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 6. | FULL | 54 | 7-16 | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 7. | FULL | 54 | 8-12 | Monitoring does not required heart rate and $SaO_2$ for $N_2O$ and oxygen inhalation sedation. | Thank you for your comment. We agree with your comment but the recommendation applies to moderate sedation in general. In a previous recommendation on personnel and training, sedation with nitrous oxide alone (up to 50% in oxygen) is compared to minimal sedation. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 8. | FULL | 55 | 13 | States that vital signs that usually include blood pressure should return to normal, but it is not recommended to measure blood pressure earlier in the guideline. | Thank you but we disagree with your comment. The guideline is non setting specific, and assessment will invariably differ across a range of settings where different target levels of sedation are aimed for by the sedation team. Blood pressure |

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| | | | | | | | can only be used as a marker for discharge criteria if it has been recorded as part of the initial assessment, this is routine practice in hospital settings and especially where moderate to deep sedation is the target level. The nature of the non-setting specific recommendations reflect the diverse populations that the guideline addresses, and it is not necessary for example within dental settings when mild sedation is the target level for a blood pressure to be routinely recorded. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 15. | FULL | 55-56 | 24 -1 | All techniques are grouped together for conscious sedation. We are concerned about the inclusion of oral midazolam within minimal sedation. It is not clear why a lower level of training is recommended for oral midazolam compared to IV midazolam – this is contrary to dental guidance. Oral and Transmucosal sedation should be listed as techniques that can be used to produce 'moderate sedation.' This relates to point 9 above. | Thank you. We agree with your comment and the recommendations on dentistry and painful procedures have been amended accordingly. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 9. | FULL | 56 | 26-28 | Why do you not add propofol to the list of alternative sedation techniques to consider? Propofol has been used satisfactorily in anxious older children/young people for dental treatment. Older children can use patient- controlled propofol sedation. Experienced sedationist who use propofol for sedation are also in greater supply than those who use sevofluorane for sedation! | Thank you for your comment. The term "Alternative techniques" has been introduced and defined for dentistry. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 10. | FULL | 56 | 20 | Why add the word " painful" –dentists routinely use local anaesthesia so that dentistry is not painful. Conversely, if a patient is anxious and the procedure is not painful (eg as in impression taking), sedation may still be required. | Thank you, we agree with your comment. The word "painful" has been removed from the recommendation. |

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| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 11. | FULL | 58 | 23-30 | There is little evidence to support fasting prior to conscious sedation. We think it is inappropriate for the guideline to be so prescriptive on fasting when it is included a research recommendation.<br>Fasting increases the likelihood of fainting in adolescents. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
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| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 12. | FULL | 59 | 2-10 | Training for conscious sedation in dentistry for standard techniques is well established and so we do not think this needs to be the subject of a research recommendation. | Thank you for your comment. The research recommendation is aimed to cover all clinical setting. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 13. | FULL | 62 | 15-16 | The use of the term *Conscious sedation* is correct here – shouldn't this be in the rest of the guideline? | Thank you for your comment. "Conscious sedation" has been added to the recommendations in the dental setting and defined in the glossary. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 14. | FULL | 64 | 22-23 | In dentistry both members of the dental team involved in the care of the sedated patient can be trained in sedation. However, only one operator (who is often the sedationist) will administer the sedation. Reassurance may be required that a dentist (operator sedationist) working with a qualified dental nurse (who does not give the sedation and will assist ) is a suitable team according to NICE guidance. DSTG have concerns that this matter is lacking clarity. | Thank you for your comment. The difference between delivering and administering sedation has been explained in the glossary. |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers Group | 15. | FULL | 68 | 7- 14 | The paucity of evidence of the benefits of fasting, the results of Keidon 2004 (page 71), and the clinical experience that fainting is more likely in fasted patients brings into question the justification for the fasting recommendations for patients who are having minimal-moderate sedation (excluding endoscopy). | Thank you for your comment. The recommendations on fasting have been amended following consultation |
| SH | Liverpool University Dental Hospital and Dental Sedation Teachers | 16. | FULL | 88 | 1 (REC 24) | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare |

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| | Group | | | | | sufficient. Continuous recording of monitoring is not necessary. | record. |
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| SH | Neonatal & Paediatric Pharmacists Group (NPPG) | 1 | NICE | 12 | 1.4.4 | We would question that it is essential for all health care professional delivering sedation for for procedures should be trained to give servoflurane, propofol and opioids with ketamine or whether a person trained to deliver these is required to be available when all procedural sedation is to be given | Thank you, we agree with your comment; this is clear in the training recommendations. |
| SH | Neonatal & Paediatric Pharmacists Group (NPPG) | 2 | NICE | 15 | 1.7.1.1 | For minimal sedation we would suggest that buccal midazolam is now potentially a better option than intranasal. Buccal midazolam is formulated as a special medicine in a good formulation. Intranasal is usually still delivered using the injection which is very toxic to the mucosa and whilst effective it makes most children cry on administration.<br>We would also question the use of midazolam for a painful procedure when it is a sedative with no analgesic properties. | Thank you for your comment. Route of administration is a local clinician choice. Recommendations are based on both direct and indirect evidence application.<br>The recommendation has been amended accordingly. |
| SH | Neonatal & Paediatric Pharmacists Group (NPPG) | 3 | NICE | 15 | 1.8.2 | Painless imaging often only requires some sort of sedative and thus chloral and midazolam have been the main stay of practice until this point. Therefore we are confused that chloral is recommended only for those less than 15kg and the only alternative above this is propofol or sevoflurane. | Thank you for your comment. The recommendation on painless procedures has been changed accordingly |
| SH | Neonatal & Paediatric Pharmacists Group (NPPG) | 4 | NICE | GENERAL | | One of the biggest problems with sedation is in children is the issue of what to do if the first medication fails. Some robust guidance on this would be welcomed in terms of alternatives, time frames and the issue of increasing dosing. | Thank you for your comment. There is discussion about this in the full guideline, section 6.12.1.3 (Evidence to recommendations for painless imaging), third paragraph:<br>"The GDG recognised that chloral hydrate may not always be effective and that intravenous midazolam is a drug commonly used to either increase the depth of |

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| | | | | | | | sedation or prolong sedation.” |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 1 | FULL | 29 | 9-10 | This definition is not consistent with the definition of conscious sedation as used in the field of dentistry and deep sedation is not advocated. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 2 | FULL | 49 | 1 | A table is presented with headings of different levels of Sedation, however no definition has been provided of these sedation levels at this stage. The term Deep Sedation is referred to and in the field of dental sedation this term is generally equated with general anaesthesia. This needs to be clearly explained. | Thank you for your comment. Definitions of minimal, moderate, conscious, deep sedation and general anaesthesia are provided in the Glossary of terms |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 3 | FULL | 51 | 22 | Fasting: Having read the evidence to support the issue of fasting thee appears to be limited support for the need for fasting and yet a blanket recommendation for the 2,4,6, rule has been recommended, with the exception of nitrous oxide sedation. For dental patients fasting children can have detrimental effects. The child already anxious, if starved can become more upset and agitated leading to adverse events.<br><br>In dental practice only conscious sedation is practised. All patients must be able to maintain their own airways and vital reflexes, the risk of aspiration is therefore negligible. We would welcome separate guidance for dental patients with regard to fasting. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Newcastle School of Dental Science sedation Department and Northern | 4 | FULL | 52 | 27 | We believe that all team members involved in the provision of sedation should have knowledge and understanding of the topics | Thank you. This recommendation pertains to the healthcare professional delivering sedation. Support staff may need differing |

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| | Deanery for Postgraduate Education | | | | | stated. Both clinician and assistant must have a broad knowledge of the techniques used.<br><br>We would welcome the addition that those assisting within the team also have knowledge and understanding | levels of training according to the area that they are providing support. |
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| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 5 | FULL | 53 | 11 | We believe that all team members delivering moderate sedation must be ILS trained | Thank you, we cannot recommend branded training. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 6 | FULL | 53 | 15 | We welcome the recommendation that anaesthetic agents should only be delivered by appropriately trained health care professionals. However we would like this statement to clearly state that the individual should be a specialist anaesthetist, to ensure they have an appropriate level of anaesthetic training. | Thank you for your suggestion. We do not name professionals / state the specialist group within recommendations. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 7 | FULL | 53 | 21 | We would like to recommend that all the team involved in the delivery of sedation have documented evidence of competency in their specific tasks within the team | The GDG acknowledge that all training relating to sedation should have a competency focus for knowledge skills and attitudes. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 8 | FULL | 54 | 8 | For moderate sedation we believe that Blood Pressure must also be monitored continuously. | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 9 | FULL | 55 | 22 | At this stage the document refers to specific areas of care, however this is not clear. The section of Painful Procedures in the mind of the dental profession might also include dental procedures, however this is not covered in this section.<br><br>We would like to recommend that this is | Thank you for your comment. This chapter (Summary of Recommendations) is a list of all the recommendations included in the full guideline. For more explanation on the various clinical settings, please refer to chapter 6 (paragraph 6.12). |

