

Sedation for diagnostic and therapeutic procedures in children and young people

NICE guideline

Draft for consultation, March 2010

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

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Introduction

Advances in the treatment of paediatric diseases has led to an increase in the number of painful or distressing diagnostic or therapeutic procedures for which many children will need effective sedation or anaesthesia. The choice between sedation and anaesthesia will depend on the type of procedure. Some types of procedure are very common and healthcare providers and practitioners need to understand whether sedation or anaesthesia is the most cost effective method of managing them.

In adults, many procedures can be undertaken with local anaesthesia and reassurance. In children and young people this is often not possible because the procedures are too frightening, too painful or need to be carried out in children who may be ill, in pain or have behavioural problems.

The aims of sedation during diagnostic or therapeutic procedures include reducing fear and anxiety, providing pain control and minimising movement. The importance of each of these aims will vary depending on the nature of the procedure and the characteristics of the patient.

There are many sedation techniques available but there is insufficient guidance on which techniques are effective and what resources, including staff training, are required to deliver them safely.

Sedation is not always effective enough and so occasionally the procedure has to be delayed until the child can be anaesthetised, perhaps in another healthcare setting or on another day. Consequently, sedation failure is distressing for the child and also has major NHS cost implications.

Excessive doses of sedation can cause unintended loss of consciousness and dangerous hypoxia. Planned anaesthesia, in comparison, is effective but might have resource implications.

Patient-centred care

This guideline offers best practice advice on the care of children and young people under the age of 19 undergoing sedation for diagnostic or therapeutic procedures.

Treatment and care should take into account patients' needs and preferences. People undergoing sedation should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). Healthcare professionals should also follow the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk).

If the patient is under 16, healthcare professionals should follow the guidelines in 'Seeking consent: working with children' (available from www.dh.gov.uk).

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Families and carers should be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

Care of young people in transition between paediatric and adult services should be planned and managed according to the best practice guidance described in 'Transition: getting it right for young people' (available from www.dh.gov.uk).

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Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people undergoing sedation. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

Key priorities for implementation

Pre-sedation assessment, patient information and consent

- Ensure that trained healthcare professionals carry out pre-sedation assessments and document the results in the patient healthcare record.

- Establish suitability for sedation by assessing:
 - current medical condition and any surgical problems
 - weight (growth assessment)
 - past medical problems (including any associated with previous sedation or anaesthesia)
 - current and previous medication (including any known allergies)
 - physical status (including the airway)
 - psychological and developmental status.

- Seek further specialist advice before delivering sedation if:
 - there is concern about a potential airway or breathing problem or
 - the child or young person is assessed as ASA¹ grade 3 or greater.

- Choose the most suitable sedation technique based on:
 - what the procedure involves
 - target level of sedation
 - contraindications
 - side effects
 - patient preference.

- Ensure that both the following are available when considering sedation:
 - a healthcare professional and assistant trained (see section 1.4) in delivering and monitoring sedation in children and young people and
 - immediate access to resuscitation and monitoring equipment (see section 1.5).

¹ ASA=American Society of Anesthesiologists

Personnel and training

- Healthcare professionals delivering sedation should have knowledge and understanding of:
 - sedation drug pharmacology and applied physiology
 - assessment of the child or young person
 - monitoring
 - recovery care
 - complications and their immediate management, including paediatric life support

- Healthcare professionals delivering sedation should have practical experience of:
 - effective delivery of the sedation technique used and management of complications
 - observing clinical signs (for example airway patency, breathing rate and depth, pulse, pallor and cyanosis, depth of sedation)
 - using monitoring equipment.

- Ensure that members of the sedation team have the following competencies:

Minimal sedation^a	Moderate sedation	Deep sedation
All members have basic life support skills	All members have basic life support skills	All members have basic life support skills
	At least one team member should have intermediate life support skills in airway management using mask ventilation and use of defibrillator	At least one team member should have advanced life support skills including advanced airway skills and cardiac arrest management
^a and sedation with nitrous oxide alone (up to 50% in oxygen)		

- Healthcare professionals delivering sedation should have documented evidence (for example, a certificate or a comprehensive record) of competency including:
 - satisfactory completion of a theoretical training course covering the principles of sedation practice

- practical experience of sedation techniques, including details of:
 - ◇ children and young people managed under supervision
 - ◇ successful completion of work-based assessments.

