



*National Institute for
Health and Clinical Excellence*

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Sedation in children and young people

**Sedation for diagnostic and therapeutic
procedures in children and young
people**

NICE clinical guideline 112 Sedation for diagnostic and therapeutic procedures in children and young people

Ordering information

You can download the following documents from

www.nice.org.uk/guidance/CG112

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – a summary for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

For printed copies of the quick reference guide or ‘Understanding NICE guidance’, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N2380 (quick reference guide)
- N2381 (‘Understanding NICE guidance’).

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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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 procedures are very common and healthcare providers and practitioners need to understand under which circumstances either sedation or anaesthesia is most cost effective.

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, augmenting 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 or young person can be anaesthetised. This may need to take place in a different healthcare setting or on another day. Consequently, sedation failure is distressing for the child or young person and also has major NHS cost implications.

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

Definitions

Age ranges

This guideline covers infants, children and young people under 19 years.

- **Infants:** children from birth to 1 year.
- **Neonates:** infants aged up to 1 month.

Levels of sedation

The definitions of minimal, moderate, conscious and deep sedation used in this guideline are based on those of the American Society of Anesthesiologists (ASA).

- **Minimal sedation:** A drug-induced state during which patients are awake and calm, and respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
- **Moderate sedation:** Drug-induced depression of consciousness during which patients are sleepy but respond purposefully to verbal commands (known as conscious sedation in dentistry, see below) or light tactile stimulation (reflex withdrawal from a painful stimulus is not a purposeful response). No interventions are required to maintain a patent airway. Spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- **Conscious sedation:** Drug-induced depression of consciousness, similar to moderate sedation, except that verbal contact is always maintained with the patient. This term is used commonly in dentistry.
- **Deep sedation:** Drug-induced depression of consciousness during which patients are asleep and cannot be easily roused but do respond purposefully to repeated or painful stimulation. The ability to maintain ventilatory function independently may be impaired. Patients may require assistance to maintain a patent airway. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Specialist sedation techniques

Sedation techniques that have a reduced margin of safety and increased risk of unintended deep sedation or anaesthesia, accompanied by airway obstruction and/or inadequate spontaneous ventilation. Healthcare professionals using specialist sedation techniques need to be trained to administer sedation drugs safely, to monitor the effects of the drug and to use equipment to maintain a patent airway and adequate respiration.

Prescribing drugs

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications, for ages or at doses for which they do not have a UK marketing authorisation at the date of publication ('off-label use'), if there is good evidence to support that use. A brief explanation is given in a footnote in each case, with further details in appendix D. Informed consent should be obtained and documented for any use outside the UK marketing authorisation.

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. Children and young people undergoing sedation and their parents and carers 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's advice on consent (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent).

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

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 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).

Key priorities for implementation

Pre-sedation assessment, communication, patient information and consent

- Ensure that trained healthcare professionals (see section 1.4) carry out pre-sedation assessments and document the results in the healthcare record.
- Establish suitability for sedation by assessing all of the following:
 - 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 allergies)
 - physical status (including the airway)
 - psychological and developmental status.
- Seek advice from a specialist before delivering sedation:
 - if there is concern about a potential airway or breathing problem
 - if the child or young person is assessed as American Society of Anesthesiologists (ASA) grade 3¹ or greater
 - for infants, including neonates.
- Ensure that both the following will be available during sedation:
 - a healthcare professional and assistant trained (see section 1.4) in delivering and monitoring sedation in children and young people
 - immediate access to resuscitation and monitoring equipment (see section 1.5).
- Choose the most suitable sedation technique based on all the following factors:
 - what the procedure involves

¹ The ASA physical status classification system (grades 1–6) is a system to classify and grade a patient's physical status before anaesthesia.

- target level of sedation
- contraindications
- side effects
- patient (or parent or carer) preference.

Personnel and training

- Healthcare professionals delivering sedation should have knowledge and understanding of and competency in:
 - sedation drug pharmacology and applied physiology
 - assessment of children and young people
 - monitoring
 - recovery care
 - complications and their immediate management, including paediatric life support.
- Healthcare professionals delivering sedation should have practical experience of:
 - effectively delivering the chosen sedation technique and managing complications
 - observing clinical signs (for example, airway patency, breathing rate and depth, pulse, pallor and cyanosis, and depth of sedation)
 - using monitoring equipment.
- Ensure that members of the sedation team have the following life support skills:

	Minimal sedation^a	Moderate sedation	Deep sedation
All members	Basic	Basic	Basic
At least one member		Intermediate	Advanced
^a including sedation with nitrous oxide alone (in oxygen) and conscious sedation in dentistry.			