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| | | | | | | summarised at this stage before talking about the individual disciplines. | |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 10 | FULL | 56 | 25 | Reference is made to the use of midazolam for achieving moderate sedation for dental procedures.<br><br>Clarification is needed as to the most appropriate route of administration here in this section as different routes can produce varying levels of sedation. For example oral and transmucosal sedation are very unpredictable and can lead to over sedation. | Clinicians involved in paediatric sedation are able to make local decisions in relation to this |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 11 | FULL | 58 | 37 | We note that the GDG suggest a standard teaching method and assessment tool be developed in the field of sedation.<br><br>We would like to advise that within the dental profession there are many teaching programmes already established with sound assessment procedures. Also the National Examining Board for Dental Nurses runs a Certificate in Dental Sedation Nursing which is a nationally recognised course.<br><br>We believe that the dental courses currently running could be modified to form a template for training in all medical fields. | Thank you for your comment. The research recommendation is aimed to cover all clinical setting. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate Education | 12 | FULL. **NICE** | 19 | 6 | We would welcome clarification regarding a "National Registry". How would this work and who would qualify to be on it. | This is a research recommendation. |
| SH | Newcastle School of Dental Science sedation Department and Northern Deanery for Postgraduate | 13 | FULL | GENE RAL | | The document appears to support the use of "Deep Sedation". This is not in line with other UK guidance on sedation particularly within the field of dentistry. The term | Thank you for your comment. "Conscious sedation" is now used in the recommendation in the dentistry setting. "Conscious sedation" is also defined in the |

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|  | Education |  |  |  |  | “conscious Sedation” is advocated as the safest form of sedation particularly for children. | glossary. |
| SH | Oridion Medical 1987 Ltd | 1 | FULL | 51 | 12 | Unclear why additional studies are suggested given the large number of randomized studies published concerning the utility of capnography during procedural sedation.<br><br>The study performed by Lighdale et al published in Pediatrics 2006, aptly demonstrates the utility of capnography in pediatric sedated patients: Microstream capnography improves patient monitoring during moderate sedation: a randomized, controlled trial.<br><br>Other randomized studies have demonstrated the value in sedated adults:<br><br>Capnographic monitoring of respiratory activity improves safety of sedation for endoscopic cholangiopancreatography and ultrasonography – Qadeer, Vargo et al, Gastroenterology 2009<br><br>Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices?<br><br>Burton JH, Harrah JD, Germann CA, Dillon<br><br>DC.Acad Emerg Med. 2006<br><br>Dietch, K., Miner, J., Chudnofsky, C., | Thank you for your comment. We agree and have deleted the research recommendation. |

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| | | | | | | Dominici, P., & Latta, D. (In press.). Does end tidal CO2 monitoring during emergency department procedural sedation and analgesia with propofol decrease the incidence of hypoxic events? A randomized, controlled trial. *Annals of Emergency Medicine* 2009, | |
| SH | Oridion Medical 1987 Ltd | 2 | FULL | GENE RAL | | Suggest clarifying the recommended monitoring during imaging procedures such as MRI in which the patient cannot be visually observed for assessment of ventilation. In this case, capnography may be recommended even if deep sedation is not intentionally targeted due to the inability to observe the patient during the procedure. | Thank you for your comment. The developers feel the recommendations on monitoring to be accurate. |
| SH | Royal College of Anaesthetists | 1 | FULL | GENE RAL | | Our PLG are particularly concerned that emphasis from the outset appears to be on cost effectiveness. This gives the impression that the object of the guideline is to safe money rather than meeting the needs and best interests of the patient. This may affect professional decision making and should be re-considered. Paragraph one's reference to 'cost' is a particular is poorly placed.<br><br>The Guideline needs to further consider intravenous access, beyond the reference to propofol alone. | Thank you but we disagree with your comment. As stated for example in the introduction to chapter 4, 'each stage of the journey has been considered by the GDG for the purpose of maximising the success and safety of sedation'.<br><br>Intravenous access has been discussed in section 6.4.4, GDG discussion of the evidence for Ketamine. |
| SH | Royal College of | 2 | FULL | 14 | 1.6.2. | The consideration to refer to an anaesthetist | Thank you for your comment. The |

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|  | Anaesthetists |  | NICE |  |  | comes across as a last resort when all else has failed. This option should be present in the mind of another healthcare professional from the outset and not under discharge criteria.<br>The shorter version discusses the 'child and young person' throughout. Will there be a different version of recommendations for infants, or are neonates and sickly babies considered as routinely cared for by paediatric anaesthetists? Particular consideration should focus on the premature baby.<br>Training and clinical standards and the need to develop standardised assessment tools are key. | recommendation about referral to anaesthesia specialist has been moved under personnel and training section.<br><br>The NICE version reflects the recommendations from the full guideline version.<br><br>The need to develop standardised assessment tools is outside of the remit of this guideline.<br><br>There is discussion about infants for painless imaging procedures in section 6.13.1.2, Evidence to recommendations for painless imaging.<br>We have also added special consideration for neonates and infants to the recommendation on pre-sedation assessment. |
| SH | Royal College of Anaesthetists | 3 | FULL<br>NICE | 17 AND 18 | 4.1 | The 'suggestion' should be strengthened to increase the likelihood that a reliable assessment tool is developed for country wide use as soon as possible. Recognition by the Resuscitation Council, Advanced Life Support Group or similar should be considered | Thank you for your comment. We will discuss with the NICE implementation team. |
| SH | Royal College of Anaesthetists | 4 | FULL<br>NICE | 17 AND 18 | 4.2 | Admirable, providing the training as nationally acknowledged as being fit for purpose. | Thank you for your comment. |
| SH | Royal College of Nursing | 1 | GENERAL | GENERAL |  | The Royal College of Nursing welcomes this guideline. It is very comprehensive, easy to follow and timely. RCN members were closely involved during the scoping of this guideline and have monitored its development with interest. We are very pleased to see such a comprehensive draft out for consultation. | Thank you for your comment |

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| SH | Royal College of Nursing | 2 | GENE RAL | GENE RAL | | This guideline when adopted will greatly inform the standards of clinical practice involving procedural sedation that RCN members provide and enhance the quality and consistency of care of children and young people in health care settings. | Thank you for your comment |
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| SH | Royal College of Nursing | 3 | GENE RAL | GENE RAL | | Of necessity, this guideline is very medically orientated and the rigor in which the therapeutic agents have been scrutinised is to be commended. However there are still the more holistic aspects to be considered, for which admittedly there is less evidence but inclusion of advice would greatly enhance the child's experience.<br><br>Good practice would justify the inclusion of psychological preparation. The use of local anaesthetic prior to the insertion of a canula for induction. In addition parents should be offered the choice of staying with their child certainly during induction and for the recovery.<br><br>In the event of psychological trauma post procedure recourse to the appropriate services should also be advised. | Thank you for your comment. We recognise the importance of psychological preparation of the child undergoing sedation, and recommendations were formed through formal GDG consensus process. The guideline is not intended to be a definitive textbook for sedation care, and there are some areas highlighted in the comment that are outside of the original scope for the guideline. |
| SH | Royal College of Nursing | 4 | FULL | GENE RAL | | Trained professional is used throughout this document. We consider that this is a loose term, in relation to assessment and prescribing sedatives this is more likely to be doctor or anaesthetist, and in term of administration and monitoring is likely to be a nurse. The nurse should ideally be a children's nurse but this may be difficult where minor procedures are undertaken in minor trauma clinics and accident and | Thank you. NICE guidelines do not name professionals. NICE guidelines make recommendations on treatment and processes of care rather than specifying roles of different health care professionals. |

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|  |  |  |  |  |  | emergency departments. However a children's nurse ought to be in attendance. |  |
| SH | Royal College of Nursing | 5 | FULL | GENE RAL |  | Also appropriate training is referred to throughout the document and in terms of basic and intermediate life support is achievable, but in terms of a certificate of competency in administration and monitoring children for sedation, is probably ideal but without availability of training days is probably not going to happen in the short term. | Thank you for your comment. This is a provider issue, outside the scope of this guideline. |
| SH | Royal College of Nursing | 6 | FULL | GENE RAL |  | Some district general hospitals (DGH) are privileged to have a general anaesthetics list for their MRI patients who are over 15kg and or over 2 years old. They use chloral hydrate as recommended for under 15kg patients with a good success rate.<br><br>Many DGHs will be using chloral hydrate and do not have anaesthetic support for the older children and continuing to try and use chloral hydrate for older children without success. The section on Chloral hydrate (only briefly mentioned) should be bigger and bolder to make people aware that for children over 15kg they will have to review the alternatives and promote effective sedation with anaesthetic support. | Thank you for your comment. Your point relates to service delivering modelling of our guidance and focused on implementation, which is outside the scope of our development brief. |
| SH | Royal College of Nursing | 7 | FULL | GENE RAL |  | The document seems repetitive in some parts and the length makes it difficult to follow at times. Perhaps summary and introduction could be shortened as repeated exactly in main sections.<br>• Coverage of main issues | Thank you for your comment.<br>The NICE version is considered to be a summary of the full guideline |

