



Complete Summary

GUIDELINE TITLE

Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 May. 34 p. (SIGN publication; no. 58). [130 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN). Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2002 Feb. 28 p. (SIGN publication; no. 58).

Any amendments to the guideline will be noted on the [Scottish Intercollegiate Guidelines Network \(SIGN\) Web site](#).

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- [March 14, 2007, Sedative-hypnotic drug products](#): Revisions to product labeling to include stronger language concerning potential risks including severe allergic reactions and complex sleep-related behaviors, such as sleep-driving.

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** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Any paediatric condition requiring sedation for a diagnostic or therapeutic procedure

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Anesthesiology
Dentistry
Emergency Medicine
Family Practice
Pediatrics
Radiology

INTENDED USERS

Advanced Practice Nurses
Dentists
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To present evidence-based recommendations for safe sedation of children undergoing diagnostic and therapeutic procedures
- To provide answers to the following three key questions related to paediatric sedation:
 - 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?

TARGET POPULATION

Children in Scotland 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

Note: Specifically excluded from this 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. A guideline for sedation in the dental setting is currently being prepared by the Chief Dental Officer and when published will supersede the dental guidelines in this document.

INTERVENTIONS AND PRACTICES CONSIDERED

Preparation for Sedation

1. Obtaining informed consent
2. Use of restraint
3. Parental involvement in the preparation of the child for sedation and during the procedure
4. Maintenance of minimum safe standards for sedation by providing adequate facilities and trained personnel
5. Clinical assessment and classification of physical status according to American Society of Anaesthesiologists (ASA) criteria
6. Determination of situations requiring extra caution and where general anaesthesia or anaesthetist-supervised sedation should be considered
7. Behavioural management including the "tell-show-do" method
8. Use of topical local anaesthesia
9. Securing venous access
10. Fasting
11. Continuous monitoring and recording of data, including level of sedation, respiration, pulse, skin colour, arterial haemoglobin oxygen saturation, temperature, blood pressure

Sedation Techniques and Principles

1. Choosing appropriate techniques based on risk involved, environment and clinical setting, patient's characteristics, type of procedure, and availability of personnel
2. Use of non-pharmacological techniques including distraction (e.g., breathing exercises, blowing bubbles), guided imaging, and play therapy for painless procedures
3. Avoidance of sedative combinations
4. Management and recovery of patients entering deep sedation
5. Considerations for conversion to general anaesthesia
6. Use of non-sedative analgesia for painful procedures
7. Considerations for use of inhaled nitrous oxides
8. Considerations for use of opioids

Specialty Requirements

1. Specialty requirements for paediatric gastrointestinal endoscopy, oncology, cardiology, and nephrology
 - General anaesthesia

- Local anaesthesia
 - Behavioural techniques
 - Use of sleep deprivation
 - Scheduling post-feeding
2. Specialty requirements for dentistry
 - Local anaesthesia
 - Nitrous oxide/oxygen sedation (inhalation sedation)
 - Visual monitoring during inhalation sedation
 - Single agent sedation with midazolam
 - Avoidance of general anaesthetics, sedative combinations, or intravenous sedation
 3. Specialty requirements for radiology
 - Imaging when asleep, post-feeding, and with no sedation for infants <4 months of age
 - Sedation using low-potency oral agents for older children
 - Sedation administration technique
 - General anaesthesia for interventional procedures
 - Use of oral benzodiazepines
 4. Specialty requirements for accident & emergency
 - Behavioural techniques
 - Local anaesthesia (topical, infiltration, nerve block)
 - Use of nitrous oxide
 - Oral, intravenous, or nasal opioids
 - General anaesthesia

Recovery and Discharge

1. Criteria for discharge in hospital setting
2. Criteria for discharge in non-hospital setting

MAJOR OUTCOMES CONSIDERED

- Sedation requirements
- Degree of sedation
- Fear, pain, and anxiety levels
- Adverse effects of sedation and anesthesia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic review of the literature was carried out using an explicit search strategy devised by an information specialist in collaboration with members of the guideline development group. Internet searches were carried out on the Web sites of the Canadian Practice Guidelines Infobase, the New Zealand Guidelines Programme, the United Kingdom Health Technology Assessment programme, and the Agency for Health Care Policy and Research (AHCPR, now known as Agency

for Healthcare Research and Quality, AHRQ). 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 Web site](#), in the section covering supplementary guideline material. The main searches were supplemented by later material identified by individual members of the development group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized 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

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document: SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Available from the [SIGN Web site](#).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the [SIGN Web site](#).

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or randomized controlled trial 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

Grade 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+

Grade 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 rate as 2++

Grade D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of the Scottish Intercollegiate Guidelines Network (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.

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 grateful to all of these experts for their contribution to this guideline.

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

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Preparation for Sedation

C: 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.

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.

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 liters/minute 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)
- Electrocardiogram (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 (i.e., flumazenil) and opioids (i.e., naloxone)
- Defibrillator with appropriate paediatric equipment and paddles
- Temperature monitoring for younger children undergoing long procedures
- Capnograph to monitor expired carbon dioxide (CO₂) levels is useful but not compulsory.

