Scottish Intercollegiate Guidelines Network

58

Safe Sedation of Children Undergoing Diagnostic and Therapeutic Procedures
A national clinical guideline

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Revised Edition May 2004
KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

LEVELS OF EVIDENCE

1++ High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1- Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++ High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
2 Non-analytic studies, e.g. case reports, case series
3 Expert opinion

GRADES OF RECOMMENDATION

A At least one meta-analysis, systematic review of RCTs, or RCT rated as 1++ and directly applicable to the target population; or
A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4; or
Extrapolated evidence from studies rated as 2+

GOOD PRACTICE POINTS

☑ Recommended best practice based on the clinical experience of the guideline development group

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1 Introduction

1.1 BACKGROUND

There is wide variation in the selection criteria and in the techniques used for the preparation, monitoring and management of children requiring sedation for diagnostic and therapeutic procedures. A recent survey of 268 Scottish hospital departments revealed that although sedation of children was undertaken by one in four departments, only three had a protocol for paediatric sedation. This suggests that despite the multiplicity of published guidelines for sedation in both adult and paediatric specialties, these are not being applied consistently in clinical paediatric practice. This guideline was therefore developed, drawing together the existing evidence and following wide consultation. This methodology fosters multidisciplinary ownership and will ensure that this guideline is implemented widely across Scotland.

The practice of sedating children for procedures is often based more on consensus and clinical tradition than on scientific evidence. Even within the body of expert opinion, a review of the literature suggests that practice is often more influenced by available resources (including perceived or actual shortage of paediatric anaesthetic services) than by validated evidence of benefit.

1.2 REMIT OF THE GUIDELINE

The guideline seeks to answer three key questions:

- What are the requirements for safe paediatric sedation in terms of patient selection, patient preparation, personnel, monitoring, record keeping and post-procedure care?
- Which sedation techniques are appropriate to achieve safe sedation of children?
- How do these sedation techniques perform in terms of efficacy, adverse effects and safety?

This guideline is applicable to all children under 16 years of age, of normal physical and mental development, undergoing painful or non-painful diagnostic or therapeutic procedures in the hospital, community, general medical or dental practice settings. A guideline for sedation in the dental setting is currently being prepared by the Chief Dental Officer and when that is published, it will supersede the dental guidance in this document.

Specifically excluded from this SIGN guideline are patients who require assisted ventilation, intensive care sedation, premedication for general anaesthesia, postoperative analgesia, sedation in palliative care, sedation in psychiatry, night sedation, and sedation in the home setting.

1.3 PRINCIPLES OF GOOD SEDATION PRACTICE

All sedation techniques carry risk. Good clinical practice suggests that a combination of non-pharmacological and pharmacological methods should be considered to ensure optimal management of the emotional and physical consequences of diagnostic and therapeutic procedures in children. While it may be possible to manage many children undergoing a particular procedure with non-pharmacological techniques, others undergoing the same procedure may require general anaesthesia. Thus an individualised approach is required to minimise fear, anxiety, pain, and distress while at the same time accomplishing the procedure safely, reliably and efficiently and respecting the rights of the child.

The concept of sedation encompasses reduction of fear, anxiety or stress, induction of drowsiness or sleep and provision of pain control, comfort and a sense of well-being. Agents with sedative properties may have varying degrees of effects on consciousness level, anxiety, memory and pain. Anxiety may be best alleviated by good communication, a sympathetic approach and paediatric expertise. Pain should be prevented whenever possible by the pre-emptive use of local and systemic analgesics or alternative measures to reduce pain perception.
1.4 DEFINITIONS OF SEDATION

Sedation is a continuum from the awake state. The American Society of Anesthesiologists (ASA) uses the following definitions for levels of sedation:

**Minimal sedation (anxiolysis)** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

**Moderate sedation/analgesia (conscious sedation)** is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation (reflex withdrawal from a painful stimulus is not a purposeful response). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

**Deep sedation/analgesia** is a drug-induced depression of consciousness during which patients cannot be easily roused but respond purposefully following repeated or painful stimulation. The ability to maintain ventilatory function independently may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. In the UK, deep sedation is considered to be part of the spectrum of general anaesthesia.

**General anaesthesia** is a drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

To promote consistency across Scotland, in this guideline sedation means minimal or moderate sedation/analgesia as defined above. When the child does not respond purposefully to verbal commands and/or light tactile stimulation, the standards of care of that child must be identical to that for general anaesthesia. When using sedation in the primary care or outpatient setting, there should be no intention to progress to either deep sedation or general anaesthesia, even when sedation fails.

1.5 STATEMENT OF INTENT

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. However, it is advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient’s case notes at the time the relevant decision is taken.

1.6 REVIEW AND UPDATING

This guideline was first issued in February 2002 (as SIGN publication number 58) but was found to contain referencing errors and errors in the assignment of grades to recommendations. This revised guideline (May 2004) corrects these errors but does not consider any recently published evidence and replaces the original guideline. Details about future revisions will be noted on the SIGN website: www.sign.ac.uk
2 Preparation for sedation

2.1 CONSENT

It is essential that written, informed consent is obtained and documented prior to the procedure and this should include an explanation of the procedure and sedation technique proposed. In an emergency, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility, if it is impossible to obtain consent in time and if the treatment is vital to the survival or health of the child. The person performing the sedation should obtain the consent. A discussion must include explanation of the various appropriate alternatives and both the risks and benefits of each option. Parents should be informed of the possibility that sedation may fail and that either the procedure may have to be abandoned or the child may require a general anaesthetic either as a follow on or at a future date. If conscious sedation fails in the primary care or outpatient setting, there is usually no intention to progress to either deeper sedation or general anaesthesia. The procedure should be abandoned.

In Scotland, the legal and ethical framework has changed recently with greater emphasis being placed on the rights of the child and involvement of children in the consent process. In the light of the Children (Scotland) Act (1995), written informed consent should be obtained from the child where appropriate or from the parent or legal guardian for any procedure. The risks, benefits and alternatives should be explained in detail.

2.2 RESTRAINT

Gentle protective containment of the child with bolsters, pads and light straps to gain and maintain the correct positioning for diagnostic imaging or to protect the restless child from self-injury is acceptable. Parents may gently restrain their own child, for example to limit movement during cannulation. The Royal College of Nursing have also produced guidelines on restraining children. Forcible restraint is not acceptable whether carried out by parents or staff. This applies to elective, urgent and emergency situations. However, for very brief procedures, gentle containment or restraint may reduce or eliminate the need for sedation and the benefit to the child may outweigh the risks eg a lumbar puncture in a child with meningitis or use of a high speed dental drill. Skilled technique, use of local anaesthesia, distraction and parental involvement will often allow an acceptable standard of care.

2.3 PARENTAL INVOLVEMENT

Separation of children from their parents often accentuates anxiety and results in uncooperative behaviour, especially in toddlers and pre-school children. Parents may remain throughout the entire procedure where appropriate, as the presence of a parent may reduce the need for pharmacological intervention.

Parental involvement in the preparation of the child and during the procedure has a sedative-sparing effect and may greatly reduce the distress caused by separation anxiety.

Anxious parents may transmit their anxiety to their child and may be advised against being present if appropriate. In such cases, another relative or guardian may stay with the child.
2.4 ENVIRONMENT AND CLINICAL SETTING

The response of an individual to the administration of sedatives is unpredictable. The progression of the depth of sedation along the continuum to anaesthesia must be anticipated and must be capable of being managed whenever sedatives are given.

It is generally accepted that sedation in children should only be performed in an environment where the facilities, personnel and equipment to manage paediatric emergency situations are immediately available. The plan for access to back up, in case of emergencies, should be explicit and clearly identified, with an outline of the process being available for immediate use.\(^3\,5\,15\,25\)

\[\text{D Sedation in children should only be performed in an environment where the facilities, personnel and equipment to manage paediatric emergency situations are immediately available.}\]

\[\text{☑ Sedation of children for diagnostic or therapeutic procedures should not be undertaken in general medical practice and out-of-hours centres (for dentistry, see section 5).}\]

Children should be sedated as near as possible to the location of the procedure and should not be sedated at home prior to attending for a procedure.

Wherever possible, sedated children should not be moved between hospitals. If this is necessary, transfer should only be undertaken by appropriately trained and skilled personnel and with airway, breathing and circulation appropriately stabilised and controlled.