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| | | | | | | Overall key issues are covered. | |
| SH | Royal College of Nursing | 8 | FULL | 38 | 17 | Surely adverse event ought to include where the sedation was ineffective or inadequate and the child, young person and/or their family were distressed, for example<br><br>• Situations where the sedation was successful but the child was clearly in pain<br><br>• Situations where the child inadvertently slipped into deep sedation<br><br>• Where there were serious drug reactions to the agents used | The outcome measures for efficacy of sedation included the following behavioural ratings:<br>1. pain as assessed by the patient or parent or other observer using validated pain scales e.g. Visual Analogue Scale (VAS), Children's Hospital of Eastern Ontario Pain Scale (CHEOPS), FACE.<br>2. procedural distress and/or anxiety as assessed by the patient or parent or other observer using validated scales e.g. Visual Analogue Scale (VAS), Observation Scale of Behavioral Distress (OSBD).<br>3. patient or parent satisfaction including preference.<br>Serious drug reactions to agents used were reported in the safety tables produced on the basis of the literature review.<br>Inadvertent anaesthesia is not an outcome which was reported in the studies reviewed for this guideline. |
| SH | Royal College of Nursing | 9 | FULL | 49 | 5 | Healthcare professionals delivering sedation should be registered with a professional body in the UK and be accountable.<br><br>Rationale for this modification is the variable standards of EU locum practitioners. | Thank you for your comment. Healthcare professionals are registered and licensed to practice in the UK. The glossary has been amended accordingly. |
| SH | Royal College of Nursing | 10 | FULL | 49 | 14 | Deep sedation is not the aim of procedural sedation and ought to be done where monitoring is routine and the interpretation and clinicians are experts such as an ITU or | Thank you for your comment, we disagree with this because deep sedation can be delivered safely by adequately trained healthcare practitioners |

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| | | | | | | a theatre environment.<br><br>Deep sedation ought only to be done under anaesthetist led teams. | |
| SH | Royal College of Nursing | 11 | FULL | 47 | 14 | The child's ability to consent – we are in full agreement with the comments on P65 lines 5-13 but think the consent of the child ought to be included at this earlier point | Thank you for your comment. We do not agree because the healthcare professional should assess the child and the situation first before offering any choice about sedation. |
| SH | Royal College of Nursing | 12 | FULL | 52 | 33 | On going care and what to advise parents to watch out for following discharge to home | Thank you for your comment. We believe advice will be shaped at local level. The guideline provides clear discharge criteria following the sedation experience. |
| SH | Royal College of Nursing | 13 | FULL | 62 | 1 | Section 4 of patient journey does not seem to address the totality of the patient experience:<br><br>4.1 pre-sedation assessment, communication, patient information and consent<br>4.2 fasting<br>4.3 psychological preparation<br>4.4 personnel and training<br>4.5 clinical environment and monitoring<br>4.6 discharge criteria<br><br>There is no mention of the actual process of administration and monitoring during sedation (safe administration), which is buried within other sections such as clinical environment and monitoring - this is a key nursing role and needs including.<br><br>The ordering of sections is unusual - psychological preparation - for some children psychological preparation for imaging may be effective without the need for sedation and feeding small babies may | Thank you for your comment. The guideline is not a protocol and focuses on problems not process<br><br>Personnel and training details have been given. Further details of training will depend upon the type of procedure and sedation technique. This is too detailed for this guideline. National courses and accreditation needs to be developed; this might be discussed with the NICE implementation team. |

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| | | | | | | result in them being asleep and some imaging to take place without sedation – perhaps this should be before fasting<br><br>– Personnel and training perhaps should be at the end and include an indication of personnel usually involved at each stage of the patient journey.<br><br>Also training and personnel involved lack specific details. | |
| SH | Royal College of Nursing | 14 | FULL | 65 | 31 | Recommendation 1<br>The professional responsible for doing the procedural sedation should be the one who makes the assessment as they are ultimately responsible. | We think this is inferred |
| SH | Royal College of Nursing | 15 | FULL | 66 | | Recommendation 2-4 agreed | Thank you for your comment |
| SH | Royal College of Nursing | 16 | FULL | 67 | | Recommendation 5<br>See earlier comment that healthcare professionals delivering sedation should be registered with a professional body in the UK and be accountable. | Thank you for your comment. Healthcare professionals are registered and licensed to practice in the UK. The glossary has been amended accordingly. |
| SH | Royal College of Nursing | 17 | FULL | 67 | | Recommendation 6&7 could be merged and ought to come before the considerations of which techniques to use as that might influence choice and decisions or lack of consent render subsequent considerations irrelevant. | Thank you for your suggestion, the developers believe these recommendations to be accurate |
| SH | Royal College of Nursing | 18 | FULL | 73 | | Recommendations 8- 11 agreed<br>Some clarity on whether blood glucose ought to be harvested following fasting periods longer than 4 hours would be welcome. | Thank you for your comment. The recommendations on fasting have been amended following consultation |
| SH | Royal College of Nursing | 19 | FULL | 80 | | Recommendation 12-15 agreed<br>Consider inserting in 13 the use of check back to ensure that the child has | Thank you for your comments. The recommendation has been changed accordingly. |

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| | | | | | | understood the information. | |
| SH | Royal College of Nursing | 20 | FULL | 81 | 17 | Agree the need for in service training and assessment to cover vicarious liability of the healthcare providers but also feel the healthcare professionals delivering sedation or having a responsible pivotal role in the management of the child during the process and in recovery should be registered with a professional body in the UK and be accountable | Thank you for your comment. Healthcare professional is defined in the glossary as 'trained and registered'. Vicarious liability is outside of the remit of this guideline. |
| SH | Royal College of Nursing | 21 | FULL | 81 | | Detail as to training and assessment all supported and Recommendations 16-21 all agreed with the above caveat – re accountability of healthcare professionals | Thank you for your comment. |
| SH | Royal College of Nursing | 22 | FULL | 81 | 39 | There are many references in the draft guidelines to practitioners trained in use of anaesthetic agents. Whilst fully appreciating that it is not within the remit of NICE / guideline developers to oversee the educational/training for practitioners it would be helpful to have a recommendation based on evidence, best practice and risks of useful training to undergo. What might be a useful question to have answered here is an indication of the likely training different practitioners, for example, nurse sedationists might undergo. This would be particularly helpful for areas that do not always have access to general anaesthetics lists but require sedation for older children. | Thank you but we are not able to provide a definitive list of training for each different healthcare professional. |
| SH | Royal College of Nursing | 23 | FULL | 86 | 28-34 | Comment earlier about vicarious liability and accountability of healthcare professionals is particularly relevant at this point | Thank you for your comment. Healthcare professional is defined in the glossary as 'trained and registered'. Vicarious liability is outside of the remit of this guideline. |
| SH | Royal College of Nursing | 24 | FULL | 87 | | Recommendations 22 could be merged with 24 as the keeping of contemporaneous records is a professional requirement for the registered nurse. | Thank you for your comment. The developers believe these recommendations to be accurate. The recommendations state "continuous", not "contemporaneous". |

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| SH | Royal College of Nursing | 25 | FULL | 87 | | Recommendation 23<br>Children requiring this level of sedation and this level of supervision and monitoring should be managed in specialist areas | Thank you for your comment, training and equipment needed are specified Sections 4.4, Personnel and training and 4.5, Clinical environment and monitoring. |
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| SH | Royal College of Nursing | 26 | FULL | 88 | | Recommendation 24 and 25 agreed and above applies | Thank you for your comment |
| SH | Royal College of Nursing | 27 | FULL | 88<br><br>-89 | SEC TION 4.6.3 | Discussion with regards to discharge. Standardisation and consistency required. Safe discharge to a known location with demonstrably competent adult carer/s who have consented and who are aware of the child's continuing need for supervision. Also those who have printed documentation and points of contact to help, support or advise in the event of any incident or concerns they may have. This is critical. Perhaps standard post sedation safe discharge advice letters could be prepared according to a best practice protocol given the lack of evidence as to what constitutes a safe discharge. | Thank you but section 4.6.3 is reflective of the GDG debate at the time.<br><br>Best practice protocols – these are issues that will need to be addressed by the NICE implementation team and local providers. |
| SH | Royal College of Nursing | 28 | FULL | 90 | | Recommendation 26<br>Would add to the discharge criteria "checklist"<br><br>• Can take fluids and has voided urine.<br><br>Nausea vomiting and pain are not only adequately managed but there is a clear plan of care to inform the carers on what to do if they return. It is a concern that they may be therapeutically managed only to return when the medication wears off. | Thank you for your comment. The GDG felt this was not necessary |
| SH | Royal College of Nursing | 29 | FULL | 90 | | Recommendation 27<br>Agreed | Thank you for your comment |
| SH | Royal College of Nursing | 30 | FULL | 317 | | Recommendation 28 | Thank you for your comment |