Clinical environment and monitoring

- For deep sedation continuously monitor, interpret and respond to all of the following:
 - respiration
 - oxygen saturation
 - heart rate
 - end tidal CO₂ (capnography)
 - three-lead electrocardiogram (ECG)
 - blood pressure (monitor every 5 minutes)
 - depth of sedation
 - pain
 - coping
 - distress.

1 Guidance

The following guidance is based on the best available evidence and consensus of the Guideline Development Group (GDG) members. The full guideline ([hyperlink to be added in final published version]) gives details of the methods, the evidence used to develop the guidance.

1.1 ***Pre-sedation assessment, communication, patient information and consent***

1.1.1 Ensure that trained healthcare professionals carry out pre-sedation assessments and document the results in the healthcare record.

1.1.2 Establish suitability for sedation by assessing:

- current medical condition and any surgical problems
- weight (growth assessment)
- past medical problems (including any associated with previous sedation or anaesthesia)
- current and previous medication (including any known allergies)
- physical status (including the airway)
- psychological and developmental status.

1.1.3 Seek further specialist advice before delivering sedation if either:

- there is concern about a potential airway or breathing problem,
or
- the child or young person is assessed as ASA² grade 3 or greater.

1.1.4 Choose the most suitable sedation technique based on:

- what the procedure involves
- target level of sedation

² ASA=American Society of Anesthesiologists

- contraindications
- side effects
- patient preference.

1.1.5 Ensure that both the following are available when considering sedation:

- a healthcare professional and assistant trained (see section 1.4) in delivering and monitoring sedation in children and young people and
- immediate access to resuscitation and monitoring equipment (see section 1.5).

1.1.6 To enable the child or young person and their parents or carers to make an informed decision, offer them verbal and written information on:

- the proposed sedation technique
- the alternatives
- the associated risks and benefits.

1.1.7 Obtain and document informed consent for sedation (see recommendation 1.1.6).

1.2 Fasting

1.2.1 Before starting sedation, confirm and record the time of last food and fluid intake in the healthcare record.

1.2.2 For elective procedures, apply the 2-4-6 rule.³

1.2.3 For urgent procedures in a child or young person who has not fasted, base the decision to proceed with sedation on clinical emergency and the target depth of sedation.

³ Fasting times should be as for general anaesthesia:

- 2 hours for clear fluids
- 4 hours for breast milk
- 6 hours for solids.

- 1.2.4 Fasting is not required for minimal sedation and for sedation with nitrous oxide alone (up to 50% in oxygen).

1.3 *Psychological preparation*

- 1.3.1 Ensure that the child or young person is prepared psychologically for sedation by offering advice about:

- the procedure itself
- what the child or young person should do and what the healthcare professional will do
- the sensations associated with the procedure (for example, a sharp scratch, numbness)
- how to cope with the procedure.

- 1.3.2 Ensure that the information is appropriate for the developmental stage of the child or young person.

- 1.3.3 Offer parents and carers the opportunity to be present during sedation. If a parent or carer decides to be present, offer them advice about their role during the procedure.

- 1.3.4 For an elective procedure, consider referral to a mental health specialist for children who are severely anxious or who have a learning disability.

1.4 *Personnel and training*

- 1.4.1 Healthcare professionals delivering sedation should have knowledge and understanding of:

- sedation drug pharmacology and applied physiology
- assessment of the child or young person
- monitoring
- recovery care
- complications and their immediate management, including paediatric life support.

1.4.2 Healthcare professionals delivering sedation should have practical experience of:

- effective delivery of the sedation technique used and management of complications
- observing clinical signs (for example airway patency, breathing rate and depth, pulse, pallor and cyanosis, depth of sedation)
- using monitoring equipment.

