NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Sedation for diagnostic and therapeutic procedures in children and young people

1.1 Short title

Sedation in children and young people

2 Background

a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Nursing and Supportive Care to develop a clinical guideline on sedation for diagnostic and therapeutic procedures in children and young people for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) NICE clinical guidelines support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued have the effect of updating the Framework.

c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and

their carers and families, if appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

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

b) It is estimated that more than 2 million children and young people are taken to emergency departments each year following accidental injury. Many of these children and young people will undergo procedures that require sedation. For example, in 2005–6 there were 866 children aged 14 and younger who required a closed reduction of a dislocated joint. Sedation is also frequently used for invasive diagnostic procedures such as lumbar punctures, bone marrow biopsies and endoscopies. In 2005–6 there were 4700 gastroscopies, 9000 diagnostic spinal punctures and 2100 bone marrow biopsies carried out on children aged 14 and younger. Sedation is also commonly used in dental practice where the use of general anaesthesia is now restricted to the hospital setting.

c) Sedation is only one of the management options available for children and young people undergoing therapeutic or diagnostic procedures. Non-pharmacological techniques may also be useful in reducing anxiety and managing behaviour, and analgesia may be used to provide pain control. These techniques may be used in combination with sedation or as an alternative to sedation. Another alternative to using sedation for diagnostic or therapeutic procedures is to carry out the procedure under general

anaesthesia, in which case the usual standards of care for patients undergoing anaesthesia must be met.

d) Sedation is a drug-induced depression of consciousness. The aims of sedation during diagnostic or therapeutic procedures may include reducing fear and anxiety, providing pain control and minimising movement. The importance of each of these aims will vary depending on the nature of the procedure and the characteristics of the patient. For example, in younger children sedation may be necessary to ensure that movement is minimised during non-painful procedures such as a magnetic resonance imaging (MRI) scan; in older children sedation may be necessary to minimise the physical and psychological consequences of a painful procedure such as a lumbar puncture.

e) The effect of sedation drugs on consciousness level is a continuum ranging from the awake state, through progressively deeper levels of sedation to anaesthesia. Anaesthesia is an unresponsive state in which vital airway and breathing reflexes are likely to be suppressed. The American Society of Anesthesiologists (ASA) has published useful definitions of sedation levels, classifying them as ‘minimal’, ‘moderate’ and ‘deep’. Minimal sedation equates to anxiolysis and has no appreciable effect on vital reflexes. In a state of moderate sedation the patient is able to breathe adequately without assistance and responds purposefully to verbal stimulus or tactile stimulation. This is often referred to as conscious sedation. During deep sedation, the patient cannot be roused easily but will respond purposefully to repeated or painful stimuli and may require assistance with their airway or breathing. The level of sedation that is appropriate will depend on the nature of the procedure and the needs of the individual. Deeper levels of sedation require more advanced management because the patient’s protective reflexes are affected and they have the potential to progress to anaesthesia.

f) The level of sedation achieved depends on the drug used and the dose at which it is given. When choosing between sedation techniques, healthcare professionals must consider the effectiveness of the drug in achieving the required level of sedation, the duration of that effect, and the margin of safety between the dose required to achieve sedation and the dose that is likely to cause anaesthesia.

g) There may be serious adverse effects if the level of sedation is greater than intended. If breathing is unintentionally depressed and this complication is not recognised and managed appropriately, then this may lead to hypoxic brain injury or death. Sedation drugs may also have other unexpected adverse effects such as prolonged emergence, paradoxical excitement or post-sedation nausea and vomiting.

h) If sedation is unsuccessful, this can result in a painful and traumatic experience for the child. It may be necessary to complete the procedure under general anaesthesia or the procedure may need to be abandoned and rescheduled. If the child becomes distressed due to a failure to provide adequate sedation, their parent or carer may chose to refuse consent for further procedures. A distressing experience may also have long-term psychological consequences for the patient, especially if they are required to undergo repeated procedures.

i) There is significant variation in practice across the NHS, with sedation being carried out by a variety of healthcare professionals using a wide range of techniques, within different clinical settings. The Scottish Intercollegiate Guidelines Network (SIGN) published a guideline on this topic in 2004. This covered moderate sedation but not deep sedation, and the evidence base it considered has not been updated since 2002. The aim of this guideline is to provide recommendations to both improve the effectiveness and safety of

all types of procedural sedation and to reduce current variations in standards of care.