2.4.1 FACILITIES

There is no evaluative evidence, but there is widespread agreement in guidelines on the standards that sedation facilities should meet.\(^2\,5\,6\,8\,9\,10\,15\,16\)

\[\text{D Facilities undertaking paediatric sedation should possess:}\]

- oxygen (a reliable source to deliver face-mask or nasal oxygen and a self-inflating positive pressure oxygen delivery system that delivers at least 90% oxygen at 15 l/min for at least 60 minutes with age-appropriate equipment)
- suction equipment
- tipping trolley or bed, or chair in dentistry
- resuscitation bags and masks of appropriate sizes
- oral, nasopharyngeal and laryngeal mask, airways and endotracheal tubes of appropriate sizes
- pulse oximeter (with size appropriate pulse oximeter probes)
- ECG machine
- non-invasive blood pressure (NIBP) monitor with appropriate range of cuff sizes
- fully stocked emergency trolley including resuscitation drugs and specific reversal agents for benzodiazepines (ie flumazenil) and opioids (ie naloxone)
- defibrillator with appropriate paediatric equipment and paddles
- temperature monitoring for younger children undergoing long procedures
- capnograph to monitor expired CO\(_2\) levels is useful but not compulsory.

For primary care / community dental clinics providing paediatric inhalation sedation techniques on ASA I and II patients (see section 5), this list can be modified according to current professional guidelines.\(^20\) These suggest that equipment for basic life support should be available and that endotracheal tubes, pulse oximeters, ECG monitor, NIBP monitor, temperature monitor, and capnograph are not required.

Inhalation sedation in dentistry with nitrous oxide should only be undertaken using a dedicated relative analgesia machine which conforms to British Standards to ensure delivery of safe minimum levels of oxygen and safe maximum levels of nitrous oxide.
2.4.2 PERSONNEL

Sedation practitioners are normally responsible for taking consent, for the prescription and administration of drugs, and for monitoring the child undergoing sedation. They must be competent to use such techniques and to manage complications of these techniques. These personnel should have a thorough understanding of the pharmacokinetics and pharmacodynamics of the sedative drugs being utilised. They should be trained in, and be capable of providing paediatric basic life support, at the minimum, while training in paediatric advanced life support is strongly encouraged. They must be able to rescue a child whose sedation level becomes deeper than planned. Sedation practitioners must have adequate ongoing experience and must demonstrate evidence of continuing education and professional development in paediatric sedation practice. Normally they will supervise the care of the sedated child and will not perform the diagnostic or therapeutic procedure itself. Sedation practitioners will monitor physiological parameters and the level of sedation and will keep a time-based record. If verbal contact with the child is lost, the level of care required is identical to that needed for general anaesthesia.14,15,26-29

Between the operator (the person carrying out the procedure) and the sedation practitioner, five roles and responsibilities need to be undertaken:4,11,30-36

(a) pre-procedure screening, evaluation and obtaining consent
(b) prescription and administration of sedation
(c) monitoring of the child
(d) performing the procedure
(e) post-procedure care and discharge.

The sedated child must be under continuous observation by a trained member of the team.

The roles and responsibilities of the “operator” (the person carrying out the procedure) and the sedation practitioner may be merged to some extent but the guiding principle should always be that the operator should not be the person responsible for monitoring the child during the procedure.

In dentistry, when nitrous oxide is administered as the sole sedative agent, the operator is also usually the sedation practitioner, and, in these circumstances, should be assisted by a trained member of staff who acts as the sedation monitor. This person should have specific assignments in the event of an emergency and current knowledge of the emergency equipment, emergency drugs and basic paediatric life support.

Sedation practitioners and operators should only undertake roles and responsibilities for which they have been specifically trained and have been shown to be competent. They must have adequate ongoing experience in their role and continuing education to maintain their skills.

The sedation practitioner and all ancillary personnel should participate in periodic reviews of the facility’s emergency resuscitation procedures to ensure proper functioning of the equipment and correct staff actions and interactions.

A medically qualified person should be identified to hold overall responsibility for the care of the sedated child until they are discharged. In dental practice, the dentist should hold overall responsibility.

Any hospital undertaking sedation of children should identify an anaesthetist and physician or surgeon to jointly lead the provision of sedation, the development, implementation and audit of local protocols and guidelines and review of facilities, personnel and training.
2.5 PATIENT SELECTION

2.5.1 CLASSIFICATION OF PHYSICAL STATUS

A careful pre-procedure health evaluation, with detailed history and clinical examination, is important to identify potential risk factors. Previous sedation history is important and a history of a previous failed sedation may indicate the need for a general anaesthetic. Accurate documentation of history and examination findings is essential and the use of a formatted clinical recording sheet is recommended.

The ASA (American Society of Anaesthesiologists) classification of physical status is:

Class I A normally healthy patient
Class II A patient with mild systemic disease
Class III A patient with severe systemic disease
Class IV A patient with a severe systemic disease that is a constant threat to life
Class V A moribund patient who is not expected to survive without an operation.

Although the ASA classifications are not totally appropriate for paediatrics, the guideline development group advises that only patients in ASA Classes I and II should be considered suitable for sedation as outpatients.

Patients in classes III to V should be regarded as high risk patients who should only be managed in a hospital setting with the involvement of an anaesthetist/intensivist appropriately trained in paediatric sedation, anaesthesia and resuscitation and with adequate ongoing experience.

Children requiring sedation should receive a full pre-procedure clinical assessment in order to classify them according to ASA criteria and to ensure there are no contraindications to sedation. Only patients in ASA Classes I and II should be considered suitable for sedation as outpatients.

Children in Class III will include many with chronic disease that may be stable and well-controlled. Local protocols for these cases may be appropriate especially where they are managed by a specialist team who knows them well.

To alert the clinician to the particular problems of sedation of infants, children up to the age of one year should be uprated by two ASA classes while those aged 1-5 years should be uprated by one class, except if sedated with nitrous oxide alone.

2.5.2 CONTRAINDICATIONS TO SEDATION

There are several conditions which preclude sedation. A particular focus of the pre-procedure assessment should be on the airway because airway obstruction is the commonest adverse event associated with sedation. If any of the following apply, the child should not be sedated.
Children who have any of the following contraindications should not normally be sedated:

- abnormal airway (including large tonsils and anatomical abnormalities of upper or lower airway)
- raised intracranial pressure
- depressed conscious level
- history of sleep apnoea
- respiratory failure
- cardiac failure
- neuromuscular disease
- bowel obstruction
- active respiratory tract infection
- known allergy to sedative drug / previous adverse reaction
- child too distressed despite adequate preparation
- older child with severe behavioural problems (as they have a higher failure rate)
- informed refusal by the parent / guardian / child.

2.5.3 ADDITIONAL CONTRAINDICATIONS TO NITROUS OXIDE SEDATION

There are several specific contraindications to the use of nitrous oxide due to its diffusibility into enclosed air pockets causing them to expand or increase in pressure:\(^{37,39}\)

Children who have any of the following additional contraindications should not be sedated with nitrous oxide:

- intracranial air (eg after skull fracture)
- pneumothorax, pneumopericardium
- bowel obstruction
- pneumoperitoneum
- pulmonary cysts or bullae
- lobar emphysema
- severe pulmonary hypertension
- nasal blockage (adenoid hypotrophy, common cold)
- pregnancy.
2.5.4 SITUATIONS WHERE CAUTION MAY BE REQUIRED WITH SEDATION

If any of the following apply, then extra caution should be exercised and where possible general anaesthesia or anaesthetist-supervised sedation should be considered:

Extra caution should be exercised when sedating children who have any of the following conditions (consideration should also be given to the use of a general anaesthetic or anaesthetist-supervised sedation as an alternative):

- neonates, especially if premature or ex-premature (these infants are particularly sensitive to the sedative and respiratory depressant effects of sedative agents)
- infants aged <1 year and children aged <5 years (there is a higher risk of complications in these age groups due to oversedation, undersedation and disinhibition)
- children with cardiovascular instability or impaired cardiac function
- renal impairment (this affects the pharmacokinetics of sedative agents with reduced clearance of native drug and active metabolites leading to prolonged duration, late re-sedation and sedation drift)
- hepatic impairment (may affect the metabolism of sedative agents resulting in prolonged duration of action; some sedative agents may precipitate hepatic encephalopathy)
- anticonvulsant therapy (sedative agents may act synergistically with anticonvulsant drugs to produce profound sedation; alternatively, some children are resistant to conventional doses of sedative drugs due to hepatic enzyme induction)
- severe respiratory disease
- gastro-oesophageal reflux
- impaired bulbar reflexes
- emergency cases
- children receiving opioids or other sedatives
- children receiving drugs which potentiate the action of sedatives (eg macrolide antibiotics potentiate and prolong the sedative effects of midazolam).

2.6 PREPARATION OF THE CHILD AND PARENTS

2.6.1 BEHAVIOURAL MANAGEMENT

For adults, a simple explanation of what to expect during a potentially uncomfortable procedure is usually sufficient to allow adequate mental preparation. In childhood, each patient may be at a different stage of cognitive development and understanding and explanations have to be given in a developmentally appropriate manner. Positive reinforcement is very helpful and techniques such as guided imagery and demonstration play therapy are helpful for explaining procedures to younger patients. Trained play therapists have been shown to reduce the requirement for sedation.