- Healthcare professionals delivering sedation should have documented up-to-date evidence of competency including:
 - satisfactory completion of a theoretical training course covering the principles of sedation practice
 - a comprehensive record of practical experience of sedation techniques, including details of:
 - ◇ sedation in children and young people performed under supervision
 - ◇ successful completion of work-based assessments.

Clinical environment and monitoring

- For deep sedation continuously monitor, interpret and respond² to all of the following:
 - depth of sedation
 - respiration
 - oxygen saturation
 - heart rate
 - three-lead electrocardiogram
 - end tidal CO₂ (capnography)³
 - blood pressure (monitor every 5 minutes)³
 - pain
 - coping
 - distress.

² For deep sedation, the healthcare professional administering sedation should be involved only in continuously monitoring, interpreting and responding to all of the above.

³ End tidal CO₂ and blood pressure should be monitored, if possible, provided that monitoring does not cause the patient to awaken and so prevent completion of the procedure.

1 Guidance

The following guidance is based on the best available evidence and consensus of the Guideline Development Group (GDG) members. The full guideline (www.nice.org.uk/guidance/CG112/Guidance) gives details of the methods and evidence used to develop the guidance.

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

1.1.1 Ensure that trained healthcare professionals (see section 1.4) carry out pre-sedation assessments and document the results in the healthcare record.

1.1.2 Establish suitability for sedation by assessing all of the following:

- 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 allergies)
- physical status (including the airway)
- psychological and developmental status.

1.1.3 Seek advice from a specialist before delivering sedation:

- if there is concern about a potential airway or breathing problem
- if the child or young person is assessed as American Society of Anesthesiologists (ASA) grade 3⁴ or greater
- for infants, including neonates.

⁴ The ASA physical status classification system (grades 1–6) is a system to classify and grade a patient's physical status before anaesthesia.

- 1.1.4 Ensure that both the following will be available during sedation:
- a healthcare professional and assistant trained (see section 1.4) in delivering and monitoring sedation in children and young people
 - immediate access to resuscitation and monitoring equipment (see section 1.5).
- 1.1.5 Choose the most suitable sedation technique based on all the following factors:
- what the procedure involves
 - target level of sedation
 - contraindications
 - side effects
 - patient (or parent or carer) preference.
- 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 all of the following:
- proposed sedation technique
 - the alternatives to sedation
 - associated risks and benefits.
- 1.1.7 Obtain and document informed consent for sedation.

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 Fasting is not needed for:
- minimal sedation
 - sedation with nitrous oxide (in oxygen)
 - moderate sedation during which the child or young person will maintain verbal contact with the healthcare professional.

- 1.2.3 Apply the 2-4-6 fasting rule⁵ for elective procedures using any sedation technique other than those in recommendation 1.2.2 (that is, apply the 2-4-6 fasting rule for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional).
- 1.2.4 For an emergency procedure in a child or young person who has not fasted, base the decision to proceed with sedation on the urgency of the procedure and the target depth of sedation.

1.3 *Psychological preparation*

- 1.3.1 Ensure that the child or young person is prepared psychologically for sedation by offering information about:
- the procedure
 - 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 or 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 and check that the child or young person has understood the information.
- 1.3.3 Offer parents and carers the opportunity to be present during sedation if appropriate. 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 referring to a mental health specialist children or young people who are severely anxious or who have a learning disability.

⁵ Fasting times should be as for general anaesthesia:

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

1.4 **Personnel and training**

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

- sedation drug pharmacology and applied physiology
- assessment of children and young people
- monitoring
- recovery care
- complications and their immediate management, including paediatric life support.

1.4.2 Healthcare professionals delivering sedation should have practical experience of:

- effectively delivering the chosen sedation technique and managing complications
- observing clinical signs (for example, airway patency, breathing rate and depth, pulse, pallor and cyanosis, and depth of sedation)
- using monitoring equipment.

1.4.3 Ensure that members of the sedation team have the following life support skills:

	Minimal sedation^a	Moderate sedation	Deep sedation
All members	Basic	Basic	Basic
At least one member		Intermediate	Advanced
^a Including sedation with nitrous oxide alone (in oxygen) and conscious sedation in dentistry.			

- 1.4.4 Ensure that a healthcare professional trained in delivering anaesthetic agents (see appendix D) is available to administer:
- sevoflurane⁶
 - propofol^{7,8}
 - opioids⁸ combined with ketamine^{8,9}.
- 1.4.5 Healthcare professionals delivering sedation should have documented up-to-date evidence of competency including:
- satisfactory completion of a theoretical training course covering the principles of sedation practice
 - a comprehensive record of practical experience of sedation techniques, including details of:
 - sedation in children and young people performed 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.
- 1.4.7 Consider referring to an anaesthesia specialist a child or young person who is not able to tolerate the procedure under sedation.