D: 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.

D: 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 trolley inventory and basic life support.

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

D: Children with 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

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

- Intracranial air (e.g., after skull fracture)
- Pneumothorax, pneumopericardium
- Bowel obstruction
- Pneumoperitoneum
- Pulmonary cysts or bullae
- Lobar emphysema
- Severe pulmonary hypertension
- Nasal blockage (adenoid hypertrophy, common cold)
- Pregnancy

D: 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 age <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 (e.g., macrolide antibiotics potentiate and prolong the sedative effects of midazolam)

D: The classic "tell-show-do" method and other behavioural techniques should be utilised to help reduce anxiety prior to procedures.

D: The child should fast 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.

C: 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.

Sedation Techniques

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

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

D: 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.

C: 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.

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

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

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.

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.

Specialty Requirements: Medical Paediatrics

D: For brief, but painful or distressing oncology procedures, a combination of behavioural techniques and local anaesthesia is recommended.

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

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

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

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

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

Specialty Requirements: 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: 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.

D: Dental surgeries where nitrous oxide/oxygen sedation takes place should be fitted with an up-to-date scavenging system.

D: Children undergoing inhalation sedation in a dental surgery should be monitored visually by an appropriately trained member of staff until fully recovered.

D: 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.

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

Specialty Requirements: 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.

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

Specialty Requirements: Accident & Emergency

D: For severe pain, opioids should be used by oral, intravenous, or nasal routes, for sedating children in the accident and emergency (A&E) setting.

Definitions:

Grades of Recommendations

A: At least one meta-analysis, systematic review of randomized controlled trials (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+

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of 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

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A combination of non-pharmacological and pharmacological sedation methods may help to ensure optimal management of the emotional and physical consequences of diagnostic and therapeutic procedures in children. An individualized approach to sedation will aid in minimizing fear, anxiety, pain, and distress while at the same time accomplishing the procedure safely, reliably, and efficiently and respecting the rights of the child.

POTENTIAL HARMS

Fasting

Long periods of fasting for young children may cause symptomatic hypoglycemia.

Risks of Sedation

- The most common complications of paediatric sedation are respiratory, and include upper airway obstruction and hypoventilation, resulting in hypoxaemia and hypercarbia.
- 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. 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.
- 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 hospitalization, and in only 14 was there no harm.
- "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. Failure to sedate sufficiently whilst accomplishing the procedure through restraint and failing to complete the task through inadequate sedation are also unacceptable.
- Some children become disinhibited by sedative agents and become restless, uncooperative and unmanageable. It is important to recognize 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.
- 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.
 - Chloral hydrate can produce deep sedation. Complications such as paradoxical excitement may occur in up to 20% of children.
 - Secobarbital (quinalbarbitone) was less effective in children of 5 years or older, in whom three out of five developed paradoxical excitement.
 - One study reported a 1% failure rate (out of 205 patients) where the children were sufficiently immobilized to allow the scan to be finished when chloral hydrate was used.
 - Ketamine, in so-called sub-anaesthetic doses, has a high incidence of adverse effects (vomiting, ataxia, delirium).

CONTRAINDICATIONS

CONTRAINDICATIONS

Children with 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.

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

- Intracranial air (e.g., after skull fracture)
- Pneumothorax, pneumopericardium
- Bowel obstruction
- Pneumoperitoneum
- Pulmonary cysts or bullae
- Lobar emphysema
- Severe pulmonary hypertension
- Nasal blockage (adenoid hypertrophy, common cold)

- Pregnancy

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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 in light of the clinical data presented by the patient and the diagnostic and treatment options 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.
- 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national guidelines is the responsibility of local National Health Service (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.

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, hospital admission rate
- Quality: patient satisfaction, parental satisfaction, behavioural upset (early, late); pain scores.

A Summary of Care Pathway for Safe Paediatric Sedation can be found in the [Implementation and Audit](#) section of the original guideline document.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 May. 34 p. (SIGN publication; no. 58). [130 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Feb (revised 2004 May)

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

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Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN). Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2002 Feb. 28 p. (SIGN publication; no. 58).

Any amendments to the guideline will be noted on the [Scottish Intercollegiate Guidelines Network \(SIGN\) Web site](#).

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide: Safe sedation of children undergoing diagnostic and therapeutic procedures, Scottish Intercollegiate Guidelines Network, 2004. 2 p. Available in Portable Document Format (PDF) from the [Scottish Intercollegiate Guidelines Network \(SIGN\) Web site](#).
- Example monitoring charts for hospital and non-hospital settings. Available from the [SIGN Web site](#).
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the [SIGN Web site](#).
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Electronic copies a from the, [SIGN Web site](#).
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 30, 2002. The information was verified by the guideline developer on October 28, 2002. This NGC summary was updated by ECRI on October 13, 2004. The information was verified by the guideline developer on January 26, 2005. This summary was updated by ECRI Institute on April 30, 2007, following the FDA advisory on Sedative-hypnotic drug products.

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