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| | | | | | | The analysis and critique of the literature is to be commended. | |
| SH | Royal College of Nursing | 31 | FULL | 323 | | Recommendation 29 and 30<br>Agreed | Thank you for your comment |
| SH | Royal College of Nursing | 32 | FULL | 329 | | Recommendation 31 and 32<br>Agreed | Thank you for your comment. |
| SH | Royal College of Nursing | 33 | FULL | 336 | | Recommendation 33<br>Agreed | Thank you for your comment |
| SH | Royal College of Nursing | 34 | FULL | GENE RAL | | Overall, the document appears consistent. It is very comprehensive. However, it has practical limitations as stated in the general earlier above. The information could be streamlined. | Thank you for your comment. |
| SH | Royal College of Nursing | 35 | NICE | GENE RAL | | Our comments above also apply.<br><br>We also consider that information could be streamlined for example pages 6, 7 and 8 are repeated in entirety in the main section. Introduction and key findings need to be a short summary, perhaps bulleted. | Thank you for your comment. The short version guideline is based upon a standard NICE template and text |
| SH | Royal College of Paediatrics and Child Health | 1 | FULL | GENE RAL | | We note that the recommendations for agents to use for sedation for MRI will have significant implications for the way services are currently delivered. For example, while paediatricians may currently manage sedation or MRI, the use of sevoflurane and propofol will mean that anaesthetists will need to manage the sedation instead. This will have resource implications. However, the guideline does provide robust arguments as to why these agents are recommended in terms of efficacy and safety. | Thank you for your comment. Your concern has been forwarded to the NICE implementation team. |
| SH | Royal College of Paediatrics and Child Health | 2 | FULL | 49<br>87 | 21<br>3 | We question whether it practical, when sedating for MRI, to monitor blood pressure every five minutes, which may disturb the | Thank you for your comment, we have added a footnote to the recommendation to address this. |

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| | | | | | | patient into a more awake spate and prompt them to move, disturbing the quality of the imaging. | |
| SH | Royal College of Paediatrics and Child Health | 3 | FULL | 52 | 7 | Although we note there is not much hard evidence in favour, we think the phrase "play specialist" should appear in the section on psychological preparation. We think that NICE should use soft sources of information such as the prevalence and uptake of play specialists, and the unanimous support they have from nurses, doctors and HCAs in emergency departments about their ability to reduce the need for any sedation / deep sedation (instead using light sedation with distraction) / general anaesthesia – depending on each case.<br><br>While these skills should be had by all professionals involved (cross reference 4.3.4. p79), we think this group of trained professionals who do this best should be mentioned.<br><br>Procedural sedation is an intervention that carries risk. We think that a guideline on the subject should cover avoidance of sedation if simple things like distraction and preparation can obviate its needs. Anecdotally we have worked in departments where doses are excessive, simply because the child is too distressed at baseline. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. A full evidence review of non-pharmacological interventions was not prioritised when shaping the scope into key clinical questions for effectiveness reviews. Service delivery recommendations on healthcare professional team constituent membership such as 'play therapists' in relation to your point was not a guideline priority.<br><br>Service delivery recommendations on healthcare professional team constituent membership was not a guideline priority.<br><br>Thank you for your comments, The guideline scope focussed on the use of sedation in children and young people, and therefore this is outside the scope of the guideline. |
| SH | Royal College of Paediatrics and Child Health | 4 | FULL | 52<br>80 | 24<br>4 | We think that it is impractical to consider referral to a mental health specialist for every child or young person with a learning disability who requires sedation for an elective procedure. This would add considerably to the waiting time for the | Thank you for your comments. Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities. |

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| | | | | | | procedure, as mental health services have long waiting times to be seen. It is not clear what the purpose of this referral would be.<br><br>We think it would be better to ensure that someone who knows the child or young person well and knows how to communicate with them and reassure them should be present – usually the parent, but sometimes a familiar carer. | |
| SH | Royal College of Paediatrics and Child Health | 5 | FULL | 79 | 26 | The phrase "trained psychosocial professionals" is unclear; in UK practice, this can be more specific. | Thank you for your comment. This has been clarified in the glossary. |
| SH | Royal College of Paediatrics and Child Health | 6 | NICE | GENE RAL | | The majority of this guideline is extremely helpful with sound evidence based recommendations being made. | Thank you for your comment |
| SH | Royal College of Paediatrics and Child Health | 7 | NICE | GENE RAL | | We would like clarification on whether neonates, especially premature infants and infants under 4 weeks of age, are covered in this guideline. | This is clarified and where care is targeted at premature infants and small infants the guideline encourages 'specialist advice' to be sought. This would be naturally from a neonatologist or paediatrician. |
| SH | Royal College of Paediatrics and Child Health | 8 | NICE | GENE RAL | | We note that propofol, sevoflurane (and ketamine) are general anaesthetic agents; should they be considered within a sedation guideline?<br><br>Note comments of GDG in full guideline (section 6.8.4, p263, lines 8-9; section 6.9.4, p279, lines 37-39) in which it was agreed that both sevoflurane and propofol should be reserved for use by specially trained sedation teams / teams who had adequate training to manage anaesthesia. | Thank you. We have reviewed the use of these drugs with the intention to cause sedation. |
| SH | Royal College of Paediatrics and Child Health | 9 | NICE | GENE RAL | | The College thinks there needs to be clear definitions of “mild, moderate and deep” sedation, and some examples of clinical | Thank you, the text has been amended accordingly |

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| | | | | | | situations in which each type might be used. While these are given in full guideline, we think they should be included in the NICE guideline. | |
| SH | Royal College of Paediatrics and Child Health | 10 | NICE | 3 | | Introduction: We note that ineffective communication due to age/development is also a factor. | Thank you for your comment. |
| SH | Royal College of Paediatrics and Child Health | 12 | NICE | 6<br>9 | | We think that ideal body weight should be estimated. | Thank you for your comment. Mention to the lean body weight has been added to the discussion in the full version of the guideline. The short version is based upon a standard NICE template and text |
| SH | Royal College of Paediatrics and Child Health | 13 | NICE | 7 | | Personnel and training: We think that this should be amended to "Healthcare professionals delivering sedation should have knowledge and understanding of and competency in:" | Thank you for your suggestion, the text has been amended accordingly |
| SH | Royal College of Paediatrics and Child Health | 14 | NICE | 8<br>13 | | The guideline suggests that for deep sedation one should "continuously monitor, interpret and respond to all of the following". The list which follows includes end tidal CO2 (capnography) and blood pressure (monitored every 5 minutes). We agree that any sedation that renders a child unconscious must be considered as being potentially more than merely moderate sedation. Careful monitoring is vital. However, if one was to try and measure blood pressure every 5 minutes one would undoubtedly disturb the child so much that the child would not be successfully sedated and would be roused. End tidal CO2 monitors are not readily available and similarly would be a difficult parameter to measure without disturbing the child. We agree with all of the other measures which need to be monitored. | Thank you for your comment, we agree that this could be determined by local clinician decision making. As stated in the full guideline document, this recommendation is based on consensus method, not on literature review. |

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| | | | | | | We would ask what evidence is available that end tidal CO2 or blood pressure monitoring is needed to safely monitor a child being sedated for an MRI. | |
| SH | Royal College of Paediatrics and Child Health | 15 | NICE | 10 | | 1.2.3: We think that anaesthesia may be safer and should be considered. | Thank you for your comment, the GDG do not agree. |
| SH | Royal College of Paediatrics and Child Health | 16 | NICE | 11 | | 1.2.4: We note that nausea and vomiting may be side effects, even if not life threatening<br><br>See: Anaesthesiology. 1996 Nov;85(5):1055-62. | Thank you for your comment. |
| SH | Royal College of Paediatrics and Child Health | 17 | NICE | 11 | | 1.3.4: We note that play therapists have a role in preparing all children for procedures, sedated or otherwise. [related to comment on full guideline, p52 line 7].<br><br>See: Clin Radiol. 1997 Dec;52(12):945-7. | Thank you for your comment. |
| SH | Royal College of Paediatrics and Child Health | 18 | NICE | 15 | | Section 1.8 – Painless imaging: This section very reasonably recommends chloral for children under 15 kgs but then goes on to suggest propofol or sevoflurane, whereas the use of intravenous midazolam is not considered. Unless good evidence is available that this is a dangerous way of sedating children we feel its exclusion does not help DGH paediatricians who are asked to sedate children for painless procedures.<br><br>We feel that the usability of this guideline is therefore compromised. General paediatricians will eagerly search this publication for usable advice. Perhaps these issues need to be addressed prior to publication of this guideline. | Thank you for your comment. The recommendation on painless procedures has been changed accordingly |

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| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 1 | FULL | GENE RAL | | There are two relevant Cochrane Reviews that have not been included in the development of the guideline:<br>Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment. Cochrane Database of Systematic Reviews 2006, Issue 1. Art. No.: CD003877. DOI: 10.1002/14651858.CD003877.pub3.<br>Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year olds. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD006334. DOI: 10.1002/14651858.CD006334.pub2.<br>It is not clear why nine trials that were cited within the above Cochrane Reviews have not been included the guideline. | These Cochrane reviews were evaluated during the scoping process.<br>All studies within *Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment* which met the inclusion criteria for this guideline were reviewed.<br>The Cochrane review<br>*Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year old* found no RCTs comparing general anaesthesia to sedation for the provision of dental care in children. |
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| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 2 | FULL | GENE RAL | | There appears to be a lack of appreciation of the definition of conscious sedation as used in dentistry (see for example reference 198) for which it is of fundamental importance that the level of sedation must be such that the patient remains conscious, and is able to both understand and respond to verbal commands (if a patient is unable to respond to verbal contact when fully conscious, the normal method of communicating with them must be maintained). | Thank you for your comment. “Conscious sedation” is now used in the recommendation in the dentistry setting. “Conscious sedation” is also defined in the glossary. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 4 | FULL | 29 | 9-10 | This definition is not conscious sedation as understood in Dentistry. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Scottish Dental Clinical | 5 | FULL | 30 | 6-8 | Non-hospital secondary care is omitted e.g. | Thank you but page 30 of the full guideline |