The classic “tell-show-do” method, and other behavioural techniques should be utilised to help reduce anxiety prior to procedures.

2.6.2 USE OF LOCAL ANAESTHESIA

Topical local anaesthesia of intact skin or buccal mucosa, using local anaesthetic creams or gels, will minimise pain perception at the site of any needling procedure in children. The onset time is 1-2 minutes for buccal analgesia and 30-90 minutes for intact skin, depending on the site, skin type and formulation used. Amethocaine gel has a faster onset than the eutectic mixture of lignocaine and prilocaine (EMLA). For small peripheral wounds, topical local anaesthesia with or without infiltration of local anaesthetic can be effectively used prior to cleaning or closure. Topical local anaesthesia should also be applied to the sites of any other needle punctures such as for lumbar puncture, bone marrow sampling or cannulation for interventional radiology or cardiology. The skin overlying these areas will then be anaesthetised and the area can be infiltrated with further local anaesthetic prior to the needling procedure.
Injection of a local anaesthetic agent can be somewhat painful due to the needle itself or to a “stinging” sensation and may require brief gentle containment of the child, preferably by the parent. Warmed, buffered local anaesthetic solutions infiltrated slowly with the smallest possible needle minimise pain of injection.\textsuperscript{27}

- Topical local anaesthesia of intact skin or buccal mucosa using local anaesthetic creams or gels should be employed at the site of any needling procedure in children.

2.6.3 VENOUS ACCESS

Venous access should be secured under topical local anaesthetic cover if at all possible prior to the administration of any sedation. An exception to this is sedation using nitrous oxide alone or in cases where oral/transmucosal sedation are used in patients who do not cooperate with cannulation.

2.6.4 FASTING

The evidence suggests that sedation of children can, unpredictably, lead to vomiting, regurgitation and aspiration. A procedure that starts with sedation may also lead to the child requiring general anaesthesia.\textsuperscript{40,41}

- The child should be fasted as for a general anaesthetic (6 hours for solids or bottle milk, 4 hours for breast milk, 2 hours for clear fluids), except if nitrous oxide is the only sedative used.

- Confirm and record the time of the last food and fluid intake before starting sedation.

Long periods of fasting for young children may cause symptomatic hypoglycaemia. Appropriate intravenous or oral dextrose-containing solutions may therefore be needed.

- In the urgent situation, recent oral intake, trauma and the administration of opioids would make sedation relatively contraindicated, due to the increased risk of regurgitation (full stomach, delayed gastric emptying) if consciousness drifts to a deeper level beyond sedation. Such patients should receive a general anaesthetic.

When nitrous oxide is to be used (for example in dental sedation, in emergency departments or for brief painful procedures in hospital) fasting is not required, provided the inspired concentration does not exceed 50% and no other drugs with sedative properties are used.\textsuperscript{42,43} Some centres advise avoidance of a large meal and fatty foods prior to sedation.

- Avoid a large meal or fatty foods prior to sedation with nitrous oxide.

2.7 MONITORING STANDARDS

Monitoring should be started from the time of administration of the sedative agent until recovery criteria are met (see section 3.5) and this should include any period when the patient is being transferred. Trained personnel and equipment for monitoring children and paediatric resuscitation drugs and equipment must be available throughout the period from the time the sedative is given until discharge.
The minimum monitoring standard should comprise regular clinical assessments of the level of sedation, respiratory rate and pattern, pulse rate, and colour. This type of monitoring is recommended for dental patients undergoing inhalation sedation. Measurement of arterial haemoglobin oxygen saturation by pulse oximetry is widely used and is highly recommended.\(^ {32-34,45-51} \) There is evidence that pulse oximetry is not an accurate monitor of adequacy of ventilation when supplementary oxygen is being administered. Capnography is a more sensitive ventilation monitor and practical non-invasive techniques have been developed for the conscious child using nasal cannulae and side stream capnometers.\(^ {45,49,50} \) End-tidal CO\(_2\) monitoring is increasingly being used as the preferred method of detecting apnoea.\(^ {32} \) Measurement of temperature, ECG and blood pressure for infants, for prolonged procedures or where verbal contact with the child is lost should be used. A method of assessing pain should be used and documented for painful procedures.

Observations from all children undergoing sedation should be recorded as a time-based record using a standardised template. All recordings, prescriptions and reactions should be documented on this chart.

Monitoring should continue after the procedure, during transfer back to the recovery or ward area and in these areas until discharge criteria are met. (Example monitoring charts for hospital and non-hospital settings are available from the SIGN website.)
3 Sedation techniques

The main factors determining the choice of technique for an individual child are:

- the risk: benefit ratio of the technique
- the environment and clinical setting
- the patient’s characteristics
- the procedure
- the availability of skilled personnel to perform and monitor the procedure.

3.1 RISKS INVOLVED

3.1.1 RISKS OF SEDATION

Accurate risk figures for children undergoing procedural sedation are not available. The most common complications of paediatric sedation are respiratory, and include upper airway obstruction and hypoventilation, resulting in hypoxaemia and hypercarbia.\(^{18,25,33,54}\)

One observational study in a North American paediatric emergency department found that 27 of 1,180 patients (2.3%) undergoing procedural sedation and analgesia developed adverse events. The procedures included intravenous, intramuscular, oral, rectal, intranasal, or inhalational agents for painful procedures or diagnostic imaging. No single drug or drug regimen was associated with a significantly higher adverse event rate.\(^{54}\) This may have been due to the low number of adverse events detected. Of 391 patients sedated with combination intravenous midazolam and fentanyl, 5.1% experienced adverse events. Similarly 4% of patients who received combination intranasal midazolam and sufentanil experienced adverse events and this compared with 1.2% and 2% respectively for patients who received inhaled nitrous oxide or intramuscular ketamine as single agents.

A review of 95 adverse sedation-related events found that there was no relationship between outcome and drug class (opioids; benzodiazepines; barbiturates; sedatives; antihistamines; and local, intravenous, or inhalation anaesthetics) or route of administration (oral, rectal, nasal, intramuscular, intravenous, local infiltration, and inhalation). Negative outcomes (death and permanent neurologic injury) were often associated with drug overdose (n = 28). Negative outcomes were also associated with drug combinations and interactions. The use of three or more sedating medications compared with one or two medications was strongly associated with adverse outcomes. Nitrous oxide in combination with any other class of sedating medication was frequently associated with adverse outcomes.\(^{18}\) Negative outcomes occur not because of the drugs themselves but because of administration practices (drug combinations, errors, lack of skills or knowledge, failure to follow procedures and monitoring standards).\(^{18}\)

In the absence of consistent evidence, current expert opinion is to avoid sedative drug combinations in children.\(^{18,29,55}\)

D Sedative drug combinations should generally be avoided in children as they are often associated with deeper levels of sedation and with more adverse effects.

If combinations of drugs are required, the other general recommendations in this guideline should be applied (see Section 2).

Allergic reactions to drugs may occur. Significant cardiac arrhythmias are much rarer in children than in adults, but bradycardia and cardiac arrest may occur, often secondary to hypoxaemia and/or hypotension.

Post-sedation complications include nausea and vomiting, disorientation, sleep disturbance, and nightmares. The latter are particularly associated with the use of ketamine. Prolonged sedation after combinations of sedatives and higher doses of low potency oral agents is also seen.
Adverse outcomes, including death, are more likely in non-hospital-based settings, and are most often due to inadequate case selection and preparation, inadequate resuscitation, inadequate monitoring and failure to intervene adequately to rescue the child from the adverse effects of sedation. In a recent retrospective series of 95 adverse sedation events in paediatrics, 51 incidents resulted in death, 9 in permanent neurological injury, 21 in prolonged hospitalisation and in only 14 was there no harm.25

An ideal sedation regimen should produce a rapid and predictable response, with an appropriate degree and duration of sedation for the procedure undertaken. In practice this may be extremely difficult to achieve and many sedation regimens are unsatisfactory. There is a significant variability in the pharmacokinetics and pharmacodynamics of sedative drugs in children such that responses to sedation may vary from slight depression of the conscious level to anaesthesia. Sedation drift to deeper levels of sedation may occur in any child at any time, including the recovery phase, and a safety net must therefore be in place to deal with this situation whenever and wherever paediatric sedation is used.19 Failure to sedate sufficiently whilst accomplishing the procedure through restraint and failing to complete the task through inadequate sedation are also unacceptable.

The sedation practitioner must be able to manage and recover a patient who enters a deeper level of sedation than intended.