⁶ Sevoflurane is used in UK clinical practice for sedating children and young people. At the time of publication (December 2010) sevoflurane did not have UK marketing authorisation for this indication. See appendix D.

⁷ Propofol is used in UK clinical practice for sedating children and young people. At the time of publication (December 2010) propofol did not have UK marketing authorisation for this age group. See appendix D.

⁸ At the time of publication (December 2010) the British National Formulary for Children (BNFc) stipulated that if deep sedation is needed an anaesthetic agent (propofol or ketamine), or a potent opioid (fentanyl) may be used. However, they should be used only under the supervision of a specialist experienced in the use of these drugs.

⁹ Ketamine is a dissociative agent: the state of dissociative sedation cannot be readily categorised as either moderate or deep sedation; the drug is considered to have a wide margin of safety.

1.5 Clinical environment and monitoring

1.5.1 For moderate sedation excluding with nitrous oxide alone (in oxygen) continuously monitor, interpret and respond to changes in all of the following:

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

1.5.2 For deep sedation continuously monitor, interpret and respond¹⁰ to changes in all of the following:

- depth of sedation
- respiration
- oxygen saturation
- heart rate
- three-lead electrocardiogram
- end tidal CO₂ (capnography)¹¹
- blood pressure (monitor every 5 minutes)¹¹
- pain
- coping
- distress.

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

¹⁰ For deep sedation, a healthcare professional should be involved only in continuously monitoring, interpreting and responding to all of the above.

¹¹ End tidal CO₂ and blood pressure should be monitored, if possible, provided that monitoring does not cause the patient to awaken and so prevent completion of the procedure.

1.5.4 After the procedure, continue monitoring until the child or young person:

- has a patent airway
- shows protective airway and breathing reflexes
- is haemodynamically stable
- is easily roused.

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 signs (usually body temperature, heart rate, blood pressure and respiratory rate) have returned to normal levels
- the child or young person is awake (or returned to baseline level of consciousness) and there is no risk of further reduced level of consciousness
- nausea, vomiting and pain have been adequately managed.

1.7 Painless imaging

1.7.1 Do not routinely use ketamine^{8,9} or opioids⁸ for painless imaging procedures.

1.7.2 For children and young people who are unable to tolerate a painless procedure (for example, during diagnostic imaging) consider one of the following drugs, which have a wide margin of safety:

- chloral hydrate¹² for children under 15 kg
- midazolam¹³.

¹² Chloral hydrate is used in UK clinical practice for sedating children and young people for painless procedures. At the time of publication (December 2010) chloral hydrate did not have UK marketing authorisation for this indication. See appendix D.

¹³ Midazolam is used in UK clinical practice for sedating children and young people up to the age of 18. At the time of publication (December 2010) midazolam did not have UK marketing authorisation for oral or buccal administration, or for children younger than 6 months. See appendix D.

1.7.3 For children and young people who are unable to tolerate painless imaging with the above drugs, consider one of the following, used in specialist techniques, which have a narrow margin of safety (see section 1.4):

- propofol^{7,8}
- sevoflurane⁶.

1.8 Painful procedures

1.8.1 For children and young people undergoing a painful procedure (for example suture laceration or orthopaedic manipulation), when the target level of sedation is minimal or moderate, consider:

- nitrous oxide (in oxygen) and/or
- midazolam¹³ (oral or intranasal).

1.8.2 For all children and young people undergoing a painful procedure, consider using a local anaesthetic, as well as a sedative.

1.8.3 For children and young people undergoing a painful procedure (for example, suture laceration or orthopaedic manipulation) in whom nitrous oxide (in oxygen) and/or midazolam (oral or intranasal) are unsuitable consider:

- ketamine^{8,9} (intravenous or intramuscular), or
- intravenous midazolam¹³ with or without fentanyl⁸ (to achieve moderate sedation).

1.8.4 For children and young people undergoing a painful procedure (for example suture laceration or orthopaedic manipulation) in whom ketamine (intravenous or intramuscular) or intravenous midazolam with or without fentanyl (to achieve moderate sedation) are unsuitable, consider a specialist sedation technique such as propofol⁷ with or without fentanyl⁸.

1.9 *Dental procedures*

1.9.1 For a child or young person who cannot tolerate a dental procedure with local anaesthesia alone, to achieve conscious sedation consider:

- nitrous oxide (in oxygen) or
- midazolam¹³.

If these sedation techniques are not suitable or sufficient, refer to a specialist team for an alternative sedation technique.

1.10 *Endoscopy*

1.10.1 Consider intravenous midazolam¹³ to achieve minimal or moderate sedation for upper gastrointestinal endoscopy.

1.10.2 Consider fentanyl⁸ (or equivalent opioid) in combination with intravenous midazolam¹³ to achieve moderate sedation for lower gastrointestinal endoscopy.