1.4.3 Ensure that all members of the sedation team have the following competencies:

Minimal sedation^a	Moderate sedation	Deep sedation
All members have basic life support skills	All members have basic life support skills	All members have basic life support skills
	At least one team member should have intermediate life support skills in airway management using mask ventilation and use of defibrillator	At least one team member should have advanced life support skills including advanced airway skills and cardiac arrest management
^a and sedation with nitrous oxide alone (up to 50% in oxygen)		

1.4.4 Ensure that a healthcare professional trained in delivering anaesthetic agents is available to administer the following sedatives:

- sevoflurane
- propofol
- opioids combined with ketamine.

1.4.5 Healthcare professionals delivering sedation should have documented evidence (for example, a certificate or a comprehensive record) of competency including:

- satisfactory completion of a theoretical training course covering the principles of sedation practice

- practical experience of sedation techniques, including details of:
 - children and young people managed under supervision
 - successful completion of work-based assessments.

1.4.6 Each healthcare professional and their team delivering sedation should ensure they update their knowledge and skills through programmes designed for continuing professional development.

1.5 *Clinical environment and monitoring*

1.5.1 For moderate sedation continuously monitor, interpret and respond to changes in all of the following:

- coping
- depth of sedation
- pain
- distress
- respiration
- oxygen saturation
- heart rate.

1.5.2 For deep sedation continuously monitor, interpret and respond to all of the following:

- respiration
- oxygen saturation
- heart rate
- end tidal CO₂ (capnography)
- three-lead electrocardiogram (ECG)
- blood pressure (monitor every 5 minutes)
- depth of sedation
- pain
- coping
- distress.

1.5.3 Ensure that data from continuous monitoring during sedation are clearly documented in the healthcare record.

1.5.4 After the procedure, continue monitoring until:

- the airway is patent
- protective airway and breathing reflexes are present
- the child or young person is haemodynamically stable
- the child or young person has returned to baseline level of consciousness.

1.6 Discharge criteria

1.6.1 Ensure that all of the following criteria are met before the child or young person is discharged:

- vital signs⁴ have returned to normal levels
- the child or young person has returned to baseline level of responsiveness and orientation
- nausea, vomiting and pain have been adequately managed
- there is no risk of further reduced level of consciousness.

1.6.2 Consider referring to an anaesthesia specialist if the child or young person is not able to tolerate the procedure under sedation.

⁴ Vital signs are measures of various physiological statistics and usually include body temperature, heart rate, blood pressure and respiratory rate.

1.7 Painful procedures

1.7.1.1 For painful procedures (for example suture laceration or manipulation of fracture) consider using:

For minimal sedation	For moderate sedation	For deep sedation
Oral or intranasal midazolam	Nitrous oxide alone (up to 50% in oxygen)	Intravenous ketamine (or intramuscular if intravenous is difficult)
Nitrous oxide alone (up to 50% in oxygen)	Intravenous midazolam with or without fentanyl	Propofol with or without fentanyl

1.8 Painless imaging

1.8.1 Do not routinely use ketamine or opioids for sedating children or young people for painless imaging procedures.

1.8.2 For children and young people who are unable to tolerate a painless procedure (for example during diagnostic imaging) consider one of the following:

- chloral hydrate (oral) for children under 15 kg or
- propofol or
- sevoflurane.

1.9 Endoscopy

1.9.1 Consider intravenous midazolam to achieve minimal or moderate sedation for upper gastrointestinal endoscopy.

1.9.2 Consider using fentanyl (or equivalent opioid) and intravenous midazolam to achieve moderate sedation for lower gastrointestinal endoscopy.

1.10 Dental procedures

1.10.1 For a child or young person who cannot tolerate a painful dental procedure with local anaesthesia alone, consider one of the following techniques to achieve moderate sedation:

- nitrous oxide and oxygen (titrated according to needs and using a maximum of 70% nitrous oxide) or
- midazolam.

If these sedation techniques are not suitable or effective, consider referral to a specialist team for other sedation techniques (for example midazolam in combination with nitrous oxide and/or sevoflurane).