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| | Effectiveness Programme (SDCEP) | | | | | Community Dental Service | represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 6 | FULL | 43 | 7-8 | Choice of technique may also depend on patient factors such as their level of anxiety | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 7 | FULL | 43 | 21 | Should this read 'non-pharmacological' rather than 'pharmacological'? | Yes. Thank you for spotting this typo. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 8 | FULL | 48 | 1 | For GA in dentistry, patient preference is not an indication. Therefore why is patient preference included as an indication for sedation?<br>Anxiety level should be included.<br>Operator opinion informed by patient assessment should be included | Thank you for your comment. The GDG felt that patient preference should be taken into account. Psychological and developmental status (which include anxiety) are indeed included in the pre-sedation assessment recommendations. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 9 | FULL | 48 | 7 | Monitoring and resuscitation together. Should separate and have equipment and drugs used for sedation complications prior to resuscitation available. | Thank you for your comment. The developers do not wish to change the wording as it was felt the current wording is clear. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 10 | FULL | 48 | 21 - 22 | Few complications are encountered in dentistry. Therefore, to obtain practical experience would require simulation which we believe should be acceptable. | Thank you for your comment. The training recommendations apply to all settings |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 11 | FULL | 49 | 1 | 5. Definition minimal + moderate should be conscious sedation according to Dental Definition.<br>6. The resuscitation skills required for minimal and moderate sedation should be the same.<br>7. Not in line with current dental guidance, but supports 2006 Resuscitation Council report (with respect to the requirement for practices to have a | 1. Definitions of minimal, moderate and conscious sedation have been added to the glossary.<br>2. The recommendations on training and monitoring apply to all clinical settings;<br>3. Thank you for your observation. The GDG supports recommendation made by the Resuscitation Council report 2006 for managing emergencies in dental practice<br>4. The recommendations on monitoring |

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| | | | | | | defibrillator)<br>8. Concern about this and other recommendations of up to 50% $N_2O$. If titrated there is no need to limit beyond what IS machines can deliver. | apply to all cases of moderate sedation. In one recommendation about personnel and training we specify that for sedation with nitrous oxide alone (up to 50% in oxygen) the sedation team should have the same skills as for minimal sedation. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 12 | FULL | 49 | L5-12 | For minimal and moderate sedation, there should be a recommendation about how monitoring is carried out. | Thank you for your comment. The GDG did not feel it was necessary to specify monitoring for minimal sedation. This is local clinical choice.<br>There is a recommendation about monitoring for moderate sedation. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 13 | FULL | 50 | 20 | As there are no recognised sedation specialists, we suggest replacing “specialist” with “further” (i.e. to seek advice from a more experienced colleague) | Thank you, we disagree with your suggestion because further is too vague. We have defined “specialist in sedation” in the glossary. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 14 | FULL | 51 | 1 | Anxiety level and seditionist opinion should be included. | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent.<br><br>Psychological and developmental status (which include anxiety) are also included in the pre-sedation assessment recommendations. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 15 | FULL | 51 | 13 | Suggest ‘appropriate alternatives’ | Thank you for your comment, the wording has been amended to provide further clarity. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 16 | FULL | 59 | 11-18 | Blood pressure measurement is not mentioned as part of assessment - this is standard is in dentistry | Thank you for your comment. Pre-sedation assessment recommends assessing the physical status. The GDG felt that blood pressure measurement is standard in dentistry for adults, but not for children. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 17 | FULL | 51 | 22 | 1. Fasting protocol contrary to current dental guidance (SDAC: reference 206, SDCEP: reference 198).<br>2. Fasting is not needed for minimal / moderate sedation | Thank you for your comment. The recommendations on fasting have been amended following consultation. |

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| | | | | | | 3. It appears that these recommendations have been made with no evidence to support them (e.g. refer to McKenna et al. Prim Dent Care. 2010 Jan;17(1):5-11). | |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 18 | FULL | 52 | 24-25 | 1. Not clear why learning difficulties are included within this group.<br>2. There should be liaison nurses for this group. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work.<br>Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities.<br>Service delivery recommendations on healthcare professional team constituent membership was not a guideline priority. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 19 | FULL | 53 | 11 | As comments 9 and 11 above | We would need more detail to answer this comment. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 20 | FULL | 54 | 8-12 | Monitoring does not required heart rate and $SaO_2$ for $N_2O$ and oxygen inhalation sedation. | Thank you for your comment. We agree with your comment but the recommendation applies to moderate sedation in general. In a previous recommendation on personnel and training, sedation with nitrous oxide alone (up to 50% in oxygen) is compared to minimal sedation. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 21 | FULL | 54 | 7-16 | Blood pressure measurement is not mentioned as part of assessment - this is standard in dentistry | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 22 | FULL | 55 | 1 | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |

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| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 23 | FULL | 55 | 8 | 3. We believe that return to a level of consciousness suitable for care by a non-healthcare qualified escort is acceptable.<br>4. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | Thank you, we agree with your comment. The recommendation has been amended. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 24 | FULL | 55 | 14-15 | 3. We believe that return to level of responsiveness and orientation suitable for care by a non-healthcare qualified escort is acceptable.<br>4. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | Thank you, we agree with your comment. The recommendation on discharge criteria has been amended. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 25 | FULL | 55 | 13 & FOOTNOTE | States that vital signs that usually include blood pressure should return to normal, but it is not recommended to measure blood pressure earlier in the guideline. | Thank you but we disagree with your comment. The guideline is non setting specific, and assessment will invariably differ across a range of settings where different target levels of sedation are aimed for by the sedation team. Blood pressure can only be used as a marker for discharge criteria if it has been recorded as part of the initial assessment, this is routine practice in hospital settings and especially where moderate to deep sedation is the target level. The nature of the non-setting specific recommendations reflect the diverse populations that the guideline addresses, and it is not necessary for example within dental settings when mild sedation is the target level for a blood pressure to be routinely recorded. |
| SH | Scottish Dental Clinical | 26 | FULL | 55-56 | 24 -1 | 3. All techniques are grouped together for | Thank you. We agree with your comment |

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| | Effectiveness Programme (SDCEP) | | | | | conscious sedation. We are concerned about the inclusion of oral midazolam within minimal sedation. It is not clear why a lower level of training is recommended for oral midazolam compared to IV midazolam – this is contrary to dental guidance.<br>4. Oral and Transmucosal sedation should be listed as techniques that can be used to produce 'moderate sedation' | and the recommendations on dentistry and painful procedures have been amended accordingly. |
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| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 27 | FULL | 56 | 27 - 28 | We do not think it is equitable to mention one technique that is only available in one centre in the UK. | Thank you for your comment. The term "Alternative techniques" has been introduced and defined for dentistry. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 28 | FULL | 58 | 23-30 | We think it is inappropriate for the guideline to be so prescriptive on fasting when this is included a research recommendation. Fasting increases the likelihood of fainting in adolescents. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 29 | FULL | 59 | 2-10 | Training for conscious sedation in dentistry for standard techniques is well established and so we do not think this needs to be the subject of a research recommendation. | Thank you for your comment. The research recommendation is aimed to cover all clinical setting. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 30 | FULL | 61 | 15-20 | We have concerns about how this would be accomplished especially in primary or non hospital secondary care. | Thank you for your comment. This is a future research recommendation. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 31 | FULL | 62 | 15-16 | Conscious sedation correct here - should be in the rest of the guideline. | Thank you for your comment. "Conscious sedation" has been added to the recommendations in the dental setting and defined in the glossary. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 32 | FULL | 64 | 22-23 | The recommendation that only one of 2 professionals can be involved in the procedure is contrary to current dental guidance. Both members of the dental team involved in the procedure can be trained in sedation. This would have a significant impact on the provision of sedation for dentistry. | Thank you for your comment. The difference between delivering and administering sedation has been explained in the glossary. |
| SH | Scottish Dental Clinical | 33 | FULL | 65 | 1-26 | Need to acknowledge that consent varies in | Thank you for your comment. This has been |

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| | Effectiveness Programme (SDCEP) | | | | | different parts of the UK. | acknowledged in the guideline. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 34 | FULL | 68 | 7- 14 | The paucity of evidence of the benefits of fasting, the results of Keidon 2004 (page 71), and the clinical experience that fainting is more likely in fasted patients brings into question the justification for the fasting recommendations. | Thank you for your comment. The recommendations on fasting have been amended following consultation |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 35 | FULL | 73 | 10-12 | Patients with learning difficulties may require increased care (including overnight) pretreatment if there is a requirement to fast. | Thank you. We think an overnight stay is unlikely to be necessary except in rare circumstances. We do not think it necessary to raise this issue in the guideline. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 36 | FULL | 84 | 1 (REC 18) | As comments 9 and 11 above | We would need more details to be able to answer this comment. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 37 | FULL | 87 | 2 | Oxygen saturation monitoring is not required for $N_2O$ and oxygen inhalation sedation | Thank you, the recommendations has been amended accordingly |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 38 | FULL | 88 | 1 (REC 24) | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 39 | FULL | 88 | 2 (REC 25) | Agree with recommendation except for return to baseline level of consciousness. | Thank you for your comment, the recommendation has been amended accordingly |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 40 | FULL | 90 | 10 (REC 26) | Agree with recommendation except for return to baseline level of consciousness. | Thank you for your comment, the recommendation has been amended accordingly |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 41 | FULL | 161 | 16 - 17 | Does not make sense with the stem line 17 | Thank you for your comment. It has been amended accordingly. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 42 | FULL | 27-280 | | We have concerns about the requirement for the ability to intubate when using propofol. We believe that for older children (>=10 years), conscious sedation for dentistry with propofol can be provided | Thank you for your comment.The terms "Conscious sedation" and "Alternative techniques" have been added to the recommendation in the dentistry setting and defined in the glossary. |

