



Sedation in under 19s: using sedation for diagnostic and therapeutic procedures

Clinical guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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Overview

This guideline covers the assessment, preparation, training and monitoring needed when using sedation in people aged under 19. It aims to help healthcare professionals decide when sedation is the most clinically and cost effective option for reducing pain and anxiety during operations for children and young people.

Who is it for?

- Healthcare professionals
- · Commissioners and providers
- Under 19s who are having sedation and their families and carers

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.

Drug recommendations

In October 2018, no drugs had a UK marketing authorisation specifically for sedation in all ages of infants, children and young people under 19. See <u>NICE's information on prescribing medicines</u>. This is particularly relevant to recommendations 1.4.4, 1.6.1, 1.6.2, 1.6.3, 1.8.1, 1.8.3, 1.8.4, 1.9.1, 1.10.1 and 1.10.2.

Key priorities for implementation

Pre-sedation assessment, communication, patient information and consent

- Ensure that trained healthcare professionals (see <u>section 1.4</u>) 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 3 or greater (the ASA physical status classification system
 [grades 1 to 6] is a system to classify and grade a patient's physical status before
 anaesthesia).
 - for infants, including neonates.
- Ensure that both the following will be available during sedation:
 - a healthcare professional and assistant trained (see <u>section 1.4</u>) 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
 - 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 all members of the sedation team have basic life support skills for minimal, moderate and deep sedation. At least 1 team member should have intermediate life support skills for moderate sedation and advanced life support skills for deep sedation. Minimal sedation includes 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	n continuously	monitor,	interpret	and respond	to all	of the	following:
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- depth of sedation
- respiration
- oxygen saturation
- heart rate
- three-lead electrocardiogram
- pain
- coping
- distress.
- Also continuously monitor, interpret and respond to the following, provided that
 monitoring does not cause the patient to awaken and so prevent completion of the
 procedure:
 - end tidal CO₂ (capnography)
 - blood pressure (monitor every 5 minutes)

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

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

In October 2018, no drugs had a UK marketing authorisation specifically for sedation in all ages of infants, children and young people under 19. See <u>NICE's information on prescribing medicines</u>. This is particularly relevant to recommendations 1.4.4, 1.6.1, 1.6.2, 1.6.3, 1.8.1, 1.8.3, 1.8.4, 1.9.1, 1.10.1 and 1.10.2.

The following guidance is based on the best available evidence and consensus of the Guideline Development Group (GDG) members. The <u>full guideline</u> 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 <u>section 1.4</u>) 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 3 or greater (the ASA physical status classification system [grades 1 to 6] is a system to classify and grade a patient's physical status before anaesthesia).
 - for infants, including neonates.
- 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 Refer to professional guidance for fasting for elective procedures using any sedation technique other than those in recommendation 1.2.2 (that is, for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional).

Note that in 2018 a change to the 2-4-6 fasting rule (fasting times should be as for general anaesthesia: 2 hours for clear fluids; 4 hours for breast milk; 6 hours for solids) was endorsed by the relevant professional bodies, supporting a reduction in the fasting period for clear fluids to 1 hour (see for example the <u>Association of Paediatric Anaesthetists of Great Britain and Ireland consensus</u> statement on clear fluids fasting for elective pediatric general anesthesia).

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.

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 all members of the sedation team have basic life support skills for minimal, moderate and deep sedation. At least 1 team member should have intermediate life support skills for moderate sedation and advanced life support skills for deep sedation. Minimal sedation includes 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 is available to administer:
 - sevoflurane
 - propofol
 - opioids combined with ketamine.
- 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.

1.5 Discharge criteria

- 1.5.1 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.

1.6 Painless imaging

- 1.6.1 Do not routinely use ketamine or opioids for painless imaging procedures.
- 1.6.2 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 hydrate for children under 15 kg
 - midazolam.
- 1.6.3 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
- sevoflurane.

1.7 Clinical environment and monitoring

- 1.7.1 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.
- 1.7.2 For deep sedation continuously monitor, interpret and respond to changes in all of the following:
 - depth of sedation
 - respiration
 - oxygen saturation
 - heart rate
 - three-lead electrocardiogram
 - pain
 - coping
 - distress.

Also continuously monitor, interpret and respond to the following, provided that monitoring does not cause the patient to awaken and so prevent completion of the procedure:

- end tidal CO₂ (capnography)
- blood pressure (monitor every 5 minutes).

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

- 1.7.3 Ensure that data from continuous monitoring during sedation are clearly documented in the healthcare record.
- 1.7.4 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.

1.8 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
 - midazolam (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 (intravenous or intramuscular), or
 - intravenous midazolam with or without fentanyl (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 propofol with or without fentanyl.

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
 - midazolam.

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 midazolam to achieve minimal or moderate sedation for upper gastrointestinal endoscopy.
- 1.10.2 Consider fentanyl (or equivalent opioid) in combination with intravenous midazolam to achieve moderate sedation for lower gastrointestinal endoscopy.

Recommendations for research

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

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.

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.

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. If 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 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	d to help create a	database with	sufficient data.	

Update information

Minor changes since publication

February 2019: Some links have been updated. Recommendation 1.2.3 has been updated to reflect a recent change in fasting time rules.

October 2014: The information about licensing of drugs for sedation in children and young people have been amended to say that at the time of publication (December 2010), no drugs have a UK marketing authorisation specifically for sedation in all ages of infants, children and young people under 19, and to emphasise that prescribers should follow current summaries of product characteristics and seek advice if needed.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> topic page on surgical care.

For full details of the evidence and the guideline committee's discussions, see the <u>full</u> <u>guideline</u> and appendices. You can also find information about <u>how the guideline was developed</u>, including <u>details of the committee</u>.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see <u>resources to help you</u> put NICE guidance into practice.

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Accreditation