It is essential that an individualised dosing of sedative, based on age, weight, comorbidity, procedure and presence of other drugs, is used for each child. Dosage of nitrous oxide inhalation sedation should be incrementally titrated according to the patient’s response.

The sedative prescription should always be double-checked by another person to ensure dosages are correct.

Conversely, some children become disinhibited by sedative agents and become restless, uncooperative and unmanageable. It is important to recognise this and avoid giving further sedation as this will lead to “stacking” of doses and either worsening of restlessness or deepening of the sedation level. Ineffective sedation may be as common as oversedation.18,54 “Stacking” is also seen when allowance is not made for the onset time and time to peak effect of a sedative agent. The target effect site is the brain and in titrating sedative drugs, sufficient time should be given for the peak brain effect to be seen before further drug is given. This applies to all routes of administration (including intravenous) and to all sedative agents including modern short acting agents.

If a child becomes disinhibited by sedative agents and becomes restless, uncooperative or unmanageable, elective or urgent procedures should be abandoned and re-scheduling for general anaesthesia considered. For emergency procedures, arrangements to convert to a general anaesthetic should be considered when appropriate.

3.1.2 RISKS OF GENERAL ANAESTHESIA

In contrast to guidelines from America, the published British guidelines do not make a distinction between deep sedation and general anaesthesia. It may be that a brief general anaesthetic is quicker, more controllable, reliable and safe for an individual child. The risks of general anaesthesia are nowadays very low with a risk of serious morbidity or mortality estimated at < 1:100,000.56

Some studies have compared general anaesthesia with sedation in paediatrics and have concluded that general anaesthesia is cost effective (when the total time for induction, procedure and recovery is considered), safe and reliable.57,58

A general anaesthetic should be considered, particularly in young children, in the medically compromised patient, for prolonged procedures, and where procedures may be painful or distressing. However, a general anaesthetic should not be performed in the general dental practice (see section 5).
3.2 SEDATION PRINCIPLES

3.2.1 DURATION

For intermediate duration painful medical procedures, titrated doses of opioids may produce adequate analgesia and an appropriate degree of sedation but care must be taken to avoid respiratory depression and the induction of anaesthesia. The potent opioids have a narrow therapeutic index and can produce chest wall, jaw and glottic rigidity and should be avoided. It is vital to match the sedative technique to the duration of the procedure as closely as possible while adapting the technique for painful and painless procedures. Nitrous oxide has the most rapid onset and offset of action and with or without local anaesthesia is a highly effective technique in cooperative children for brief, painful procedures.\(^\text{54}\)

For longer painful procedures, general anaesthesia incorporating multimodal pain control is preferred.\(^\text{59}\) In general, most oral sedative agents have relatively low potency with a slow onset and a long duration of action. They do not produce analgesia. An example of such an agent is chloral hydrate.\(^\text{3,11,40,60-74}\) Some modern oral agents are more potent with a more rapid onset and offset of effect eg midazolam.\(^\text{75-79}\) Although commonly used as pre-medication, the use of oral midazolam in paediatric dentistry is increasingly popular. These agents carry the risk of sedation drift and disinhibition or restlessness during and after the procedure. Monitoring should therefore continue during the recovery period until discharge criteria are reached.

3.2.2 SINGLE OR MULTIPLE PROCEDURES

Many children with serious systemic disease undergoing treatment need to undergo repeated painful procedures, eg the child with leukaemia who needs repeated bone marrow aspirates and lumbar punctures, or the child with burns who requires repeated debridement and dressings. In these children, the balance of risk versus benefit must be carefully weighed when considering the technique to be used. Healthy children may also require repeated procedures, eg for dentistry. If a child has had a bad pain experience, anticipatory fear and anxiety is considerably increased and sedation may be used as part of a behaviour management programme to reduce anxiety and fear for subsequent visits.

- Consider distress and anxiety in planning for repeated procedures, especially if these are painful.
- Consider using sedation as part of a behaviour modification programme to sequentially reduce fear and anxiety with the aim of weaning the child from the need for sedation.

3.2.3 ROUTE OF ADMINISTRATION

Some routes of administration of sedatives to children eg nasal, rectal, intramuscular are distressing to the child and may involve restraint of the child in order to administer them.\(^\text{15,41,77,78,80-85}\) When there are alternatives such as oral, inhalation and intravenous routes available, there is no need for these more distressing administration methods.\(^\text{57}\)

- The least distressing route of administration of the sedative agent should be used.

3.2.4 RESTRAINT

In addition to considerations of risk, it is important to recognise that sedation may be inadequate to reduce sufficiently the fear, anxiety and pain of many diagnostic and therapeutic procedures carried out upon children. For example, in the field of paediatric gastroenterology or endoscopy, using sedation may be possible only in cooperative adolescents. Many of the studies in the literature report the need for restraint of younger children in up to half of cases, even when a deeper level of sedation is used.\(^\text{57,86,87}\) Forcible restraint would not be acceptable in Scotland and many paediatric endoscopies are therefore performed under general anaesthesia.
3.3 SEDATION FOR PAINLESS PROCEDURES

Non-pharmacological techniques such as distraction (eg breathing exercises, blowing bubbles), guided imagery, or play therapy are undoubtedly effective for many children, particularly those of school age, where procedures are not painful and where parental involvement in a child-friendly environment is possible. In dental practice, many fewer children are now undergoing general anaesthesia and the majority of cases can be managed by non-pharmacological techniques with only selected cases requiring sedation or anaesthesia.

Non-pharmacological techniques are highly beneficial to cooperative children and carry negligible risks. Use of local anaesthesia also reduces the sedation requirements.

Non-pharmacological techniques should be used for painless procedures whenever possible.

Opioids or combinations of opioids and other sedatives should not be used to sedate children for painless procedures (see Section 3.4.3)

3.3.1 NURSE SPECIALIST PAEDIATRIC SEDATION

Recently, nurse specialist paediatric sedation services have been successfully introduced into specialist children’s hospitals. A limited range of sedative agents of low potency is employed for painless procedures. These nurses must have advanced airway skills, considerable paediatric critical care experience and adequate ongoing education and experience.

Nurse specialist paediatric sedation services may be appropriate for some specialist children's hospitals.

Such an approach should only be used with strict protocols, comprehensive backup and within a comprehensive clinical governance and risk management framework.

3.4 SEDATION FOR PAINFUL PROCEDURES

Sedation of children for painful procedures is carried out mainly in A&E or surgery departments where the child may be undergoing suturing or fracture reduction. Burns dressing or changing such dressings is another common reason for performing sedation for a painful procedure.

3.4.1 ANALGESIA

Drugs with sedative properties usually do not produce analgesia and should not be used alone for painful procedures. For prolonged or extensive painful procedures, particularly in younger and/or sicker children, consideration should be given to general anaesthesia incorporating multimodal analgesia (ie combinations of local anaesthesia, opioids, nonsteroidal anti-inflammatory drugs, paracetamol, and adjuncts such as ketamine or clonidine). If sedation is used, systemic analgesic agents should be given first in adequate doses and given time to reach their full effect. However, these drugs have a slow onset, requiring 1-2 hours to reach peak effect and are not potent enough to prevent and treat severe pain. Some children may require general anaesthesia even for brief procedures, whether painful or painless, because of their level of distress or lack of compliance.

For painful procedures, appropriate analgesia should be given first to prevent pain before considering sedation. Consideration should be given first to the use of analgesics that do not have sedative properties.
3.4.2 NITROUS OXIDE

Inhaled nitrous oxide has a rapid onset (time to take effect) and offset (time to recovery) of analgesia and produces dose-related sedation. Its use requires a degree of cooperation from the child.\(^{39,59,89-90}\)

**D** Inhaled nitrous oxide produces the most rapid onset and offset of analgesia and may be appropriate for painful procedures in children who are able to cooperate.

3.4.3 OPIOIDS

The opioids produce dose-related central nervous system depression with sedation and respiratory depression. They also slow gastrointestinal motility and induce nausea and vomiting. Rapid administration can induce chest wall and glottic rigidity.\(^ {18}\) Opioids potentiate the effects of other sedative agents.

- Opioids may be used for painful procedures but should not be used to sedate children undergoing painless procedures.
- Whenever opioids are given to children, the specific antagonist naloxone should be immediately available.

Combinations of sedatives and opioids are associated with a high incidence of adverse effects and often depress consciousness beyond sedation.\(^ {18,91-99}\) Recovery may also be prolonged.

**C** For painful procedures requiring systemic opioid analgesia, this should be administered first and its sedative effects assessed carefully before considering adding a second sedative agent.

Where a second agent is deemed necessary, the other general recommendations in this guideline should be applied (see Section 2).