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|  |  |  |  |  |  | safely and reliably by a trained non-anaesthetist. In several clinical settings, this is common practice. The implication of the proposed recommendations is that only trained anaesthetists can provide sedation using propofol. Implementing this recommendation would have a significant impact on the provision of patient care.<br>Much of the evidence quoted appears to refer to deep sedation and not conscious sedation as used in dentistry.<br>We suggest that the evidence and this recommendation are reconsidered. | The guidance advocates further training for more complex or alternative techniques. |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 43 | FULL | 336 | 11 | Not equitable to mention one technique only available in 1 centre in UK. | Thank you, we agree with your comment. The recommendation has been amended, |
| SH | Scottish Dental Clinical Effectiveness Programme (SDCEP) | 44 | NICE | GENE RAL |  | We are concerned about the tone within the introduction (final paragraph) which appears to imply that GA is better and safer and the only reasons for not using it are economic. | Thank you for your comment. We do not believe that the summary asserts this at all. It simply recognises that general anaesthesia is the definitive choice when sedation fails |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 1 | FULL | GENE RAL |  | There are two relevant Cochrane Reviews that have not been included in the development of the guideline:<br>Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment. Cochrane Database of Systematic Reviews 2006, Issue 1. Art. No.: CD003877. DOI: 10.1002/14651858.CD003877.pub3.<br>Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year olds. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD006334. DOI: 10.1002/14651858.CD006334.pub2.<br>It is not clear why nine trials that were cited within the above Cochrane Reviews have | These Cochrane reviews were evaluated during the scoping process.<br>All studies within *Matharu L, Ashley PF. Sedation of anxious children undergoing dental treatment* which met the inclusion criteria for this guideline were reviewed.<br>The Cochrane review<br>*Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment in under 18 year old* found no RCTs comparing general anaesthesia to sedation for the provision of dental care in children. |

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|  |  |  |  |  |  | not been included the guideline. |  |
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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 2 | FULL | GENE RAL |  | The use of multiple agent sedation techniques in paediatric conscious sedation is practiced widely in dentistry. There is a large experience of using ketamine based techniques in a number of referral practices where it is used in combination with other agents to produce conscious sedation according to the dental definition. Intravenous propofol is also widely used both within and out with hospitals to produce the same level of sedation. The implication that these agents can only be used to produce deeper levels of sedation is thus not supported by clinical experience. | Thank you for your comment.The recommendation in the dentistry setting has been amended to state the target level of sedation. The concept of alternative techniques has also been introduced. “Conscious sedation” is the target level of sedation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 3 | FULL | GENE RAL |  | There appears to be a lack of appreciation of the definition of conscious sedation as used in dentistry for which it is of fundamental importance that the level of sedation must be such that the patient remains conscious, and is able to both understand and respond to verbal commands (if a patient is unable to respond to verbal contact when fully conscious, the normal method of communicating with them must be maintained). | Thank you for your comment. “Conscious sedation” is now used in the recommendation in the dentistry setting. “Conscious sedation” is also defined in the glossary. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 4 | FULL | 28 | 5 | The remit is too wide with no differentiation between babies and adults. Suggest dividing to provide recommendations specific to under 2s, pre-cooperative, under 12 and adolescent. | Thank you but the ‘remit’ is now a retrospective document as the work has taken place. The remit is issued by the DH and we are unable to change such remits. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 5 | FULL | 29 | 9-10 | This definition is not conscious sedation as understood in Dentistry. | Thank you but page 29 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |

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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 6 | FULL | 30 | 6-8 | Non-hospital secondary care is omitted e.g. Community Dental Service | Thank you but page 30 of the full guideline represents wording from the Scope document and we are unable to change any of this. The Scope document was fully consulted on and these comments would have been appreciated at the appropriate time. |
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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 7 | FULL | 43 | 7-8 | Choice of technique may also depend on patient factors such as their level of anxiety | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 8 | FULL | 43 | 21 | Should this read 'non-pharmacological' rather than 'pharmacological'? | Yes. Thank you for spotting this typo. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 9 | FULL | 48 | 1 | For GA in dentistry, patient preference is not an indication. Therefore why is patient preference included as an indication for sedation?<br>Anxiety level should be included.<br>Operator opinion informed by patient assessment should be included | Thank you for your comment. The GDG felt that patient preference should be taken into account. Psychological and developmental status (which include anxiety) are indeed included in the pre-sedation assessment recommendations |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 10 | FULL | 48 | 7 | Monitoring and resuscitation together. Should separate and have equipment and drugs used for sedation complications prior to resuscitation available. | Thank you for your comment. The developers do not wish to change the wording as it was felt the current wording is clear. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 11 | FULL | 48 | 21 - 22 | Few complications are encountered in dentistry. Therefore, to obtain practical experience would require simulation which we believe should be acceptable. | Thank you for your comment. The training recommendations apply to all settings |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 12 | FULL | 49 | 1 | 9. Definition minimal + moderate should be conscious sedation according to Dental Definition.<br>10. The resuscitation skills required for minimal and moderate sedation should be the same.<br>11. Not in line with current dental guidance, but supports 2006 Resuscitation | 1. Definitions of minimal, moderate and conscious sedation have been added to the glossary.<br>2. The recommendations on training and monitoring apply to all clinical settings;<br>3. Thank you for your observation. The GDG supports recommendation made by the Resuscitation Council report 2006 for |

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| | | | | | | Council report (with respect to the requirement for practices to have a defibrillator)<br>12. Concern about this and other recommendations of up to 50% $N_2O$. If titrated there is no need to limit beyond what IS machines can deliver. | managing emergencies in dental practice<br>4. The recommendations on monitoring apply to all cases of moderate sedation. In one recommendation about personnel and training we specify that for sedation with nitrous oxide alone (up to 50% in oxygen) the sedation team should have the same skills as for minimal sedation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 13 | FULL | 49 | L5-12 | For minimal and moderate sedation, there should be a recommendation about how monitoring is carried out. | Thank you for your comment. The GDG did not feel it was necessary to specify monitoring for minimal sedation. This is local clinical choice.<br>There is a recommendation about monitoring for moderate sedation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 14 | FULL | 50 | 20 | As there are no recognised sedation specialists, we suggest replacing “specialist” with “further” (i.e. seek advice from a more experienced colleague) | Thank you, we disagree with your suggestion because further is too vague. We have defined “specialist in sedation” in the glossary. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 15 | FULL | 51 | 1 | Anxiety level and seditionist opinion should be included. | Thank you, we agree with your comment. This is stated in the existing text in Section 4.1.3, GDG discussion, Information and Consent.<br><br>Psychological and developmental status (which include anxiety) are also included in the pre-sedation assessment recommendations. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 16 | FULL | 51 | 13 | Suggest ‘appropriate alternatives’ | Thank you for your comment,the wording has been amended to provide further clarity |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 17 | FULL | 59 | 11-18 | Blood pressure measurement is not mentioned as part of assessment - this is standard is in dentistry | Thank you for your comment. Pre-sedation assessment recommends assessing the physical status. The GDG felt that blood pressure measurement is standard in dentistry for adults, but not for children. |
| SH | Society for the Advancement of | 18 | FULL | 51 | 22 | 4. Fasting protocol contrary to current dental guidance (SDAC: reference 206, | Thank you for your comment. The recommendations on fasting have been |

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| | Anaesthesia in Dentistry (SAAD) | | | | | SDCEP: reference 198).<br>5. Fasting is not needed for minimal / moderate sedation<br>6. It appears that these recommendations have been made with no evidence to support them (e.g. refer to McKenna et al. Prim Dent Care. 2010 Jan;17(1):5-11). | amended following consultation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 19 | FULL | 52 | 24-25 | 3. Not clear why learning difficulties are included within this group.<br>4. There should be liaison nurses for this group. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work.<br>Guideline recommendations need to be sensitive to equity and diversity principles, this is why the GDG referred to mental health services as this is where expert advice can be sought in relation to learning disabilities.<br>Service delivery recommendations on healthcare professional team constituent membership was not a guideline priority. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 20 | FULL | 53 | 11 | As comments 9 and 11 above | We would need more detail to answer this comment. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 21 | FULL | 54 | 8-12 | Monitoring does not required heart rate and $SaO_2$ for $N_2O$ and oxygen inhalation sedation. | Thank you for your comment. We agree with your comment but the recommendation applies to moderate sedation in general. In a previous recommendation on personnel and training, sedation with nitrous oxide alone (up to 50% in oxygen) is compared to minimal sedation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 22 | FULL | 54 | 7-16 | Blood pressure measurement is not mentioned as part of assessment - this is standard is in dentistry | The guideline is not a textbook for sedation practice. Clinicians involved in paediatric sedation are able to make local decisions in relation to this |