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/guidance/index.jsp?action=download&o=42224

How this guideline was developed

NICE commissioned the National Clinical Guidelines Centre for Acute and Chronic Conditions to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information about how NICE clinical guidelines are developed on the NICE website (www.nice.org.uk/HowWeWork). A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' (fourth edition, published 2009), is available from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1739).

3 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CGXX).

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 *Pre-sedation assessment*

For children and young people under the age of 19 undergoing diagnostic and therapeutic procedures under sedation, what factors should be assessed to both establish the need for sedation and to reduce the risk of adverse events?

Why this is important

Some children need sedation, some need anaesthesia, and some need behavioural management alone. There is wide variation in how this choice is made and a recommended standard method of assessment may reduce variation and improve both success and safety of sedation when it is chosen. Furthermore, an assessment tool may prevent unsuitable choices and improve the overall management of procedures in children. The GDG suggest an observational study to determine the important factors, followed by a consensus study to develop a tool. The assessment tool should be tested by a randomised comparison of children and young people who have been assessed routinely with those who have been assessed using the tool. The assessment tool aims to improve sedation success and quality, and reduce any complications.

4.2 *Training for personnel involved in sedation*

For personnel involved in delivering sedation to children and young people under the age of 19 undergoing diagnostic and therapeutic procedures what training is required to both achieve and maintain essential skills?

Why this is important

Potent drugs can cause unintended airway obstruction. Anaesthetists are skilled at managing airway obstruction because they practise this regularly. However, anaesthetists are a scarce resource so non-anaesthetists need to learn how to manage airway obstruction. The skills that are needed have been identified but can these skills be attained and maintained by professionals who need them occasionally? The GDG suggests that a standard teaching method and assessment tool are developed. This would involve an observational study of a cohort of trainees, who can be assessed, trained and then reassessed at varying intervals to determine whether the training is successful and how often it is necessary.

4.3 *Drugs combination*

For children and young people under the age of 19 undergoing minor painful procedures, what potent analgesic drugs can be combined with midazolam to provide safe moderate sedation?

Why this is important

Midazolam has a strong safety profile in inducing either minimal or moderate sedation. For painful procedures midazolam should be combined with analgesia. Ideally analgesia is achieved by local anaesthesia. Sometimes local anaesthesia is insufficient and potent opioid analgesia is necessary. The combination of potent opioid and midazolam can cause deep sedation and airway obstruction. These effects can be managed safely but involve extra resources. It would be safer if a technique could be developed that was both reliable and had a wide margin of safety. Prospective and retrospective audit data are available to help guide the choice of opioid and the doses. A randomised controlled trial is needed to test the efficacy and safety of these combinations.

4.4 *Development of a national registry of sedation*

What are the safety and efficacy profiles of sedation techniques in current practice?

Why this is important

Data on the safety and efficacy of sedation in the UK are not available. A large prospective database of sedation cases, including data on drugs, procedures, the level of sedation and any complications, would be beneficial in not only providing definitive data on the safety of sedation but also actively promoting safe practice. The GDG suggests that a national registry for paediatric sedation is established for the purpose of creating a database with sufficient data.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Sedation in children and young people' contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guidelines Centre for Acute and Chronic Conditions, and is available from [NCC website details to be added] and our website (www.nice.org.uk/CGXXfullguideline). **[Note: these details will apply to the published full guideline.]**

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/CGXXquickrefguide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1XXX). **[Note: these details will apply when the guideline is published.]**

5.3 'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/CGXXpublicinfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1XXX). **[Note: these details will apply when the guideline is published.]**

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about sedation in children and young people.

6 Related NICE guidance

NICE has not published any related guidance.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group and NICE project team

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Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

[NICE to add]

[Name; style = Unnumbered bold heading]

[job title and location; style = NICE normal]

Appendix C: The algorithms

[These details to be completed for final publication]

[NB NICE to add a note here if the algorithms are being published as a separate file on the website]

[Add a hyperlink to the QRG here if relevant]