4 The guideline

a) The guideline development process is described in detail in two publications that are available from the NICE website (see ‘Further information’). ‘The guideline development process: an overview for stakeholders, the public and the NHS’ describes how organisations can become involved in the development of a guideline. ‘The guidelines manual’ provides advice on the technical aspects of guideline development.

b) This scope defines what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on a referral from the Department of Health (see appendix).

c) The areas that will be addressed by the guideline are described in the following sections. ‘Sedation’ is used in the following sections to mean a drug-induced depression of consciousness that is not intended to result in anaesthesia.

4.1 Population

4.1.1 Groups that will be covered

a) Infants, children and young people (under 19 years) receiving sedation by any technique for painful or non-painful diagnostic or therapeutic procedures.

b) The GDG will consider whether different recommendations are required for different age groups in the population.

4.1.2 Groups that will not be covered

a) Patients requiring sedation for purposes other than for diagnostic or therapeutic procedures including:

- sedation in critically ill patients requiring mechanical ventilation

- sedation in palliative care
- sedation in the treatment of mental health conditions
- sedation given as premedication for general anaesthesia or as postoperative analgesia
- night sedation.

b) Patients having diagnostic or therapeutic procedures under general anaesthesia.

4.2 Healthcare setting

a) Hospital settings, including inpatients, outpatients, radiology and emergency departments.

b) Primary care, including dental and medical general practice settings.

4.3 Clinical management

a) Assessment of the patient to determine whether sedation is appropriate.

b) Clear communication, in a child-friendly manner, of information relating to the preparation required for the procedure or investigation, and related sedation technique. This will include the needs of the patient and their parents or carers, ensuring that implications (sedation safety and efficacy) are clearly understood by both the patient and their parent or carer prior to informed consent.

c) Preparation required for the procedure or investigation and related sedation technique.

d) The clinical environment, including the availability of equipment, facilities and staff.

e) Patient monitoring during and after sedation and criteria for discharge following sedation.

f) The effectiveness, safety and limitations of sedation techniques. This will include the use of sedation in combination with non-pharmacological techniques and in combination with analgesia. Note that guideline recommendations will normally fall within licensed indications. Where clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics and the 'British National Formulary for Children' to inform their decisions for individual patients.

g) The Guideline Development Group will take reasonable steps to identify ineffective interventions and approaches to care. If robust and credible recommendations for re-positioning the intervention for optimal use, or changing the approach to care to make more efficient use of resources, can be made, they will be clearly stated. If the resources released are substantial, consideration will be given to listing such recommendations in the 'Key priorities for implementation' section of the guideline.

4.4 Training and competence

a) Training for practitioners involved in procedural sedation, irrespective of specialty background, that will be relevant to the sedation techniques and the clinical environment.

b) Training that enables practitioners to be competent in the practical aspects of effective and safe delivery of sedation techniques relevant to the clinical situation, and the management of adverse events (for example, airway management skill in the inadvertently anaesthetised patient).

4.5 Status

4.5.1 Scope

This is the final scope.

4.5.2 Guideline

The development of the guideline recommendations will begin in January 2009.

5 Further information

The guideline development process is described in:

- ‘The guideline development process: an overview for stakeholders, the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the website.

Appendix: Referral from the Department of Health

The Department of Health asked NICE to develop a guideline on sedation for diagnostic and therapeutic procedures in infants, children and young people up to the age of 19.