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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 23 | FULL | 55 | 1 | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 24 | FULL | 55 | 8 | 5. We believe that return to a level of consciousness suitable for care by a non-healthcare qualified escort is acceptable.<br>6. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | Thank you, we agree with your comment. The recommendation has been amended. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 25 | FULL | 55 | 14-15 | 5. We believe that return to level of responsiveness and orientation suitable for care by a non-healthcare qualified escort is acceptable.<br>6. Current recommendations for sedation in dental practice are safe, and do not require prolonged stays as would be needed if these recommendations are implemented. | Thank you, we agree with your comment. The recommendation on discharge criteria has been amended. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 26 | FULL | 55 | 13 & FOOTNOTE | States that vital signs that usually include blood pressure should return to normal, but it is not recommended to measure blood pressure earlier in the guideline. | Thank you but we disagree with your comment. The guideline is non setting specific, and assessment will invariably differ across a range of settings where different target levels of sedation are aimed for by the sedation team. Blood pressure can only be used as a marker for discharge criteria if it has been recorded as part of the initial assessment, this is routine practice in hospital settings and especially where moderate to deep sedation is the target level. The nature of the non-setting specific recommendations reflect the diverse populations that the guideline addresses, and it is not necessary for example within |

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| | | | | | | | dental settings when mild sedation is the target level for a blood pressure to be routinely recorded. |
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| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 27 | FULL | 55-56 | 24 -1 | 5. All techniques are grouped together for conscious sedation. We are concerned about the inclusion of oral midazolam within minimal sedation. It is not clear why a lower level of training is recommended for oral midazolam compared to IV midazolam – this is contrary to dental guidance.<br>6. Oral and Transmucosal sedation should be listed as techniques that can be used to produce ‘moderate sedation’ | Thank you. We agree with your comment and the recommendations on dentistry and painful procedures have been amended accordingly. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 28 | FULL | 56 | 27 - 28 | We do not think it is equitable to mention one technique that is only available in one centre in the UK. | Thank you for your comment. The term “Alternative techniques” has been introduced and defined for dentistry. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 29 | FULL | 58 | 23-30 | We think it is inappropriate for the guideline to be so prescriptive on fasting when it this is included a research recommendation. Fasting increases the likelihood of fainting in adolescents. | Thank you for your comment. The recommendations on fasting have been amended following consultation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 30 | FULL | 59 | 2-10 | Training for conscious sedation in dentistry for standard techniques is well established and so we do not think this needs to be the subject of a research recommendation. | Thank you for your comment. The research recommendation is aimed to cover all clinical setting. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 31 | FULL | 61 | 15-20 | We have concerns about how this would be accomplished especially in primary or non hospital secondary care. | Thank you for your comment. This is a future research recommendation. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 32 | FULL | 62 | 15-16 | Conscious sedation correct here - should be in the rest of the guideline. | Thank you for your comment. “Conscious sedation” has been added to the recommendations in the dental setting and defined in the glossary. |
| SH | Society for the Advancement of Anaesthesia in Dentistry | 33 | FULL | 64 | 22-23 | The recommendation that only one of 2 professionals can be involved in the procedure is contrary to current dental | Thank you for your comment. The difference between delivering and administering sedation has been explained |

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| | (SAAD) | | | | | guidance. Both members of the dental team involved in the procedure can be trained in sedation. This would have a significant impact on the provision of sedation for dentistry. | in the glossary. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 34 | FULL | 65 | 1-26 | Need to acknowledge that consent varies in different parts of the UK | Thank you for your comment. This has been acknowledged in the guideline. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 35 | FULL | 68 | 7- 14 | The paucity of evidence of the benefits of fasting, the results of Keidon 2004 (page 71), and the clinical experience that fainting is more likely in fasted patients brings into question the justification for the fasting recommendations. | Thank you for your comment. The recommendations on fasting have been amended following consultation |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 36 | FULL | 73 | 10-12 | Patients with learning difficulties may require increased care (including overnight) pretreatment if there is a requirement to fast. | Thank you. We think an overnight stay is unlikely to be necessary except in rare circumstances. We do not think it necessary to raise this issue in the guideline. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 37 | FULL | 84 | 1 (REC 18) | As comments 9 and 11 above | We would need more details to be able to answer this comment. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 38 | FULL | 87 | 2 | Oxygen saturation monitoring is not required for $N_2O$ and oxygen inhalation sedation | Thank you, the recommendations has been amended accordingly |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 39 | FULL | 88 | 1 (REC 24) | We believe that a minimum of baseline, post sedation, pre-discharge and significant deviations from baseline recording is sufficient. Continuous recording of monitoring is not necessary. | Thank you for your comment. The GDG felt that continuous monitoring is necessary and should be documented in the healthcare record. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 40 | FULL | 88 | 2 (REC 25) | Agree with recommendation except for return to baseline level of consciousness. | Thank you for your comment, the recommendation has been amended accordingly |
| SH | Society for the | 41 | FULL | 90 | 10 | Agree with recommendation except for | Thank you for your comment, the |

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| | Advancement of Anaesthesia in Dentistry (SAAD) | | | | (REC 26) | return to baseline level of consciousness. | recommendation has been amended accordingly |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 42 | FULL | 161 | 16 - 17 | Does not make sense with the stem line 17 | Thank you for your comment. It has been amended accordingly. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 43 | FULL | 27-280 | | We have concerns about the requirement for the ability to intubate when using propofol. We believe that for older children (>=10 years), conscious sedation for dentistry with propofol can be provided safely and reliably by a trained non-anaesthetist. In several clinical settings, this is common practice. The implication of the proposed recommendations is that only trained anaesthetists can provide sedation using propofol. Implementing this recommendation would have a significant impact on the provision of patient care.<br>Much of the evidence quoted appears to refer to deep sedation and not conscious sedation as used in dentistry.<br>We suggest that the evidence and this recommendation are reconsidered. | Thank you for your comment.The terms “Conscious sedation” and “Alternative techniques” have been added to the recommendation in the dentistry setting and defined in the glossary.<br>The guidance advocates further training for more complex or alternative techniques. |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 44 | FULL | 336 | 11 | Not equitable to mention one technique only available in 1 centre in UK. | Thank you, we agree with your comment. The recommendation has been amended, |
| SH | Society for the Advancement of Anaesthesia in Dentistry (SAAD) | 45 | NICE | GENE RAL | | We are concerned about the tone within the introduction (final paragraph) which appears to imply that GA is better and safer and the only reasons for not using it are economic. | Thank you for your comment. We do not believe that the summary asserts this at all. It simply recognises that general anaesthesia is the definitive choice when sedation fails |
| SH | STEPS | 1 | FULL | 79 | 1 -28 | Psychological preparation:<br>This is very important as cooperation in any future procedures will depend on the right kind of preparation and support. A negative | Thank you for your comments. We have made ‘good practice’ recommendations that have been shaped by both a narrative review of the evidence and GDG consensus |

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| | | | | | | experience could cause problems with other healthcare interventions. Ideally this should be done a little time before the procedure rather than at the procedure by appropriately trained staff.<br>If appropriate written or audio-visual information should be available. | work. We anticipate that the 'good practice' recommendations will help inform local policy and agree that developing such materials/guidance would be useful implementation tools. |
| SH | STEPS | 2 | FULL | 83 | 7-21 | All personnel are adequately trained to perform the procedures and to deal with the consequences of that technique should there be any adverse or unexpected reactions. These skills should be regularly appraised. | Thank you. This is stated in the last recommendation for this section (personnel and training). |
| SH | STEPS | 3 | FULL | 89 | 17-21 | *However this should also take into account the capabilities of the person caring for the child following discharge, the presence of other medical problems and the distance the family has to travel to obtain medical assistance It is more important to individualize the times of discharge rather insist on a minimum length of stays.*<br>This needs to be systematically assessed and recorded. | Thank you for your comment, the developers believe the level of detail is adequate for the purpose of this guideline. |
| SH | STEPS | 4 | FULL | 106<br>108 | 14-24<br>3-10 | I feel these statements might be used as a blanket policy to exclude parents from induction of sedation or anaesthesia. The studies used as evidence did not seem to take into account the degree of preparation and support the parents had received before the inductions or the age of the child. Small babies and toddlers cannot be adequately prepared and therefore take comfort from a familiar adult helping to reduce separation anxiety. The attending adult must feel comfortable in their role in supporting the child and be fully prepared into how they should act and what they should do. | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We acknowledge the paucity of the 'effectiveness evidence' in the evidence to recommendations sections of the guideline and acknowledge that the role of the GDG is to interpret the evidence and form recommendations that are useful for practice. This approach is supportive of your point |