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/CG112 – click on ‘How this guidance was produced’.

How this guideline was developed

NICE commissioned the National Clinical Guidelines Centre 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/CG112).

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 having diagnostic and therapeutic procedures under sedation, what factors should be assessed to establish the need for sedation and 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. A recommended standard method of assessment could reduce

variation and improve both success and safety when sedation is chosen. Furthermore, an assessment tool could help prevent unsuitable choices and improve the overall management of procedures in children. The Guideline Development Group suggests 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 aim is for the assessment tool 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 having diagnostic and therapeutic procedures, what training is required to 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 the skills 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 only occasionally? The Guideline Development Group 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 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 having 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 analgesia 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

There are no data on the safety of sedation in the UK. A large prospective database of sedation cases, that includes data on drugs, procedures, the depth of sedation and complications, would help to define the safety of sedation and actively promote safe practice. The Guideline Development Group suggests that a national registry for paediatric sedation is established to help create 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 Guideline Centre, and is available from our website (www.nice.org.uk/guidance/CG112/Guidance).

5.2 *Quick reference guide*

A quick reference guide for healthcare professionals is available from www.nice.org.uk/guidance/CG112/QuickRefGuide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2380).

5.3 ‘Understanding NICE guidance’

A summary for patients and carers (‘Understanding NICE guidance’) is available from www.nice.org.uk/guidance/CG112/PublicInfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2381).

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. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Clinical Guideline Centre and NICE project team

Guideline Development Group

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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.

Robert Walker (Chair)

General Practitioner

Robin Beal

Secondary care member

Ailsa Donnelly

Lay member

John Harley

Clinical Governance and Prescribing Lead, North Tees PCT

Mark Hill

Head of Medical Affairs, Novartis Pharmaceuticals UK

Appendix C: The algorithms

There is a care pathway for child sedation in the quick reference guide, available at www.nice.org.uk/CG112/QuickRefGuide

Appendix D: Licensing indications

The table that follows provides a summary reference guide to pharmacological treatment. It was prepared from data available in September 2010.

Prescribers should refer to the 'British national formulary for children' and summary of product characteristics for each drug for full and up-to-date details of licensing. Informed consent should be obtained and documented for the use of any drug outside the licensed indications.

Drug	Indication	Licensed status and advice for use (taken from the 'British national formulary for children' [BNFc] 2010/11, correct at the time of publication)
Chloral hydrate	Sedation	Not licensed for sedation in painless procedures. However, dosing for painless procedures in children from neonates to 18 years is given in the BNFc; by mouth or by rectum.
Fentanyl	Analgesia and enhancement of anaesthesia and for deep sedation	Licensed for use in children older than 1 month with spontaneous respiration for analgesia, and during operations for enhancement of anaesthesia by intravenous injection over at least 30 seconds. If deep sedation is needed fentanyl may be used. It should be used only under the supervision of a specialist experienced in its use.
Ketamine	Anaesthesia (lower doses are used for sedation than for anaesthesia for surgery)	Licensed for use in anaesthesia for all ages; intravenous and intramuscular. If deep sedation is needed ketamine may be used. It should be used only under the supervision of a specialist experienced in its use.
Midazolam	Sedation	Not licensed for use in children younger than 6 months for premedication and conscious sedation. Not licensed for use by mouth or by buccal administration. Intravenous midazolam is not licensed for use in children younger than 6 months for conscious sedation. No UK marketing authorisation for oral or intranasal midazolam for sedation. However, dosing for children from age 1 month is given in the BNFc.
Nitrous oxide	Sedation	50% nitrous oxide licensed for use in sedation for all ages; inhalation. Nitrous oxide in concentrations greater than 50% is not licensed for analgesia without loss of consciousness.

Opioids	Sedation	The BNFC stipulates that if deep sedation is needed a general anaesthetic (for example, propofol or ketamine), or a potent opioid (for example, fentanyl) may be used. However, they should be used only under the supervision of a specialist experienced in the use of these drugs.
Propofol	Anaesthesia	Licensed for use in children older than 1 month in doses of 0.5% or 1%; intravenous.
	Sedation	Licensed for use in people older than 17 years. The GDG decided to recommend off-label use of propofol for sedation in children of all ages. This was because propofol is widely used in the UK for sedation in children of all ages and the doses used for sedation are much lower than those used for anaesthesia. If deep sedation is needed, propofol may be used. It should be used only under the supervision of a specialist experienced in its use.
Sevoflurane	Anaesthesia	Licensed for use in anaesthesia for all ages; inhalation.
	Sedation	Not licensed for sedation.