3.5 RECOVERY AND DISCHARGE CRITERIA

- After the procedure, the patient may be discharged if the following criteria are met:

  **For a hospital setting**
  - airway patent and stable unsupported
  - easily rousable
  - oxygen saturation > 95% breathing air
  - haemodynamically stable
  - hydration adequate, no bleeding, urine output adequate
  - returned to normal level of responsiveness and orientation for age and mental status, can walk unaided (if appropriate)
  - no nausea and vomiting
  - pain controlled.

  **For non-hospital setting**
  - airway patent and stable unsupported
  - easily rousable
  - returned to normal level of responsiveness and orientation for age and mental status, can walk unaided (if appropriate)
  - no nausea and vomiting
  - pain controlled.
Discharge should not be facilitated without prior organisation of appropriate transport or care needs having been previously agreed with the parent or responsible carer. The parent/guardian could be given a leaflet to take away with them, containing advice and information on who to contact if they are concerned about the behaviour or symptoms of the child in the 24 hours after undergoing sedation. Health professionals should familiarise themselves with the pharmacokinetics of all drugs in use, in particular, the half-life of drugs in children of differing ages and sizes and take this into account when agreeing a post-procedure minimal discharge time. If appropriate, a discharge letter to the general practitioner may also be necessary.

Example discharge assessment checklists for hospital and non-hospital settings are available from the SIGN website.

3.6 USE OF LICENSED MEDICINES FOR UNLICENSED APPLICATIONS

Many drugs required for paediatric patients are not licensed for use in children. The Royal College of Paediatrics and Child Health has set out an argued case for the use of licensed medicines for unlicensed applications, and for the use of unlicensed medicines in children.

The recommendations are that:

- those who prescribe for a child should choose the medicine which offers the best prospect of benefit for that child, with due regard to cost
- the informed use of some unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice
- health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability
- in general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers and child patients to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications
- NHS Trusts and Health Authorities/Boards should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.

The SIGN guideline development group recommends that general anaesthetic agents (propofol, thiopentone, methohexitone, ketamine, volatile agents) and potent opioids (fentanyl, alfentanil, remifentanil) are only used by those who are formally trained in paediatric or neonatal anaesthesia or intensive care and who have adequate ongoing experience. These agents should only be used in a hospital setting.

A list of sedative agents and their properties can be found in the UK National Paediatric Formulary, published by the Royal College of Paediatrics and Child Health.
4 Specialty requirements: medical paediatrics

In addition to the recommendations stated in sections 3.3 and 3.4, there are specialty requirements which may need to be considered. Procedures in medical paediatrics for which sedation may be required, include upper and lower gastrointestinal endoscopy with or without biopsy, bronchoscopy, audiology, echocardiography, cardiac catheterisation, renal biopsy, bone marrow aspiration, lumbar puncture, vascular access procedures including venepunctures, venous cannulation, arterial blood sampling and capillary blood sampling.

4.1 GASTROINTESTINAL ENDOSCOPY

There are no studies directly comparing general anaesthesia with conscious sedation in children undergoing gastrointestinal endoscopy. The indications and criteria for general anaesthesia in adults do not apply to children as the pathologies are different. Further research is needed in this area.

Many drugs and drug combinations described in the literature for use during gastrointestinal endoscopy produce a state beyond sedation. Cocktails involving three sedative agents have a very high incidence of adverse effects and should not be used. Combinations using diazepam have a higher incidence of behavioural side effects, a longer recovery time and poorer post procedure amnesia.\(^{57,103}\)

For this particular procedure, single drugs are often not sufficient for sedating children adequately to allow the procedure to be carried out. Although many studies have used restraint as part of the technique for gastrointestinal endoscopy in children,\(^{57,98,104}\) such use of restraint is unacceptable\(^{22}\) and indicates a failure of the sedation technique.

Oral midazolam may be useful pre-medication prior to gastrointestinal endoscopy in children.\(^{105}\)

In an observational study of general anaesthesia and intravenous sedation for upper and lower gastrointestinal endoscopy, IV sedation was used in 103 children and was favoured on cost grounds but 18% were deeply sedated, in 5% the procedure could not be completed, in 8% restraint was needed and in 2 cases naloxone reversal was needed. Patients aged 3 to 9 years were the most difficult to sedate and required the most medication.\(^{98}\)

For younger children, clinical experience suggests that general anaesthesia is appropriate for gastrointestinal endoscopy. This would avoid the use of restraint, the requirement for combination of sedatives and their associated incidence of adverse events and the need for high doses of sedatives which often leads to unconsciousness.

4.2 ONCOLOGY

4.2.1 BEHAVIOURAL TECHNIQUES

For brief procedures that are painful or distressing, a combination of behavioural techniques and local anaesthesia may suffice.\(^{23,74}\)

For brief procedures that are painful or distressing, a combination of behavioural techniques and local anaesthesia is recommended.

4.2.2 CONSCIOUS SEDATION

In those patients where the above is not sufficient, conscious sedation and analgesia with nitrous oxide or opioids may be required.\(^{23,106}\)

In those children where behavioural techniques are insufficient, conscious sedation and analgesia with nitrous oxide or opioids should be considered.
4.2.3 GENERAL ANAESTHESIA

Some children may require a general anaesthetic. In a comparative cross-over study of general anaesthesia and sedation for lumbar puncture, equivalence in terms of distress, discomfort, pain and well-being was noted and more children, parents and nurses preferred sedation. However, in 5/25 cases the procedure could not be completed under sedation, and younger children did not prefer sedation.

For repeated painful procedures, for more invasive procedures, for prolonged procedures and in the younger or distressed child, general anaesthesia is recommended.

C For distressing, repeated or prolonged oncology procedures, a general anaesthetic is recommended, particularly in younger children.

4.3 CARDIOLOGY

Procedures in cardiology include transthoracic echocardiography (non-painful) and cardiac catheterisation (painful).

For children undergoing echocardiography (or non-painful procedures), sleep deprivation may be a useful adjunct to sedation of infants. Post-prandial scanning may allow echocardiography in neonates and young infants.

Chloral hydrate can be a safe and effective sedative in children having echocardiography. However, children over 5 years of age, who require sedation may be less successfully sedated with chloral hydrate. Chloral hydrate can also produce deep sedation.

Minor oxygen desaturations may occur in about 6% of children and more commonly in children with Down’s syndrome.

D For non-painful cardiology procedures, behavioural methods, sleep deprivation and scheduling post-feeding may be sufficient for many children.

Where sedation is required for paediatric cardiology procedures, chloral hydrate is safe and effective in children under 5 years of age, but complications such as paradoxical excitement may occur in up to 20% of cases.

Parents should be warned that behavioural upsets are common, and they should be given verbal and written guidance on safe handling of their child until fully awake. Caution is required with sedation in children with cyanotic congenital heart disease and in those with pulmonary hypertension.

Cardiac catheterisation may be prolonged, the environment may be frightening for children and stillness is an important aspect of safety, particularly when catheters are in the heart or major vessels, when interventional procedures are to be performed and during crucial parts of the procedure. Patients may also vomit or have unstable physiology including pulmonary hypertension.

A deeper level of sedation is often required unless the child is fully cooperative.

D General anaesthesia is recommended for cardiac catheterisation procedures in children.

4.4 NEPHROLOGY

Renal biopsy is a painful procedure and requires a cooperative patient and management using a combination of behavioural techniques, local anaesthesia and systemic analgesia and/or sedation. Many combinations of agents described in the literature use techniques which are beyond sedation to produce successful results but with a high incidence of adverse effects so cannot be recommended.

Renal biopsy should be carried out under general anaesthesia or with an anaesthetist administering the sedation and monitoring the child.
5 Specialty requirements: dentistry

A guideline for sedation in the dental setting is currently being prepared by the Chief Dental Officer and when that is published, it will supersede the dental guidance in this document. In addition to the recommendations stated in sections 3.3 and 3.4, there are specialty requirements which may need to be considered.

☐ Every effort should be made to prevent dental disease in children and to provide pain-free dentistry so that the need for dental sedation is kept to a minimum.

All patients should be enrolled in an intensive preventive dental programme prior to receiving dental treatment under sedation. The preventive programme will have to be delayed if the patient attends with acute pain or infection until the acute episode has been managed. Where possible, patients being referred for specialist treatment under sedation should have completed their preventive programme prior to referral. The time required and complexity of the procedure may dictate the sedation technique (and therefore the setting).

The consensus in the literature is that attempts should have been made to carry out dental treatment under local analgesia using the “tell-show-do” technique, positive reinforcement and other acclimatisation methods before dental sedation is contemplated (see section 2.6.1). Hypnosis may be a helpful adjunct in some children.

D Attempts should be made to persuade the child to have dental treatment under local anaesthesia using the “tell-show-do” technique, positive reinforcement and other acclimatisation methods before dental sedation is contemplated.