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| SH | Sunderland Royal Hospital | 1 | NICE | GENE RAL | | The majority of this guideline is extremely helpful with sound evidence based recommendations being made. However I would criticise the guideline mainly from the perspective of a Paediatrician sedating children for diagnostic procedures such as MRI's or CT's.<br><br>The use of chloral hydrate is an extremely effective agent in babies and young children. When children are older and do not sedate easily with chloral an alternative must be used. I understand from the scope of the guideline that only published evidence can be used to provide recommendations. However I feel not to mention midazolam as a sedating agent is a significant omission. Perhaps the use of midazolam could be included emphasizing that published evidence for its use is not available. I could certainly provide details of its safe use in over 1000 children from 1998 to date using a referenced guideline. | Thank you for your comment, the recommendations on painless imaging have been amended accordingly |
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| SH | Sunderland Royal Hospital | 2 | NICE | 8 AND 13 | | it suggests that for deep sedation that one should "continuously monitor, interpret and respond to all of the following". The list which follows includes end tidal CO2 (capnography) and blood pressure (monitored every 5 minutes). I agree that any sedation which renders a child unconscious must be considered as being potentially more than merely moderate sedation. Careful monitoring is vital. However if one was to try and measure blood pressure every 5 minutes one would undoubtedly disturb the child so much that the child would not be successfully sedated | Thank you for your comment, we agree that this could be determined by local clinician decision making. |

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| | | | | | | and would be roused. End tidal $CO_2$ monitors are not readily available and similarly would be a difficult parameter to measure without disturbing the child. I am very happy with all of the other measures which need to be monitored.<br><br>I think this links to the issue regarding midazolam in the following way. I presume that the lack of evidence / published material for using midazolam has prevented its use. However I would ask what evidence is available that end tidal $CO_2$ or blood pressure monitoring is needed to safely monitor a child being sedated for an MRI. | The recommendation is based on consensus and not evidence based. |
| SH | Sunderland Royal Hospital | 3 | NICE | 15 | | I feel that the usability of this guideline is compromised. Painless imaging (Section 1.8 on Page 15) very reasonably recommends chloral for children under 15 Kgs but then goes on to suggest propofol or sevoflurane, whereas the use of intravenous midazolam is not considered. Unless good evidence is available that this is a dangerous way of sedating children I feel its exclusion does not help DGH paediatricians who are asked to sedate children for painless procedures. | Thank you for your comment. The recommendation on painless procedures has been changed accordingly |
| SH | The College of Emergency Medicine | 1 | FULL | 49 | 21 | In the Emergency Department we try to avoid monitoring blood pressure every 5 minutes when using ketamine – one measurement before the procedure and then none required. The cuff inflation provides an unnecessary stimulus at time when we want to minimise stimulation | Thank you for your comment, we have added a footnote to the recommendation to address this. |
| SH | The College of | 2 | FULL | 54 | 25 | In the Emergency Department we try to | Thank you for your comment, we agree that |

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|  | Emergency Medicine |  |  |  |  | avoid monitoring blood pressure every 5 minutes when using ketamine – one measurement before the procedure and then none required. The cuff inflation provides an unnecessary stimulus at time when we want to minimise stimulation | this could be determined by local clinician decision making. |
| SH | The College of Emergency Medicine | 3 | FULL | 87 | 3 | In the Emergency Department we try to avoid monitoring blood pressure every 5 minutes when using ketamine – one measurement before the procedure and then none required. The cuff inflation provides an unnecessary stimulus at time when we want to minimise stimulation | Thank you for your comment, we agree that this could be determined by local clinician decision making |
| SH | The Nursing and Midwifery Council | 1 | FULL | 50 | 8 | We are in agreement that you must take part in appropriate learning and practice activities that maintain and develop your competence and performance. | Thank you for your comment. |
| SH | The Nursing and Midwifery Council | 2 | FULL | 50 | 6 | We would recommend the inclusion of making certain of the identity of the child to whom the sedation is to be administered in the pre-sedation assessment , conforming with local procedures | Thank you for your comment. This is outside the scope of this guideline. |
| SH | The Nursing and Midwifery Council | 3 | FULL | 51 | 10 | We are in agreement that any advice you give must be evidence based. | Thank you for your comment. |
| SH | The Nursing and Midwifery Council | 4 | FULL | 51 | 15 | We are in agreement that you must ensure that consent has been gained and documented before beginning any sedation process. Practitioners should act according to the "Fraser competencies." http://www.surreycc.gov.uk/sccwebsite/sccwspages.nsf/LookupWebPagesByTITLE_RTF/The+Fraser+Guidelines?opendocument<br><br>We would refer nurses and midwives to our guidance *Record keeping: Guidance for nurses and midwives* (NMC, 2009). Good record keeping is essential to the provision of safe and effective care and is never an | Thank you for your comment. |

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| | | | | | | optional extra. | |
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| SH | The Nursing and Midwifery Council | 5 | FULL | 52 | 20 | We would also recommend the parent is prepared psychologically for the process.<br><br>The importance of communication is highlighted and we would endorse that communication skills are essential when caring for children, young people and their carers. Communication skills are highlighted in the essential skills clusters for pre-registration nursing education (NMC circular 07/2007) and in the *Standards of proficiency for specialist community public health nurses* (NMC, 2004). *Advice for nurses working with children and young people* (NMC, 2008) states that "communication in all forms is vital …and also reduces fear and anxiety for the children/young people and their parents." | Thank you for your comments. We have made 'good practice' recommendations that have been shaped by both a narrative review of the evidence and GDG consensus work. We are supportive of your comment and recognise the importance of effective communication in all aspects of clinical practice. |
| SH | The Nursing and Midwifery Council | 6 | FULL | 52 | 28 | We recommend healthcare professionals delivering sedation know the therapeutic uses, normal dose, side effects, precautions and contra-indications. Practitioners should ensure that they are working within their area of competence and comply with the standards within the *The code: Standards of conduct, performance and ethics for nurses and midwives* (NMC, 2008)<br><br>It is essential that nurses and midwives are adequately trained in assessment. In addition to the skills listed, it is important that nurses and midwives understand the necessity to determine the frequency of observation assessments and the importance of recognising whether a child's condition is deteriorating or improving. | Thank you, we acknowledge your comment, however the developers believe this recommendation to be accurate. |
| SH | The Nursing and | 7 | FULL | 53 | 21 | We regulate individual registrants and | Thank you for your comment. |

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| | Midwifery Council | | | | | ensure that standards are maintained through revalidation processes. Registrants need to ensure that they maintain their competencies in order to be fit for purpose. | |
| SH | The Nursing and Midwifery Council | 8 | FULL | 55 | 9 | We recommend a standard is included in this section about the reporting of adverse reactions, events or near misses including www.yellowcard.gov.uk and NPSA. | Thank you for your comment. We will discuss this with the NICE implementation team. |
| SH | The Nursing and Midwifery Council | 9 | FULL | GENE RAL | | We regulate nurses and midwives, but we do not regulate dental nurses. | Thank you for your comment. |
| SH | The Nursing and Midwifery Council | 10 | FULL | GENE RAL | | We would endorse a national registry for paediatric sedation, as this would ensure a level of consistency in practice. | Thank you for your comment. |
| SH | The Nursing and Midwifery Council | 11 | FULL | GENE RAL | | Thank you for giving us the opportunity to respond to this guideline. | Thank you for your comment. |
| SH | The Royal College of Surgeons of England | 1 | FULL | 85 | 15 | In cases where multiple sedative agents are administered concurrently and for deeper than conscious sedation, procedures should take place in secondary care units where general anaesthetic and resuscitation facilities are immediately available. | Thank you for your comment, the developers believe this section to be accurate. A definition of Specialist sedation team has been added to the glossary. |
| SH | The Royal College of Surgeons of England | 2 | FULL | 62 | 18 | In assessing pain, particular attention must be given to those children who can not express pain because of their level of speech or understanding, communication difficulties or their illness or disability. | Thank you for your comments. We agree with the points you make, this was not prioritised a key clinical question for the guideline. Communication needs are considered and recommendations reflect this. |
| SH | The Royal College of Surgeons of England | 3 | FULL | 81 | 39 | The training of healthcare professionals delivering sedation on children should include safeguarding at Level 3. | We would need more detail to be able to answer this. |
| SH | The Royal College of Surgeons of England | 4 | FULL | GENE RAL | N/A | Every hospital should have a multidisciplinary sedation committee whose role is to establish local needs for sedation and how these should be met. Local practice should be audited regularly and care pathways defined. This should involve consultation and agreement with local | Thank you for your comment. We recognize this is a local governance arrangement which the GDG are fully supportive of. |

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|  |  |  |  |  |  | departments of anaesthesia. |  |
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| SH | University Hospital of Leicester | 1 | FULL | 89 | 32, 33 | Clarify that increasing the dose or avoid repeating the dose if the child is not sedated | Thank you, but the developers did not understand your point |
| SH | University Hospital of Leicester | 2 | FULL | 110 | 9-12 | Chloral has an effect on cardiovascular function and hence it is contra indicated in child with cardiac ds as per BNF (also triclofos) and | Thank you for your comment. An appendix and footnotes were added to both the NICE and full guideline to clarify the licensing of sedation drugs. |
| SH | Welsh Assembly Government | 1 | FULL **NICE** | 4 | 12 | The following text should be added – In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent). | Thank you for your suggestion, the text was added to the NICE version. |

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