☐ A careful assessment of the child’s level of anxiety should be made.

5.1 PATIENT SELECTION AND CONSENT

☐ Only ASA I and ASA II children should undergo dental sedation in a general dental practice, a community dental practice or a specialist practice (see section 2.5).

All other children should be treated in a hospital setting with critical care facilities. A pre-procedure assessment of each patient is mandatory prior to dental sedation. The recommendations set out in section 2.5.1 should be followed. The only exception is Class III patients who have a well controlled chronic condition, and who are known to the practitioner. Such patients do not need to be treated in a hospital setting if robust local protocols for their treatment and monitoring are in place.

Informed, written consent regarding the sedation procedure for a course of dental treatment should be obtained from patients/parents when the child is unable to tolerate dental treatment in the normal manner. A list of pre- and post-operative written instructions should be provided for the patient/parent (see sections 2.3 and 8). The facilities required for sedation are outlined in section 2.4.1.

☐ As patients become more relaxed with dental treatment, attempts should be made to “wean” them off sedation by decreasing the amount of drug used at subsequent visits.
5.2 INHALATION SEDATION

In paediatric dental practice the use of sedation or relative analgesia with nitrous oxide is widely practised, with the operator administering the sedation.\textsuperscript{13,39,59,85,88-90} This is generally accepted as the safest form of dental sedation.\textsuperscript{13,85} No fasting is necessary.\textsuperscript{13,85} There should always be an appropriately trained dental nurse with the dentist in such circumstances.\textsuperscript{13,15,33} This technique relies on a degree of cooperation from the child, constant checking for verbal responsiveness, ability to open the mouth voluntarily, lack of physical restraint of the child, and constant titration of the inspired nitrous oxide concentration to the needs of the child. Such cases nearly always have local anaesthesia administered and are often attending the dental service repeatedly. In these circumstances most dentists are using nitrous oxide sedation and analgesia to help improve the experience of the child and to alter the behaviour of the child for subsequent visits. Often, less nitrous oxide is needed at the next visit and the child may be weaned from sedation altogether.

\textbf{C} \hspace{1cm} Nitrous oxide/oxygen sedation (inhalation sedation), titrated to the individual child’s needs, is recommended for use in all dental settings but particularly General Dental Practice and the Community Dental Service.

\textbf{C} \hspace{1cm} This sedation should be supplemented with local analgesia for potentially painful procedures. A trained assistant should always be present.

\textbf{C} \hspace{1cm} Inhalation sedation in dentistry (relative analgesia) should only be undertaken using a dedicated Relative Analgesia machine conforming to British Standards to ensure minimum/maximum levels of oxygen/nitrous oxide delivery.

Dentists carrying out nitrous oxide/oxygen sedation need to ensure that surgeries are fitted with an up-to-date scavenging system.\textsuperscript{7,13,32,34,39,48} Exhaust systems venting scavenged air outside of the building should be used. Masks with a two way valve outlet should also be used to minimise nitrous oxide/oxygen discharge from the oral cavity.

\textbf{D} \hspace{1cm} Dental surgeries where nitrous oxide/oxygen sedation takes place should be fitted with an up-to-date scavenging system.

Monitoring of patients visually is recommended during treatment (see section 2.7).\textsuperscript{13} Pulse oximetry is not required as the high inspired oxygen concentration means that a fall in the arterial oxygen saturation is a late indicator of ventilatory inadequacy.

\textbf{D} \hspace{1cm} Children undergoing inhalation sedation in a dental surgery should be monitored visually by an appropriately trained member of staff until fully recovered.

5.3 INTRAVENOUS SEDATION

There is insufficient scientific evidence to support the routine use of intravenous (IV) sedation for dentistry in children under the age of 16 years.\textsuperscript{13,15,96} It may be used in a specialist centre for treatment by a consultant-led team who have specialist expertise in paediatric dental sedation or in a hospital setting which meets the standards for general anaesthesia.

Short acting benzodiazepines, eg midazolam, may be appropriate to use in patients over 16 years of age.\textsuperscript{13} The UK Department of Health has restricted reimbursement to dentists only for single agent IV sedation or inhalational sedation.

\textbf{D} \hspace{1cm} Single agent sedation with midazolam is only recommended for intravenous dental sedation in patients over 16 years of age. Intravenous sedation should be avoided in younger children in primary or community dental practice.

For IV sedation, monitoring of vital signs clinically combined with pulse oximetry is mandatory. Modern side-stream capnographs may also be extremely useful (see section 2.7). If verbal contact is lost, the standards of monitoring and care should be identical to those for general anaesthesia. Specific reversal agents must be immediately available.
5.4 OTHER SEDATIVE TECHNIQUES

If individual children require complex sedation or combinations of drugs for effective sedation (see section 3.1.1), they should only be treated in a hospital setting which meets the standards for general anaesthesia. In these cases, the sedative drugs should only be administered by an appropriately trained anaesthetist with adequate ongoing experience.\(^\text{117}\)

General anaesthetic agents such as propofol and potent opioids such as fentanyl, alfentanil and remifentanil should only be administered by an appropriately trained anaesthetist in a hospital setting with full back up facilities.\(^\text{73,83,118}\)

Other routes of drug administration including the oral, rectal and intra-nasal route have no advantages over inhalation and intravenous sedation and should be restricted to a hospital setting which has full back up facilities.\(^\text{25,84,119-121}\)

There is insufficient evidence to support pre-treatment (premedication) of children with anxiolytics or sedatives prior to dental treatment in primary care. This practice should only be used in a hospital setting or specialist centre as defined above.

Guidance from the General Dental Council\(^\text{15}\) and the Scottish Executive Health Department\(^\text{122}\) recommends that general anaesthesia for dental treatment should be offered only within a hospital complex.

**General anaesthetic drugs, combinations of sedative drugs, or other routes of administration should only be used in a hospital setting.**

**Physical restraints and HOME (Hand Over Mouth Exercise) have no place in the dental treatment of children and should not be used.**
6 Specialty requirements: radiology

In addition to the recommendations stated in sections 3.3 and 3.4, there are specialty requirements which may need to be considered.

6.1 PAINLESS IMAGING PROCEDURES

Many techniques in diagnostic radiology such as CT, MRI and Nuclear Medicine require the child to lie absolutely still for the acquisition of the images which may take from a few minutes (modern CT) up to an hour (SPECT, Nuclear Medicine or MRI).

These examinations are painless if venous access is in situ and so once the child is positioned in the scanner, he/she need not be disturbed further.

Many painless procedures in paediatric diagnostic imaging can also be accomplished without pharmacological intervention if there are child-friendly facilities, good preparation procedures for child and family, a cooperative child and modern imaging equipment.

All efforts should be made to help the child to cooperate without sedation (eg demonstration play therapy). Modern equipment, especially spiral CT and open MRI scanners, decrease the need for sedation and anaesthesia.

Painless procedures may be performed on small babies without any sedatives after they have received a feed and are provided with:

- warmth
- quiet
- containment (to maintain correct position)
- topical local anaesthesia for single needling procedures
- sucrose.

This is an exception to the usual fasting guidelines so should only be used if no sedative agents are given.

D Children up to the age of 4 months should be imaged when asleep, post-feeding, and with no sedation.

6.2 SEDATION FOR RADIOLOGY

Children up to 10 Kg in weight, who cannot be imaged while awake, can be sedated with a single oral agent, provided the rest of this guideline is implemented. One study reported a 1% failure rate (out of 205 patients) where the children were insufficiently immobilised to allow the scan to be finished when oral chloral hydrate was used. No adverse events occurred relating to the airway or breathing.

One report described a group of 35 children under 5 years of age, requiring CT scanning, who have been sedated with oral secobarbitol (quinalbarbitone). Around 91% of the children were adequately sedated with this technique. No problems with respiratory depression were encountered. Sedation failures were associated with the children spitting out the sedative. Secobarbitol (quinalbarbitone) was less effective in children of 5 years or older, in whom three out of five developed paradoxical excitement.

An alternative for short procedures is oral midazolam, but there is a high incidence of patient movement.

Recovery may be slow after these techniques.

C For painless imaging procedures lasting less than 60 minutes, children from 4 months to 5 years of age, may be sedated using a single low-potency oral agent.
D  As failure of sedation is often due to only part of the dose being swallowed, the drug should be given in the radiology department by the sedation practitioner. Administration from a syringe is more successful than by spoon. The bitter taste of some agents should be partially disguised in a small volume of sweet juice.

☑ A quiet area should be available within the radiology department to encourage sleep. Venous access should be obtained before this and monitoring attached as soon as the child permits. Transfer to the scanner should be short and smooth.

Visual observation and access to the child is restricted in a tunnel MRI scanner especially when the head is being examined.126

☑ Within the coil, extra care should be taken to position the head in extension for a clear airway.

☑ The sedation practitioner must stay with the child in the MRI room and the child must be under continuous observation from the time of administration of sedation until discharge criteria are met.

☑ Specialised MRI-compatible monitoring equipment should be used.

Interventional procedures under radiological control are painful and also require the child to keep still.112,127

D  Interventional procedures under radiological control should be performed under general anaesthesia with topical and infiltration local anaesthesia for puncture sites.

Oral benzodiazepines can be effective in allaying anxiety in individual children for certain procedures eg urethral catheterisation for micturating cystourethrogram for which sedation is not routine.128

C  Oral benzodiazepines may be used to allay anxiety in individual children for distressing procedures.

☑ The standards of preparation, case selection, monitoring and documentation should be those recommended in this guideline. Where the patient does not respond to verbal or light tactile stimulation, these standards must be identical to those for general anaesthesia.

General anaesthesia may be more cost-effective than sedation for imaging of children (see section 3.1.2).

General anaesthesia may be more cost-effective than sedation for imaging of children (see section 3.1.2).
7 Specialty requirements: accident & emergency

In addition to the recommendations stated in sections 3.3 and 3.4, the following specialty requirements may need to be considered.

Children attending accident and emergency (A&E) departments for painful procedures can often be managed successfully with adequate sympathetic behavioural techniques (including play therapy, distraction, guided imagery) and local anaesthesia (topical, infiltration, nerve block).

Nitrous oxide is very effective in school age children who are able to cooperate and is particularly helpful as patients do not need to be fasted if nitrous oxide is used as the sole sedative/analgesic agent.

Systemic analgesia may be needed for control of mild or moderate pain with oral paracetamol and/or ibuprofen or diclofenac but slow onset means that these agents should be considered as continuing pain control after painful procedures.

For severe pain, opioids may be used by oral, intravenous, or nasal routes.

For severe pain, opioids should be used by oral, intravenous, or nasal routes, for sedating children in the A&E setting.

The potent opioids (such as fentanyl, alfentanil and remifentanil) and general anaesthetic agents (such as propofol, ketamine) should not be used by non-anaesthetists. Although ketamine can be given orally, intravenously or intramuscularly in so-called sub-anaesthetic doses there is a high incidence of adverse effects (vomiting, ataxia, delirium).

Fasting guidelines (see section 2.6.4) should be applied to children in A&E departments. The standards of preparation, case selection, monitoring and documentation should be those recommended in this guideline. Where the patient does not respond to verbal or light tactile stimulation, these standards must be identical to those for general anaesthesia.

Some children may require a general anaesthetic. For repeated painful procedures, for more invasive procedures, for prolonged procedures and in the younger or distressed child, general anaesthesia is recommended.
8 Information for patients and parents

In preparing any information for patients and parents healthcare professionals should be sensitive to the fact that sedation is generally a rare event in a person’s life and that the quality of patient preparation can influence the outcome of the sedative procedure.

Whilst the approaches taken to provide information on the sedation procedure to patients and their parents or guardians will vary depending on the situation, healthcare staff should ensure that they provide background information on what sedation is, what it is required for, and how it is to be achieved.

Techniques of analgesia for painful procedures should be discussed in detail with patients (if age permits) and parents, and any available choices of technique should be provided.

Special care should be taken to mention to patients and their parents or guardians the possibility that the selected method of sedation might fail and that if this happens the sedative procedure may be either abandoned or replaced by another method that gives a deeper level of sedation, or, indeed, general anaesthesia.

Parents, carers and patients themselves can reduce the need for sedation by using psychological tools such as relaxation and distraction techniques. Awareness of these techniques should be encouraged.

Parents and guardians can be involved in procedures to provide physical support for the patient, which may include gentle restraint during, for example, cannulation. All parties should understand that forcible restraint is not acceptable in any situation (see Sections 2.2 and 3.2.4).

The consent issue (see Section 2.1) should be clearly explained, particularly with reference to the Children (Scotland) Act 1995. Proper informed consent only occurs when a patient understands both the risks and the benefits of a procedure. Therefore, staff should clearly describe the risks and benefits.

8.1 ORGANISATIONS WHICH PROVIDE USEFUL INFORMATION

The following websites are aimed at the general public and have some useful information for lay people on the sedation of children and young people. Healthcare professionals may also find them useful.

**Your anaesthetic**
www.youranaesthetic.info
Website is supported by the Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland

**Action for Sick Children**
www.actionforsickchildren.org

**Children’s Hospital Medical Center of Cincinnati**
www.cincinnatichildrens.org/health/info/pain-mgt/sedation/sedation.htm
9 Implementation and audit

9.1 LOCAL IMPLEMENTATION

Implementation of national clinical guidelines is the responsibility of local NHS organisations and is an essential part of clinical governance. It is acknowledged that not every guideline can be implemented immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

9.2 KEY POINTS FOR AUDIT

Recommended audit markers are:

- local protocols for paediatric sedation
- critical incident monitoring: adverse respiratory / cardiovascular events, admission to high dependency or intensive care, prescription or dosing errors, incidence and severity of disinhibition
- failure of technique: abandonment rate, general anaesthetic conversion rate
- efficiency: total procedure time including preparation and recovery, recovery time, hospital admission rate
- quality: patient satisfaction, parental satisfaction, behavioural upset (early, late); pain scores

9.3 SUMMARY OF CARE PATHWAY FOR SAFE PAEDIATRIC SEDATION

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10 Development of the guideline

10.1 INTRODUCTION

Sign is a collaborative network of clinicians, other healthcare professionals, and patient organisations, funded by NHS Quality Improvement Scotland. SIGN guidelines are developed by multidisciplinary groups of practising clinicians using a standard methodology based on a systematic review of the evidence. Further details about SIGN and the guideline development methodology are contained in “SIGN 50: a guideline developer’s handbook”, available at www.sign.ac.uk

10.2 THE GUIDELINE DEVELOPMENT GROUP

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Dr Donald Miller  Consultant Anaesthetist, Glasgow
Dr James Paton  Reader and Hon Consultant Paediatrician, Royal Hospital for Sick Children, Glasgow
Ms Clare Taylor  Patient Representative, former Greater Glasgow Health Council (1994-2001)
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The membership of the guideline development group was confirmed following consultation with the member organisations of SIGN. Declarations of interests were made by all members of the guideline development group. Further details are available from the SIGN Executive. Guideline development and literature review expertise, support, and facilitation were provided by the SIGN Executive.

10.3 SYSTEMATIC LITERATURE REVIEW

The evidence base for this guideline was synthesised in accordance with SIGN methodology. A systematic review of the literature was carried out using an explicit search strategy devised by an information specialist (Dr Helen Marlborough, Glasgow University) in collaboration with members of the guideline development group. Internet searches were carried out on the Website of the Canadian Practice Guidelines Infobase, the New Zealand Guidelines Programme, the UK Health Technology Assessment programme, and the AHCPR. Searches were also carried out on the search engines Northern Light and OMNI, and all suitable links followed up. Systematic searches were carried out on Cochrane Library, CINAHL, Embase, Healthstar and Medline from 1988-1998. The Medline version of the main search strategies can be found on the SIGN website, in the section covering supplementary guideline material. The main searches were supplemented by later material identified by individual members of the development group. All selected papers were evaluated using standard methodological checklists before conclusions were considered as evidence. The references were selected based on both the SIGN scoring procedures and against a set of guiding principles for applicability to Scottish practice.
10.4 CONSULTATION AND PEER REVIEW

10.4.1 NATIONAL OPEN MEETING

A national open meeting is the main consultative phase of SIGN guideline development, at which the guideline development group present their draft recommendations for the first time. The national open meeting for this guideline was held on 11 October 1999 and was attended by 130 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

10.4.2 SPECIALIST REVIEW

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. SIGN is very grateful to all of these experts for their contribution to this guideline.

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10.4.3 SIGN EDITORIAL BOARD

As a final quality control check, the guideline was reviewed by an Editorial Group comprising the relevant specialty representatives on SIGN Council:

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Royal College of General Practitioners

Dr Cameron Howie  
Royal College of Anaesthetics representative

Dr Chris Kelnar  
Royal College of Paediatrics and Child Health

Prof Gordon Lowe  
Chairman of SIGN

Ms Juliet Miller  
Director of SIGN

Prof Nigel Pitts  
Dental Health Services Research Unit

Dr Jim Rennie  
Scottish Council for Postgraduate Medical & Dental Education

Prof Joanna Wardlaw  
Royal College of Radiologists
References

SAFE SEDATION OF CHILDREN UNDERGOING DIAGNOSTIC AND THERAPEUTIC PROCEDURES


## SEDATION FOR SPECIFIC PROCEDURES

### Medical paediatrics: Gastrointestinal endoscopy

- **A** General anaesthesia should be the first choice for paediatric gastrointestinal endoscopy.

### Medical paediatrics: Oncology

- **D** For brief procedures that are painful or distressing a combination of behavioural techniques and local anaesthesia is recommended.
- **C** For distressing, repeated or prolonged oncology procedures, a general anaesthetic is recommended, particularly in young children.

### Medical paediatrics: Cardiology

- **D** For non-painful cardiology procedures, behavioural methods, sleep deprivation and scheduling post-feeding may be sufficient for many children. General anaesthesia is recommended for cardiac catheterisation procedures in children.

### Medical paediatrics: Nephrology

- **D** Renal biopsy should be carried out under general anaesthesia or with an anaesthetist administering the sedation and monitoring the child.

### Accident & Emergency

Children attending A&E departments for painful procedures can often be managed successfully with adequate sympathetic behavioural techniques (including play therapy, distraction, guided imagery) and local anaesthesia (topical, infiltration, nerve block).

- **D** For severe pain, opioids should be used by oral, intravenous, or nasal routes.
- **C** Nitrous oxide is very effective in school-age children who are able to cooperate and is particularly helpful as patients do not need to be fasted if nitrous oxide is used as the sole sedative/analgesic agent.

### Radiology

- **D** Children up to the age of 4 months should be imaged when asleep, post-feeding, and with no sedation.
- **C** For painless imaging procedures lasting less than 60 minutes, children from 4 months to 5 years of age, may be sedated using a single low-potency oral agent.
- **D** As failure of sedation is often due to only part of the dose being swallowed, the drug should be given in the radiology department by the sedation practitioner. Administration from a syringe is more successful than by spoon. The bitter taste of some agents should be partially disguised in a small volume of sweet juice.
- **D** Interventional procedures under radiological control should be performed under general anaesthesia with topical and infiltration local anaesthesia for puncture sites.

### Dentistry

- **D** Attempts should be made to persuade the child to have dental treatment under local anaesthesia using the “tell-show-do” technique, positive reinforcement and other acclimatisation methods before dental sedation is contemplated.
- **C** Oral benzodiazepines may be used to allay anxiety in individual children for distressing procedures.

### Contraindications

- **D** Interventions should be avoided under radiological control if the child has any of the following contraindications:
  - Active respiratory tract infection
  - History of sleep apnoea
  - Known allergy to sedative drugs / previous adverse reaction
  - Known history of severe pulmonary hypertension
  - Known history of severe pulmonary hypertension
  - Known history of severe pulmonary hypertension

### Recovery and Discharge

- **D** After the procedure, the patient may be discharged if the following criteria are met:
  - **For a hospital setting**
    - Airway patent and stable unsupported
    - Easily rousable
    - Oxygen saturation >95% breathing air
    - Haemodynamically stable
    - Hydration adequate, no bleeding, urine output adequate
    - Return to normal level of responsiveness and orientation for age and mental status, can walk unaided (if appropriate)
    - No nausea and vomiting
    - Pain controlled.
  - **For non-hospital setting**
    - Airway patent and stable unsupported
    - Easily rousable
    - Return to normal level of responsiveness and orientation for age and mental status, can walk unaided (if appropriate)
    - No nausea and vomiting
    - Pain controlled.

### Nitrous oxide/oxygen sedation

- **D** Nitrous oxide/oxygen sedation (inhalation sedation), titrated to the individual child’s needs, is recommended for use in all dental settings but particularly General Dental Practice and the Community Dental Service.
This guideline is applicable to all children under 16 years of age undergoing painful or non-painful diagnostic or therapeutic procedures in the hospital, community, general medical or dental practice settings.

Sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

When using sedation in the primary care or out patient setting, there should be no intention to progress to either deep sedation or general anaesthesia, even when sedation fails.

### PREPARING FOR SEDATION

It is essential that consent is obtained prior to the procedure and this should include an explanation of the procedure, the sedation technique proposed and possible adverse effects. Written informed consent should be obtained from the child or from the parent or legal guardian.

### Facilities and personnel

- **Sedation in children should only be performed in an environment where the facilities, personnel and equipment to manage paediatric emergency situations are immediately available.**
- **Sedation of children for diagnostic or therapeutic procedures should not be undertaken in general medical practice and out-of-hours centres.**
- **The roles and responsibilities of the “operator” (the person carrying out the procedure) and the sedation practitioner may be merged to some extent but the guiding principle should always be that the operator should not be the person responsible for monitoring the child during the procedure.**
- **A medically or dentally qualified person should be identified to hold overall responsibility for the care of the sedated child until they are discharged.**

### Clinical assessment

- **Children requiring sedation should receive a full pre-procedure clinical assessment and only children who are normally healthy or have mild systemic disease, should be considered suitable for sedation as out patients.**
- **Children with contraindications to sedation should not be sedated.**
- **Extra caution should be exercised when sedating neonates and children under 5 years of age.**
- **Consider use of a general anaesthetic or anaesthetist-supervised sedation as an alternative.**

### Parental involvement

- **Parental involvement in the preparation of the child and during the procedure has a sedative-sparing effect and may greatly reduce the distress caused by separation anxiety.**

### Fasting

- **The child should be fasted as for a general anaesthetic (6 hours for solids or bottle milk, 4 hours for breast milk, 2 hours for clear fluids), except when nitrous oxide is the only sedative used.**

### Monitoring

- **Observations from all children undergoing sedation should be recorded using a standardised template. All recordings, prescriptions and reactions should be documented on this chart and continued until discharge criteria are met.**

### SEDATION TECHNIQUES

#### Sedation for painless procedures

- **Non-pharmacological techniques should be used for painless procedures whenever possible.**
- **Inhaled nitrous oxide produces the most rapid onset and offset of analgesia and may be appropriate for painful procedures in children who are able to cooperate.**
- **Opioids may be used for painful procedures but should not be used to sedate children undergoing painless procedures. Whenever opioids are given to children, the specific antagonist naloxone should be immediately available.**

#### Sedation for painful procedures

- **For painful procedures, appropriate analgesia should be given first to prevent pain before considering sedation. Consideration should be given first to the use of analgesics that do not have sedative properties.**

### SEDATION PRINCIPLES

- **Sedative drug combinations should be avoided in children as they are often associated with deeper levels of sedation and with more adverse effects.**
- **If a child becomes disinhibited by sedative agents and becomes restless, uncooperative or unmanageable, elective or urgent procedures should be abandoned and re-scheduling for general anaesthesia considered. For emergency procedures, arrangements to convert to a general anaesthetic should be considered when appropriate.**
- **The sedation practitioner must be able to manage and recover a patient who enters a deeper level of sedation than intended.**

- **General anaesthetic agents should not be used to sedate children.**
- **An individualised dosing of sedative, based on age, weight, co-morbidity, procedure and presence of other drugs should be devised for each child. Dosage of nitrous oxide inhalation sedation should be incrementally titrated according to the patient’s response.**
- **The least distressing route of administration of the sedative agent should be used.**
- **The sedative prescription should always be double-checked by another person to ensure dosages are correct.**
- **For repeated procedures, consideration should be given to using sedation as part of a behaviour modification programme to sequentially reduce fear and anxiety with the aim of weaning the child from the need for sedation.**

### USEFUL WEB SITES

- **Action for Sick Children:**
  - [www.actionforsickchildren.org](http://www.actionforsickchildren.org)
- **American Society of Anesthesiologists (ASA):**
  - [www.asahq.org](http://www.asahq.org)
- **American Association of Pediatric Dentistry:**
  - [www.aapd.org](http://www.aapd.org)
- **General Dental Council:**
  - [www.gdc-uk.org](http://www.gdc-uk.org)
- **Royal College of Paediatrics and Child Health (RCPCH):**
  - [www.rcpch.ac.uk](http://www.rcpch.ac.uk)
- **Your anaesthetic:**
  - [www.youranaesthetic.info](http://www.youranaesthetic.info)
- **Cincinnati Children’s Hospital Medical Center:**
  - [www.cincinnatichildrens.org/family/pep/pain/2073](http://www.cincinnatichildrens.org/family/pep/pain/2073)
- **American Society of Anesthesiologists (ASA):**
  - [www.asahq.org](http://www.asahq.org)
- **General Dental Council:**
  - [www.gdc-uk.org](http://www.gdc-uk.org)
- **Royal College of Paediatrics and Child Health (RCPCH):**
  - [www.rcpch.ac.uk](http://www.rcpch.ac.uk)
- **Your anaesthetic:**
  - [www.youranaesthetic.info](http://www.youranaesthetic.info)